Alberta College of Pharmacy

Reset Form

# Licensee Self-Assessment

This self-assessment is based on and references requirements outlined in the NAPRA Model Standards for Pharmacy Compounding of Hazardous and Non-Hazardous Sterile Preparations. Please refer to these Standards for complete lists of requirements and guidelines.

Items marked with H apply only to hazardous compounding, items marked with NH apply only to non-hazardous compounding. All other items apply to both hazardous and non-hazardous compounding. Each question must be answered. To fill out and save this document, it must be downloaded and opened with Adobe Reader.

## Core requirements - personnel

| Standard | Guidance | Response |
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| The pharmacy licensee is responsible for developing, organizing, and supervising all activities related to pharmacy compounding of sterile preparations. | The licensee is responsible for developing, organizing and supervising all activities related to pharmacy compounding of sterile preparations. | Select |
| | The licensee is familiar with the relevant NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous and Hazardous Sterile Preparations. | Select |
| | Where compounding is undertaken for another pharmacy, the dispensing facility should include a policy for acquiring compounded sterile preparations for patients in their Policies and Procedures Manual. | Select |
| The sterile compounding supervisor develops, organizes and oversees all activities related to the compounding of sterile preparations. | The sterile compounding supervisor oversees activities related to the compounding of sterile preparations. This person works with the Licensee and with the compounding personnel. | Select |
| | The sterile compounding supervisor successfully completed training (i.e., courses) in the compounding of sterile preparations, maintained up-to-date knowledge and demonstrated the required competencies. | Select |
| | The sterile compounding supervisor is evaluated for knowledge and abilities, at the same frequency as compounding personnel, by a third party. | Select |
| | The sterile compounding supervisor ensures that all policies and procedures are in place and readily accessible to staff. | Select |
| | Policies and procedures must be reviewed at least every 3 years or when there is a change in standards or the pharmacy's policies or procedures. | Select |

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| | Only a pharmacy technician or pharmacist may compound sterile preparations. This must not be delegated to a pharmacy assistant or another unregulated individual. | Select |
| | The sterile compounding supervisor is responsible for the training of and competency assessment program for all employees involved in the compounding of sterile preparations. | Select |
| | The sterile compounding supervisor ensures the cleaning and disinfecting personnel understand and follow the training and work procedures. | Select |
| | The sterile compounding supervisor ensures the competency of the certifier chosen to conduct the environmental sampling. This includes ensuring that the certification is completed according to current applicable certification standards for the facilities and equipment used to compound sterile products. This also includes a review of all certification reports (not just microbial data) and clarifying any discrepancies directly with the certifier. | Select |
| | The sterile compounding supervisor analyzes 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. | Select |
| The compounding pharmacist or pharmacy technician performs or supervises compounding activities; ensuring compliance with policies and procedures related to the compounding of sterile preparations. | All compounding personnel ensure that all standards of practice associated with dispensing the preparation have been met before dispensing or releasing a preparation to the patient, including an assessment of therapeutic appropriateness, patient consultation and education, documentation and other patient care activities. | Select |
| | All compounding personnel ensure that there is a compounding procedure/worksheet that is complete and has calculations and measurements for each preparation produced. | Select |
| | All compounding personnel enforce /ensure compliance with required rules relating to asepsis, hygiene, cleanliness and safety. | Select |
| | All compounding personnel ensure application and compliance with existing compounding procedures and follow the compounding process defined in the compounding protocol. | Select |
| | All compounding personnel ensure 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. | Select |

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| All compounding personnel have received specific training and completed a competency assessment program in the workplace. | The initial training and assessment program for compounding personnel compose of the following:<br>1) reading and understanding the policies and procedures related to compounded sterile preparations;<br>2) theoretical training, with assessment covering various topics;<br>3) individualized practical training and assessment in the workplace clean room;<br>4) 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. | Select |
| | A competency assessment program for all compounding personnel must be implemented in the workplace. | Select |
| | All compounding personnel pass GFS and a media fill test before working in the compounding area for sterile products. | Select |
| | 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. | Select |
| | All compounding personnel 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. | Select |
| | A pharmacist, whose activities are limited to supervising a pharmacy technician 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. | Select |
| All cleaning and disinfecting personnel have received initial training and completed a competency assessment program in the workplace. | The initial training and assessment program contains:<br>1) theoretical training and assessment covering the issues and particularities of cleaning and disinfecting the premises and equipment used for compounding sterile preparations;<br>2) practical training; and<br>3) assessment in the areas reserved forth compounding of sterile preparations. | Select |
| | A competency assessment program for cleaning and disinfecting personnel must be implemented in the workplace. | Select |

