Ontario College of Pharmacists
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HAZARDOUS STERILE PREPARATION ASSESSMENT CRITERIA

The following chart outlines the community and hospital operations assessment criteria that are used by Operations Advisors (Community (COAs) and Hospital (HOAs)) when conducting an assessment of hazardous sterile preparations. This document is divided into sections which have been taken from relevant legislation, policies, guidelines or standards of practice. The guidance section illustrates specific insights or activities required to ensure adherence to the standard and is provided to assist practitioners in understanding expectations and preparing for the assessment.

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

HAZARDOUS STERILE PREPARATIONS

CORE REQUIREMENTS - PERSONNEL

STANDARD	GUIDANCE
The pharmacy manager or Pharmacy department head is responsible for developing, organizing and supervising all activities related to pharmacy compounding of hazardous sterile preparations.	☐ The pharmacy manager or Pharmacy department head must be responsible for developing, organizing and supervising all activities related to pharmacy compounding of hazardous sterile preparations.
	☐ The pharmacy manager or Pharmacy department head must be familiar with the relevant NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.
	☐ Where compounding is undertaken for another pharmacy, the dispensing facility should include in its general procedures manual information about policies and procedures for acquiring compounded sterile preparations for patients.
	☐ The pharmacy must have a process in place to ensure when dispensing a prescriber's order for office use that a valid patient-healthcare professional relationship exists.
	☐ When dispensing a prescriber's order for office use, the pharmacy must have a process in place to ensure the preparation of a compounded product at an appropriate scale, time and frequency.
	☐ Pharmacy staff should review the Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051) on the Health Canada website.
The hazardous sterile compounding supervisor develops, organizes and oversees all activities related to the compounding of hazardous sterile preparations.	☐ There must be a sterile compounding supervisor designated to supervise activities related to the compounding of hazardous sterile preparations. This person works with the pharmacy manager or pharmacy department head and with the compounding personnel.

	☐ 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 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).
	☐ The sterile compounding supervisor must ensure that all established policies and procedures are in place and readily accessible to staff. Policies and procedures must be reviewed at least every 3 years or when there is a change in standards.
	☐ The sterile compounding supervisor must be responsible for the training of and competency assessment program for all employees involved in the compounding of hazardous sterile preparations.
	☐ The sterile compounding supervisor must ensure the cleaning and disinfecting personnel understand and follow the training and work procedures created in collaboration with the head of environmental services and the head of infection prevention and control.
	☐ The sterile compounding supervisor must ensure the competency of the certifier and the personnel chosen to conduct the sampling, and that the certification is performed in accordance with the most recent certification standards.
	☐ The sterile compounding supervisor must analyze the data obtained via air sampling, surface sampling or GFS and the trends observed with respect to the microbial load. If necessary, the sterile compounding supervisor should consult a microbiologist or infectious diseases specialist.
The hazardous compounding pharmacist or pharmacy technician must be responsible for ensuring that all standards of practice associated with dispensing the preparation have been met before dispensing or releasing a preparation to the patient. A pharmacist must complete an assessment of therapeutic appropriateness, patient consultation and education, documentation and other patient care activities.	☐ The compounding pharmacist or pharmacy technician must be responsible for ensuring that there is a compounding procedure/worksheet that is complete and has calculations and measurements for each preparation produced.
	☐ The compounding pharmacist or pharmacy technician must be responsible for enforcing/ensuring compliance with required rules relating to asepsis, hygiene, cleanliness and safety.
	☐ The compounding pharmacist or pharmacy technician must be responsible for ensuring application and compliance with existing compounding procedures and to follow the compounding process defined in the compounding protocol.
	☐ The compounding pharmacist or pharmacy technician must be responsible for ensuring that verification is performed during the various stages of compounding. All required verification and quality control measures must ensure the quality, sterility and verification of the final preparation.
All hazardous compounding personnel have received specific training and completed a competency assessment program in the workplace.	☐ The initial training and assessment program for compounding personnel must have the following components: reading and understanding the policies and procedures related to compounded sterile preparations; theoretical training, with assessment covering various topics; individualized practical training and assessment in the workplace clean room; assessment of aseptic techniques, based on gloved fingertip sampling (GFS) and a media fill test, for the various types of sterile preparations to be compounded.