## Personnel involved in aseptic compounding

| Standard | Guidance | Response |
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| There is a quality assurance program in place that addresses the personnel involved in aseptic compounding. | There is a quality assurance program in place that addresses the content of the program itself, the results & actions taken, the product preparation process and documentation. In addition, all personnel must also ensure that sterile preparations are compounded in compliance with established procedures. | Select |
| | The quality assurance program includes GFS and a media fill test; it must be performed under real compounding conditions and it must represent the most complex preparation according to the microbiological risk. | Select |
| There is a quality assurance program in place 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, he/she must also ensure that sterile preparations are compounded in compliance with established procedures. | Select |
| | The quality assurance program must have four components:<br>1) verification of equipment, including the PEC,<br>2) verification of controlled areas (clean room and anteroom),<br>3) verification of aseptic compounding processes,<br>4) verification of final preparations. Each component of the quality assurance program and its activities must be documented. | Select |
| | 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:<br>1) Compliance (no action required): mandatory specifications have been attained.<br>2) Alert (tendency toward non-compliance): increased vigilance is required to prevent non-compliance.<br>3) Action required (non-compliant): more in-depth investigation, immediate corrective action and/or preventive action are needed to avoid return to non-compliance. | Select |

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| | 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. The sterile compounding supervisor must:<br>• investigate missing documentation, situations of non-compliance and deviations from protocols;<br>• identify trends concerning microbial load in controlled areas and types of microorganisms found;<br>• consult a microbiology specialist, if necessary;<br>• take corrective and preventive actions. | Select |
| Conduct of personnel in controlled areas must meet NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous and/ or Hazardous Sterile Preparations. | Personnel afflicted with any of these conditions shall be excluded from sterile compounding activities and sterile compounding areas until the condition has been remedied:<br>• uncontrolled weeping skin condition<br>• burns to the skin, including sunburns<br>• cold sores (active herpes simplex viral infection)<br>• conjunctivitis (viral or bacterial)<br>• active respiratory infection with coughing, sneezing or runny nose<br>• fresh piercings<br>• other fresh wounds<br>A person with permanent tattoos may compound sterile products. However, a recent tattoo on the face, neck or arms is considered a fresh skin wound, and the individual must cease sterile compounding activities and wait until the skin is completely healed before resuming such activities. | Select |
| | Personnel are required to remove all personal outer garments, jewelry, studs and other accessories from fingers, wrist, forearms, face, tongue, ears, neck (including ear buds) and remove all cosmetics/ hair products before entering controlled area. Long hair is tied back. | Select |
| | Personnel are required to keep natural nails neat and trimmed, skin on hands and forearms are undamaged. Remove nail polish and other nail applications. | Select |
| | Food items, drinks, chewing gum, candy, personal electronic devices are prohibited from controlled areas, and only essential conversation is allowed. | Select |

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| | The pharmacy must have detailed aseptic compounding policies and procedures that includes all activities related to completion of the final sterile preparation. These policies and procedures must be updated as appropriate and must include:<br>• performing hand and forearm hygiene;<br>• garbing of personnel;<br>• disinfecting and introducing products and equipment into the clean room;<br>• disinfecting the PEC/C-PEC;<br>• disinfecting and introducing products and equipment into the PEC/C-PEC;<br>• using aseptic techniques to compound sterile preparations in the PEC/C-PEC;<br>• decontaminating final hazardous compounded sterile preparations;<br>• verifying, labelling and packaging final compounded sterile preparations. | Select |
| | Hand and forearm hygiene is required for sterile compounding, regardless of the type of 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. | Select |
| | Hand hygiene must be performed in the correct sequence as outlined in section 6.6.2.1 of the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous and/ or Hazardous Sterile Preparations. Hand hygiene is performed in the anteroom for at least 30 seconds from fingertip to forearm and includes the use of a nail pick. Hands and arms are then dried with a non-linting / non-shedding disposable towel before ABHR with persistent activity is applied. | Select |
| | Garbing is performed in the sequence described in the policies and procedures manual and it is required regardless of the type of PEC that is used. | Select |
| | Shoe covers or dedicated shoes are required at all times in the clean area of the anteroom and the clean room. All shoes must be closed, dry, clean and easy to maintain. Additionally, the garbing sequence outline in the policies and procedures manual must be consistent with the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous and/ or Hazardous Sterile Preparations. | Select |
| | All compounding personnel must use meticulous aseptic technique when preparing compounded sterile preparations. Compounding must occur in the critical area of the PEC, such that critical sites are exposed to first air. | Select |