	☐ A competency assessment program for all compounding personnel must be implemented in the workplace. This program must include the following: a theoretical test measuring required knowledge of policies and procedures, the aseptic compounding process, and accidental exposure and spills; a practical test in the workplace clean room (including GFS and a media fill test, with simulations involving a sterile product) to evaluate compliance with operating procedures and knowledge of aseptic compounding processes.
	☐ Any other person who enters the sterile compounding area or who is involved in sterile compounding processes must be adequately trained and comply with specific policies and procedures.
	☐ 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.
	☐ A pharmacist, whose activities are limited to supervising a pharmacy technician or pharmacy assistant during the compounding of sterile preparations, must possess a good understanding of the policies and procedures related to sterile compounding and demonstrate the ability to determine whether the compounding personnel are compliant with aseptic process. They must pass the practical section of the training program regarding assessment of the aseptic compounding process, the media fill test and GFS, if there is a possibility that this Pharmacist will compound sterile preparations on an occasional basis.
All cleaning and disinfecting personnel for hazardous sterile compounding have received initial training and completed a competency assessment program in the workplace.	☐ The initial training and assessment program for cleaning and disinfecting personnel must have the following components: theoretical training and assessment covering the issues and particularities of cleaning and disinfecting the premises and equipment used for compounding sterile preparations; practical training and assessment in the areas reserved for the compounding of sterile preparations.
	☐ A competency assessment program for cleaning and disinfecting personnel must be implemented in the workplace.

PERSONNEL INVOLVED IN ASEPTIC COMPOUNDING

STANDARD	GUIDANCE
There is a quality assurance program in place that addresses the personnel involved in hazardous aseptic compounding.	☐ The quality assurance program for the aseptic compounding process for personnel must include GFS and a media fill test, and must be performed under real compounding conditions and must represent the most complex preparations according to the microbiological risk.
There is a quality assurance program in place for hazardous sterile compounding that addresses the content of the program itself, the results & actions taken, the product preparation process and documentation.	☐ The sterile compounding supervisor must establish a quality assurance program to ensure the clear definition, application and verification of all activities that will affect the quality of compounded sterile preparations and the protection of personnel. In addition, must also ensure that sterile preparations are compounded in compliance with established procedures.
	☐ The quality assurance program must have four components; 1) verification of equipment, including the C-PEC, 2) verification of controlled areas (clean room and anteroom), 3) verification of aseptic compounding processes, 4) verification of final preparations.

	☐ Each component of the quality assurance program and its activities must be documented. For each of the specified components, the sterile compounding supervisor must establish a verification process, the results of which are assigned one of three levels; 1) Compliance (no action required): mandatory specifications have been attained, 2) Alert (tendency toward noncompliance): increased vigilance is required to prevent non-compliance, 3) Action required (noncompliant): more in-depth investigation, immediate corrective action and/or preventive action are needed to avoid return to non-compliance.
	☐ Written documentation related to the quality assurance program must be verified, analyzed and signed by the sterile compounding supervisor and retained for a period designated in federal/provincial/ regulations.
Conduct of personnel in controlled areas must meet NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ The conduct of personnel in any controlled area must meet NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations including health, presentation, and behavior of the personnel.
	☐ Compounding personnel must use first air and meticulous aseptic technique when preparing hazardous compounded sterile preparations.
	☐ Hand and forearm hygiene is required for sterile compounding, regardless of the type of C-PEC that is used. Hand and forearm hygiene is required for anyone entering the clean room. The pharmacy must have a detailed policy and procedure that describes the garbing requirements, and hand/forearm hygiene. These policies and procedures must be updated as appropriate.
	☐ Compounding personnel must verify the final sterile product including: perform a visual inspection of each unit for evidence of particulate to verify the clarity, colour and volume of the solution, to check the container for possible leaks and to verify the integrity of the container; verify the information on the label; place final hazardous compounded sterile preparations that require storage at 2°C to 8°C in the refrigerator pending verification and delivery to patients or the patient care unit.
	☐ Each preparation must be inspected by a person other than the individual who performed the aseptic compounding.

COMPOUNDED STERILE PREPARATION PROTOCOLS, COMPOUNDED STERILE LOG PREPARATION & PATIENT FILE	
STANDARD	**GUIDANCE**
Effective documentation and record keeping processes are in place according to standards of practice and NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ Protocols for the compounding of sterile hazardous preparations must include all of the information required to prepare the compound.
	☐ A compounded sterile hazardous preparation log must be completed during the compounding process. The pharmacy must keep such a log for each individual patient.
	☐ A compounded sterile hazardous preparation log must be completed during the compounding process. The pharmacy must keep such a log for sterile preparations made in batches.
The Pharmacy has access to the current required references as listed in the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ The organization/pharmacy must have access to NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.
	☐ The organization/pharmacy must have access to the relevant current chapters of USP.
	☐ The organization must have access to National Institute for Occupational Safety and Health (NIOSH), NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, current version.

CORE REQUIREMENTS – FACILITIES AND EQUIPMENT	
STANDARD	**GUIDANCE**
The clean room is designed, constructed and maintained to meet all NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ Facilities for the compounding of hazardous sterile preparations must be designed and built in accordance with NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations, with provincial and local regulations and for health system facilities, with other applicable standards regulating the construction of buildings.
	☐ Compounding areas must have at least two separate controlled rooms, enclosed and physically separated by a wall: a clean room, where the C-PEC is located and an anteroom, located next to the clean room.
	☐ The clean room must be physically separated from contiguous areas by walls, doors and pass-throughs.
	☐ The clean room must only be used for the compounding of hazardous sterile preparations.
	☐ ISO Class 7 air quality must be maintained in the clean room under dynamic operating conditions.
	☐ The air supplied to areas used for compounding hazardous sterile preparations must pass through a high efficiency particulate air (HEPA) filter to ensure a very high level of cleanliness. The intake air must come from the ceiling via diffusers, each fitted with a terminal HEPA filter.
	☐ The particle count must be performed by trained, qualified personnel at least every 6 months as part of an internal quality control program for facilities and C-PECs. The particle count may also be measured by a qualified certifier.

	☐ Facilities that compound both hazardous and nonhazardous sterile preparations must have two clean rooms: one for the compounding of hazardous sterile preparations and the other for the compounding of non-hazardous sterile preparations, as well an anteroom for each type of compounding.
	☐ Return air exhausts should be installed at the bottom of walls, forcing the particles to flow downward.
	☐ The surfaces of ceilings, walls, floors, doors, door frames, shelves, counters and cabinets in controlled areas must be smooth, impervious, non-friable, free from cracks and crevices, nonporous and resistant to damage from cleaning and disinfecting products. Dust-collecting overhangs, such as door sills, utility pipes, windowsills, window curtains and window blinds, must be avoided.
	☐ All joints must be sealed.
	☐ If a recessed panel ceiling must be installed, the panels must be specifically designed for use in a clean room.
	☐ 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, the floor must be coved up the side wall, at least 10–15 cm.
	☐ There must be no carpets, rugs, “sticky mats” or anti-fatigue mats.