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| | All Compounding personnel's final sterile product check includes:<br>1) visual inspection of each unit for evidence of particulate to verify the clarity, colour and volume of the solution,<br>2) checking the container for possible leaks and to verify the integrity of the container;<br>3) verification of the information on the label;<br>4) placing 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. | Select |
| | Each preparation must be inspected by a person other than the individual who performed the aseptic compounding. | Select |

## Compounded sterile preparation protocols, compounded sterile log preparation, and patient file

| Standard | Guidance | Response |
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| Effective documentation and record keeping processes are in place according to standards of practice and NAPRA's Model Standards for Pharmacy Compounding of Non-Hazardous and/or Hazardous Sterile Preparations. | Protocols for the compounding of sterile preparations must include all of the information required to prepare the compound. | Select |
| | A compounded sterile preparation log must be completed during the compounding process. The pharmacy must keep such a log for each individual patient. | Select |
| | A compounded sterile preparation log must be completed during the compounding process. The pharmacy must keep such a log for sterile preparations made in batches. | Select |
| The pharmacy has access to the current required references as listed in the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations. | The pharmacy has access to NAPRA's Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations. | Select |
| | The pharmacy has access to the Trissel LA. Handbook of injectable drugs. | Select |
| | The pharmacy has access to the relevant current chapters of USP. | Select |
| The pharmacy has access to the current required references as listed in the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. | The pharmacy has access to NAPRA's Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. H | Select |
| | The organization has access to the current version of the National Institute for Occupational Safety and Health's (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. H | Select |
| | The pharmacy has access to the relevant current chapters of USP. H | Select |

## Core requirements - facilities and equipment

| Standard | Guidance | Response |
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| The clean room is designed, constructed and maintained to meet all NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations or NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. | The clean room is designed, constructed and maintained to meet all NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous and/ or Hazardous Sterile Preparations. | Select |
| | Facilities for the compounding of sterile products must be designed and built in accordance with NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous and/ or Hazardous Sterile Preparations, with provincial and local regulations and, for health system facilities, with other applicable standards regulating the construction of buildings. | Select |
| | Compounding areas must have at least two separate controlled rooms, enclosed and physically separated by a wall: a clean room, where the PEC is located, and an anteroom, located next to the clean room. | Select |
| | The clean room must be physically separated from the contiguous areas by walls, doors and pass-throughs. | Select |
| | Facilities that compound both hazardous and non-hazardous 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. | Select |
| | ISO Class 7 air quality must be maintained in the clean room under dynamic operating conditions. | Select |
| | The non-hazardous clean room is kept under positive pressure relative to the anteroom and adjacent areas. The pressure differential between the non-hazardous clean room and the anteroom must be maintained at all times. | NH Select |
| | All hazardous control rooms (clean rooms/anterooms) are identified with appropriate and informative signs (e.g., pictograms indicating cytotoxicity, the need for special care, hazards, restricted access, dress code). | H Select |
| | The pharmacy staff are familiar with the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings (i.e. Bacillus Calmette–Guérin [BCG]). | H Select |
| | The hazardous clean room must be kept under negative pressure relative to the adjacent areas. The pressure differential between the hazardous clean room and the anteroom must be maintained at all times. | H Select |