	☐ Controlled rooms are identified must be identified with appropriate and informative signs (e.g., pictograms indicating cytotoxicity, the need for special care, hazards, restricted access, dress code.
	☐ Pharmacy staff should review the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. (i.e. Bacillus Calmette–Guérin [BCG])
	☐ The clean room must be kept under negative pressure relative to the adjacent areas.
An anteroom is designed, constructed and maintained to meet all NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ Facilities for the compounding of hazardous sterile preparations must be designed and built in accordance with NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations, with provincial and local regulations and, for health system facilities, with other applicable standards regulating the construction of buildings.
	☐ The anteroom must be separated into two spaces by a visible demarcation line: the first space or area, referred to as “dirty”, is located at the entrance to the anteroom, in the section adjacent to the non-controlled area; the second space or area, referred to as “clean”, is adjacent to the dirty area on one side and the clean room on the other.
	☐ Controlled rooms are identified must be identified with appropriate and informative signs (e.g., pictograms indicating cytotoxicity, the need for special care, hazards, restricted access, dress code.
	☐ Activity in the anteroom, with higher generation of particulates, must be kept to a minimum and must shall be limited to those activities that are essential to or that directly support the work undertaken in the clean room. (ex. Garbing, hand hygiene, labelling, staging).

	☐ Access of supplies, equipment and personnel into the clean room must be through the anteroom. No supplies, equipment or personnel shall enter into the clean room from a non-controlled area.
	☐ ISO Class 7 air quality must be maintained in the clean room and the anteroom under dynamic operating conditions.
	☐ Facilities that compound both hazardous and non-hazardous sterile preparations may share a single anteroom. (This layout is not recommended) If anteroom is shared it must meet the NAPRA standard.
	☐ The air supplied to areas used for compounding hazardous sterile preparations must pass through a high efficiency particulate air (HEPA) filter to ensure a very high level of cleanliness. The intake air must come from the ceiling via diffusers, each fitted with a terminal HEPA filter.
	☐ Return air exhausts should be installed at the bottom of walls, forcing the particles to flow downward.
	☐ The particle count must be performed by trained, qualified personnel at least every 6 months as part of an internal quality control program for facilities and C-PECs. The particle count may also be measured by a qualified certifier.
	☐ The surfaces of ceilings (with all joints sealed), walls, floors, doors, door frames, shelves, counters and cabinets in controlled areas must be smooth, impervious, non-friable, free from cracks and crevices, nonporous and resistant to damage from cleaning and disinfecting products. Dust-collecting overhangs, such as door sills, utility pipes, windowsills, window curtains and window blinds, must be avoided.
	☐ Joints between the ceiling and walls should be free of sharp corners where foreign substances could accumulate. In all rooms reserved for the compounding of sterile preparations, any holes, cracks or breakage in ceilings must be repaired and sealed at the earliest opportunity.
	☐ If a recessed panel ceiling must be installed, the panels must be specifically designed for use in a clean room.
	☐ 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 anteroom, the floor must be coved up the side wall, at least 10–15 cm.
	☐ There must be no carpets, rugs, “sticky mats” or anti-fatigue mats.
The storage of hazardous drugs are in compliance with NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ Hazardous products must be stored separately from non-hazardous products in a dedicated room and include a separate unpacking area
	☐ Hazardous drugs must be stored within a negative-pressure room with all air exhausted to the exterior. The storage area must have at least 12 air changes per hour (ACPH)
	☐ Hazardous drugs must be stored in a negative-pressure room. Alternatively, hazardous sterile preparations and the refrigerator in which they are stored may be placed in the clean room for compounding hazardous sterile preparations. 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