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| An anteroom is designed, constructed and maintained to meet the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations and /or NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. | An anteroom is designed, constructed and maintained to meet all NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations and /or NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. | | Select |
| | The anteroom is located between the clean room and the non-controlled areas of the pharmacy, acting as a transition space. The anteroom has two doors: one door between the clean room and the anteroom, and the other door between the anteroom and the non-controlled area. The pharmacy must have a process that allows only one door to be open at a time (i.e., to prevent both doors from being open at the same time). | | Select |
| | The anteroom must be separated into two spaces by a visible demarcation line. | | Select |
| | Activity in the anteroom, with higher generation of particulates, must be kept to a minimum and must be limited to those activities that are essential to or that directly support the work undertaken in the clean room. (e.g. Garbing, hand hygiene, labelling, staging). | | Select |
| | Access of supplies, equipment and personnel into the clean room must be through the anteroom. No supplies, equipment or personnel must enter into the clean room from a non-controlled area. | | Select |
| | Non-hazardous ISO Class 8 air quality must be maintained in the anteroom under dynamic operating conditions, unless the anteroom is also supporting a hazardous drug clean room, in which case ISO class 7 air quality must be maintained. | NH | Select |
| | Hazardous - ISO Class 7 air quality must be maintained in the clean room and the anteroom under dynamic operating conditions. | H | Select |
| | Facilities that compound both hazardous and non-hazardous sterile preparations should have two anterooms: one for the compounding of hazardous sterile preparations and the other for the compounding of non-hazardous sterile preparations. If space is limited, they may share a single anteroom. This layout is not recommended, but if space constraints dictate that facilities for compounding hazardous and non-hazardous sterile preparations share an anteroom, the conditions listed in the NAPRA Standards must be met. | | Select |

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| General Facility - designed, constructed and maintained to meet all NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations and/ or Hazardous Sterile Preparations. The following requirements are needed for all Hazardous/ Non-Hazardous Clean Room and Anterooms. | The air supplied to areas used for compounding 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. | Select |
| | Return air exhausts must be installed at the bottom of walls, forcing the particles to flow downward. | Select |
| | The return air from the clean room must be exhausted to the exterior of the building for hazardous sterile preparations. | Select |
| | Particle generating equipment (i.e. computers, refrigerators, etc.) in the clean room or anteroom are positioned by an air return so air flows over and out of the room taking particles with it. The airflow has been confirmed by smoke testing. | Select |
| | 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 PECs. The particle count may also be measured by a qualified certifier.<br><br>Particle counts are taken under dynamic conditions as noted on the certification reports. Particles measured are greater than or equal to 0.5 micrometers. ISO class area is certified to have appropriate counts. | Select |
| | The viable air samples obtained must be either:<br><br>1) sent to a certified external laboratory; or<br><br>2) incubated in the community or health care facility pharmacy, provided that:<br><br>- the incubator used is certified periodically;<br><br>- procedures are in place for use and maintenance of the incubator and for surveillance of temperatures;<br><br>- personnel are properly trained and are competent to read and interpret the results and to take appropriate preventive or corrective actions. | Select |
| | 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. | Select |
| | 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. | Select |
| | If a recessed panel ceiling must be installed, the panels must be specifically designed for use in a clean room. | Select |

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| | 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. | | Select |
| | The floor must be coved up the side wall, at least 10–15 cm. | | Select |
| | There must be no carpets, rugs, “sticky mats” or anti-fatigue mats. | | Select |
| The storage of drugs are in compliance with the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous and/ or Hazardous Sterile Preparations. | The final packaging maintains each preparation’s stability, integrity and storage conditions. | | Select |
| | The pharmacy must have a storage procedure, and this procedure must be followed at all times. | | Select |
| | Alternative storage must be provided when conditions are beyond acceptable temperature variations and when refrigerators and freezers are being cleaned. | | Select |
| | Hazardous products must be stored separately from non- hazardous products in a dedicated room and include a separate unpacking area. | H | Select |
| | 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). | H | Select |
| | 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. 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. | H | Select |