When a segregated compounding area (i.e. where a BSC/CACI that is not placed in an environment meeting the standards for ISO Class 7 air quality) is used, the specific conditions outlined in NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations standards must be met.	☐ Beyond-use times of 12 hours or less must be used for preparations compounded in segregated areas.
	☐ The segregated area must have walls to separate the room from other areas.
	☐ The C-PEC must be certified every 6 months and maintains ISO Class 5 air quality or better.
	☐ The room must have a minimum of 12 ACPH.
	☐ The room must maintain negative pressure of at least –2.5 Pa relative to adjacent spaces.
	☐ Only low or medium-risk preparations may be compounded.
	☐ Only one preparation may be compounded at a time.
	☐ The preparations must be compounded in an area that is reserved for the compounding of sterile preparations and that minimizes contamination.
	☐ The sink must be at least 1 metre away from the C-PEC.
	☐ The preparation area must have no unsealed windows or doors leading to the exterior of the building or is in a high traffic area or adjacent to construction sites, warehouses or food preparation sites.
	☐ Personnel must be fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting.
Personal Protective Equipment (PPE) for the compounding of hazardous sterile preparations must meet the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ Compounding personnel must wear clean room scrubs, not street clothes.
	☐ Gloves used in the clean room, in the clean area of the anteroom and during aseptic processes in all C-PECs (including isolators) must be: non-powdered; compliant with standard D-6978-05 of ASTM; sterile (outer glove only).
	☐ Two pairs of disposable shoe covers are required at all times in the clean area of the anteroom and in the clean room, even if dedicated shoes are worn.
	☐ A disposable hair cover must be worn during the compounding of hazardous sterile preparations.
	☐ If the compounder has facial hair, a disposable beard cover must be worn while compounding hazardous sterile preparations.
	☐ A gown must be worn and have been tested by the manufacturer for resistance to permeability by hazardous drugs. It must close in the back, and it must have long sleeves with fitted cuffs at the wrists.
	☐ NAPRA outlines the uses for and limitations of different types of masks and when a surgical, N95, N100 mask or chemical cartridge respirator (NIOSH-approved) mask should be used. Any mask must first be fit-tested.
Equipment for the compounding of hazardous sterile preparations is designed, built, and maintained in accordance with NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ For hazardous compounding, C-PECs must be BSCs or CACIs that meets the requirement.
	☐ The Containment Primary Engineering Control (C-PEC) must ensure an ISO Class 5 air quality environment for the exposure of critical sites when sterile preparations are being compounded.
	☐ Certification of each C-PEC must be certified at least every 6 months, when relocated, after major repairs or when viable air sampling indicates that the C-PEC may not be in compliance with specifications.

	☐ The Biological Safety Cabinet (BSC) must be positioned in an ISO Class 7 clean room or better, under negative pressure and adjoining an ISO Class 7 anteroom. The BSC must not be placed near doors or other sources of drafts that might adversely affect unidirectional airflow. If multiple BSCs are used, they must be positioned to prevent interference with one another.
	☐ The compounding aseptic containment isolator (CACI) must be positioned in an ISO Class 7 clean room or better, under negative pressure and adjoining an ISO Class 7 anteroom. Compounding personnel working in a CACI must comply with the garbing procedure for compounding of hazardous sterile preparations, both to maintain air quality and to protect themselves from spills.
	☐ Sterile Isopropyl alcohol (IPA) 70% must be available for use in the appropriate areas.
	☐ Refrigerator and freezer when used to store hazardous medications must be commercial, biomedical-grade units.
	☐ Refrigerator and freezer designated for hazardous drugs must be used only for this purpose. They must not be used to store food or other medications/solutions, etc.
	☐ Preventive maintenance for C-PECs and other equipment must be performed when no compounding is in progress, before cleaning and disinfection operations.
	☐ The automated compounding device (ACD) must be positioned in the PEC such that compounding occurs while critical sites are exposed to first air.
	☐ Carts used to bring supplies into the anteroom from outside the controlled area must not cross the demarcation line. Likewise, carts taken into the anteroom from the clean room shall not be moved beyond the clean side of the demarcation line.
	☐ An incubator is used to maintain a constant temperature for the culture of microorganisms. The incubation temperature must be controlled (20°C to 25°C or 30°C to 35°C, depending on the culture medium and incubation period).
	☐ Equipment used for cleaning and disinfection and its storage must be specifically designated for cleaning areas used for the compounding of hazardous sterile preparations.
There is a cleaning, disinfecting, deactivating and surface decontaminating procedure in place that addresses all hazardous compounding areas.	☐ Personnel must comply with the requirements for cleaning and disinfecting as outlined in NAPRA.
	☐ Cleaning and disinfecting personnel must comply with the pharmacy's hand hygiene and garbing procedure before entering sterile compounding areas and performing housekeeping duties.
	☐ The pharmacy must have a policy in place to ensure the use of sterile 70% isopropyl alcohol (IPA) for the disinfection of gloved hands surfaces/equipment/supplies used in the compounding of hazardous sterile products.
	☐ 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.