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| When a segregated compounding area (LAFW is not placed in an environment meeting the standards for ISO Class 7 air quality, or CAI does not meet the requirements of 5.3.3.1) is used, the specific conditions outlined in NAPRA's Model Standards for Pharmacy Compounding of Non- Hazardous Sterile Preparations must be met. | Only low-risk preparations are compounded. (LAFW/CAI) | NH | Select |
| | 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:<br>• The PEC is certified every 6 months and maintains ISO Class 5 air quality or better.<br>• Only low-risk preparations are compounded.<br>• Only one preparation is compounded at a time.<br>• The preparations are compounded in an area that is reserved for the compounding of sterile preparations and that minimizes contamination.<br>• The sink is not directly adjacent to the PEC and is separated from the immediate area of the PEC.<br>• 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.<br>• Personnel are fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting. | NH | Select |
| 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. | The segregated area must have walls to separate the room from other areas. | H | Select |
| | The segregated area must have a minimum of 12 ACPH. | H | Select |
| | The segregated area must maintain negative pressure of at least −2.5 Pa relative to adjacent spaces. | H | Select |
| | Only low or medium-risk preparations are compounded in segregated compounding areas. | H | Select |
| | The sink must be at least 1 metre away from the C-PEC in the segregated compounding area. | H | Select |
| When a segregated compounding area is used (non-hazardous or hazardous) the specific conditions outlined in NAPRA's Model Standards for Pharmacy must be followed. | Beyond-use times of 12 hours or less must be used for preparations compounded in segregated areas. | | Select |
| | The PEC must be certified every 6 months and maintains ISO Class 5 air quality or better under dynamic operating conditions. | | Select |
| | Only one preparation is compounded at a time. | | Select |
| | The preparations must be compounded in an area that is reserved for the compounding of sterile preparations and that minimizes contamination. | | Select |
| | The sink must not be directly adjacent to the PEC and is separated from the immediate area of the PEC. | | Select |

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| | The preparation area must have no unsealed windows or doors leading to the exterior of the building. The preparation area must not be in a high-traffic area or adjacent to construction sites, warehouses or food preparation sites. | Select |
| | Personnel must be fully compliant with procedures for hand and forearm hygiene, asepsis, garbing, and cleaning and disinfecting. | Select |
| Personal Protective Equipment (PPE) for the compounding of sterile preparations must meet NAPRA's Model Standards for Pharmacy Compounding of Non-Hazardous/ Hazardous Sterile Preparations. | Before entering the anteroom, compounding personnel must remove personal outer garments (e.g coat, hat, jacket, scarf, sweater, vest, boots, and outdoor shoe) and change into dedicated, low-shedding apparel suitable for the controlled area (e.g., scrubs). | Select |
| | Before entering the anteroom, compounding personnel must tie up hair, remove jewelry, studs and other accessories from fingers, wrists, forearms, face, tongue, ears and neck (this includes personal electronic devices or accessories, such as cell phone, iPod and earbuds, which are not permitted in the anteroom or clean room). | Select |
| | Before entering the anteroom, compounding personnel must 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. Must also remove nail polish and other nail applications (nail extensions and other synthetic nail-lengthening products are prohibited). | Select |
| | A disposable hair cover must be worn during the compounding of sterile preparations. | Select |
| | A face mask must be worn during the compounding of sterile preparations. | Select |
| | If the compounder has facial hair, a disposable beard cover must be worn while compounding 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. | Select |
| Personal Protective Equipment (PPE) for the compounding of non-hazardous sterile preparations must meet the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations. | One pair of shoe covers or dedicated shoes are required at all times in the clean area of the anteroom and in the clean room. Dedicated shoes must be cleaned and disinfected once a week. NH | Select |
| | Non-powdered sterile gloves, which cover the cuffs of the non-shedding gown, must be used in the clean room, in the clean area of the anteroom and during aseptic processes. NH | Select |
| | A non-shedding protective gown (enclosed at the neck and with sleeves that fit snugly around the wrists) must be worn. NH | Select |

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| Personal Protective Equipment (PPE) for the compounding of hazardous sterile preparations must meet the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. | 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). | H | Select |
| | For hazardous preparations, 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. | H | Select |
| | 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. | H | Select |
| | For hazardous preparations, a chemical cartridge respirator must be worn when deactivating, decontaminating and cleaning underneath the work surface of a C-PEC. | H | Select |
| | 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. | H | Select |
| Equipment for the compounding of non-hazardous sterile preparations is designed, built, and maintained in accordance with NAPRA's Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations. | For non-hazardous compounding, PECs must be a LAFW or CAI that meets the requirement. | NH | Select |
| | The compounding aseptic isolator (CAI) must be positioned in an ISO Class 7 clean room adjacent to an ISO Class 8 anteroom. | NH | Select |
| | 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. | NH | Select |
| | If compounding with non-sterile API's, the pharmacy has appropriate equipment to sterilize the finished product. | NH | Select |
| 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. | H | Select |
| | 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. | H | Select |
| | 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. | H | Select |