	☐ Surface decontamination, deactivation and disinfection of the C-PEC must be completed according to the frequencies set out in NAPRA.

VERIFICATION OF EQUIPMENT AND FACILITIES

STANDARD	GUIDANCE
There is an environmental verification program in place that meets that meets the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ The environmental verification program should include verification for chemical contamination by hazardous materials on surfaces used for receipt, storage, preparation and verification of products and preparations, in addition to verification of microbiological contamination of controlled areas twice per year.
	☐ The differential pressure between controlled areas must be kept constant.
	☐ Pressure must be measured continuously, and an alarm system must be in place to immediately advise personnel of noncompliance with specifications and to direct that action be taken.
	☐ The indicators for proper operation of any device (BSC, CACI, ACD, etc.) must be verified every day, and data must be recorded in the general maintenance log.
	☐ The temperature of controlled sterile compounding areas must be verified and documented at least once a day.
	☐ Sampling of viable, non-viable and surface particles in controlled areas and the C-PEC.
	☐ A written sampling plan for controlled areas and the C-PEC must be established and include sampling of viable, nonviable and surface particles.
	☐ If there is growth of any viable particles obtained via air sampling, surface sampling or GFS, the genus of the microorganism must be identified. Corrective and preventive actions (e.g., cleaning, disinfecting) must be completed.
	☐ An environmental program must be established to ensure that facilities that engage in hazardous compounding uphold the quality and safety standards set by the industry.
There is a quality assurance program in place that addresses the verification of equipment and facilities for hazardous sterile compounding.	☐ Equipment that supports compounding activities, especially refrigerators, freezers, incubators and air sampling devices, must be certified with respect to its installation and operation and must be calibrated before being put into service and thereafter as recommended by the manufacturer.
	☐ 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.
	☐ An investigation must be undertaken when a contamination or a problem involving non-compliance in the aseptic compounding process is discovered.
	☐ The general maintenance logs must be complete, accurate and maintained as per standards of practice and NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.

BEYOND USE DATE (BUD) AND DATING METHODS

STANDARD	GUIDANCE
The pharmacy's operating procedures describe the risk assessment process used to establish the BUD and the storage conditions according to NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.	☐ The BUD must not exceed the earliest of the dates established by the following two criteria; 1) expiration date based on chemical and physical stability according to reference texts, 2) storage time related to risk of microbial contamination.
	☐ Levels of risk for microbial contamination must apply to preparations compounded in a compliant, certified C-PEC that maintains ISO Class 5 air quality or better and that is located in an ISO Class 7 clean room or a compliant certified CACI that meets the criteria specified when placed in environments with particle counts exceeding ISO Class 7.
	☐ Low Risk preparations are prepared and must meet beyond-use dates; • final product compounded using up to 3 "sterile units", • no more than 2 septum punctures at the injection site for each sterile unit, • simple aseptic transfer technique; drug prepared for one patient (patient specific dose). ☐ Risk of contamination Low; • At controlled room temperature BUD must be no more than 48 hours, • With storage in refrigerator BUD must be no more than 14 days, • With storage in freezer BUD must be no more than 45 days.
	☐ Medium Risk preparations are prepared and must meet beyond-use dates; • final product compounded using four or more "sterile units", • complex manipulations; prolonged preparation time, • batch preparations (preparing more than one unit of the same composition during one compounding session). ☐ Risk of contamination Medium; • At controlled room temperature BUD must be no more than 30 hours, • With storage in refrigerator BUD must be no more than 9 days, • With storage in freezer BUD must be no more than 45 days.
	☐ High Risk preparations are prepared and must meet beyond-use dates; • non-sterile ingredients or equipment used before terminal sterilization, • non-sterile preparations, containing water, stored for more than 6 hours before terminal sterilization, • improper garbing or gloving by compounding personnel. ☐ Risk of contamination High; • At controlled room temperature BUD must be no more than 24 hours, • With storage in refrigerator BUD must be no more than 3 days, • With storage in freezer BUD must be no more than 45 days.
	☐ The pharmacy must have a policy in place to specify the beyond use dating of single-dose vials. No storage of an open ampoule is permitted; as such, no BUD applies.
	☐ The pharmacy must have a policy in place to specify the beyond use dating of multi dose vials.
	☐ To establish a longer BUD, sterility tests must be performed for a given preparation or batch.
	☐ An 0rganization choosing to extend the BUD of a sterile preparation should review the Extending the Beyond Use Date for Sterile Preparations guideline on the OCP website.

LABELLING	
STANDARD	**GUIDANCE**
Labelling of the final compounded sterile preparation meets NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations and provincial requirements.	☐ Each container for a compounded sterile preparation must be labelled.
	☐ 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 cytotoxic); storage method; date when the sterile preparation was compounded; BUD; preparation batch number.

RECALL OF STERILE PRODUCTS OR FINAL COMPOUNDED STERILE PREPARATIONS	
STANDARD	**GUIDANCE**
There is a process in place when a sterile hazardous product or preparation does not meet requirements due to issues of internal control and/or a complaint or a product recall.	☐ If as a result of internal control, a complaint or a product recall shows that the grade or quality of a product or preparation does not meet requirements, the pharmacist or pharmacy technician must be able to: 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.

RECEIPT, TRANSPORT AND DELIVERY OF HAZARDOUS PRODUCTS	
STANDARD	**GUIDANCE**
The pharmacy has policies and procedures in place to ensure safe receipt, transport and delivery of compounded hazardous sterile preparations.	☐ Personnel involved in receipt, transport and delivery of products (pharmacist, pharmacy technician, pharmacy assistant and driver) receive training including the procedure for dealing with accidental exposure or spills when applicable.
	☐ The garbing of personnel for unpacking intact hazardous products that have been received from the supplier sealed in impervious plastic must meet the NAPRA requirements.
	☐ If a shipping container for hazardous drugs appears damaged upon receipt, appropriate procedures must be followed.
	☐ 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.
	☐ Before any product is introduced into the anteroom, it must be removed from its cardboard shipping box. The product must then be wiped with a sporicidal agent.
	☐ During packaging, compounding personnel must: put each final hazardous compounded sterile preparation in a clear plastic bag (or an amber bag, if the preparation must be protected from light); place items with an attached needle in a second rigid container; indicate storage requirements on the final package; indicate additional precautions on the final packaging; indicate transport precautions and instructions on the outside packaging of each item.
	☐ Policies and procedures must be developed and implemented for the transport of hazardous compounded sterile preparations and their delivery to patient care units, pharmacists and patients.

	☐ Policies and procedures must be developed and implemented for the transport of hazardous compounded sterile preparations and their delivery to other hospitals.
	☐ A spill kit must be available in locations where hazardous products are handled and must be present on carts used for transporting hazardous products.

INCIDENT AND ACCIDENT MANAGEMENT	
The pharmacy has policies and procedures in place to address incident and accident management with respect to hazardous sterile compounding.	☐ Policies and procedures must be in place and followed in case of accidental exposure of personnel to hazardous products.
	☐ Policies, procedures and training for managing spills must be in place for employees who clean up spills.
	☐ When an incident or accident involving a hazardous compounded sterile preparation occurs, an event report and explanation form must be completed.

HAZARDOUS WASTE MANAGEMENT	
The pharmacy has a hazardous waste management process in place.	☐ The pharmacist and pharmacy technicians must ensure that medications and sharp or pointed instruments are disposed of safely, in compliance with environmental protection laws in force in the jurisdiction.
	☐ The pharmacist and pharmacy technician must ensure that medications to be destroyed are safely stored in a location separate from other medications in inventory.
	☐ Policies and procedures for the management of hazardous waste must be developed and followed. These policies and procedures must comply with local, provincial and federal requirements.