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| Equipment for the compounding is designed, built, and maintained in accordance with NAPRA Model Standards for Pharmacy Compounding of Non-hazardous and/ or Hazardous Sterile Preparations. | The Primary Engineering Control (PEC) must ensure an ISO Class 5 air quality environment for the exposure of critical sites when sterile preparations are being compounded. | Select |
| | Each PEC or C-PEC must be certified at least every 6 months, when relocated, after major repairs or when viable air sampling indicates that the PEC or C-PEC may not be in compliance with specifications. | Select |
| | Sterile Isopropyl Alcohol (Sterile IPA) 70% must be available for use in the appropriate areas. | Select |
| | Refrigerators and freezers, when used to store medications, must be commercial, biomedical-grade units and only used for this purpose. | Select |
| | Refrigerators and freezers, which are designated for hazardous drugs, must be used only for this purpose. They must not be used to store food or other medications/solutions, etc. | Select |
| | Preventive maintenance for PECs and other equipment must be performed when no compounding is in progress, before cleaning and disinfection operations. | Select |
| | The automated compounding device (ACD) must be positioned in the PEC such that compounding occurs while critical sites are exposed to first air. | Select |
| | The ACD must be calibrated before each use, after it is moved, after cleaning and as needed, according to the manufacturer's recommendations | Select |
| | 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. | Select |
| | 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). | Select |
| | When the incubator is in operation, the incubator temperature must be read and recorded in the general maintenance log at least once a day and must be calibrated and maintained according to the manufacturer's recommendations. | Select |
| | Scales, balances, and other equipment used for measuring or weighing are calibrated at least annually. | Select |
| | If compounding with non-sterile API's, the pharmacy has appropriate equipment to sterilize the finished product. | Select |
| There is a cleaning and disinfecting procedure in place that addresses all sterile compounding areas. | Equipment used for cleaning and disinfection and its storage must be specifically designated for cleaning areas used for the compounding of non-hazardous sterile preparations. | Select |
| | Equipment used for cleaning and disinfection and its storage must be specifically designated for cleaning areas used for the compounding of hazardous sterile preparations. | Select |

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| | Personnel working in sterile compounding must comply with the requirements for cleaning and disinfecting as outlined in NAPRA. | Select |
| | Cleaning and disinfecting personnel must comply with the pharmacy's hand hygiene and garbing procedure before entering sterile compounding areas and performing housekeeping duties. Housekeeping personnel must also don two pairs of ASTM International–approved gloves before starting work. The outer gloves must be sterile. | Select |
| | 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 sterile products. | Select |
| | ISO 5 PEC is cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination. | Select |
| | Daily cleaning includes PECs, counters, carts and easily cleanable, high touch work surfaces. Daily cleaning includes floors - starting from clean room and working outwards (does not occur during compounding). Waste/ garbage is removed daily. | Select |
| | Monthly cleaning includes ceilings, walls, shelves, bins, carts, chairs, and the area outside the C-PEC. This area must be decontaminated along with cleaning and disinfecting. | Select |
| Hazardous rooms - There is a cleaning, disinfecting, deactivating and surface decontaminating procedure in place that addresses all hazardous compounding areas. | Hazardous rooms' surface decontamination, deactivation and disinfection of the C-PEC must be completed according to the frequencies set out in NAPRA. H | Select |

## Verification of equipment and facilities

| Standard | Guidance | Response |
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| There is an environmental verification program in place that meets the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous and/or Hazardous Sterile Preparations. | An environmental verification program must be established to ensure that facilities maintain established specifications and uphold the quality and safety standards set by the industry. The 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. | Select |
| | The differential pressure between controlled areas must be kept constant. | Select |

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| | 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. A procedure must be developed to outline and explain the actions to be taken should the pressure differential deviate from specifications. In the absence of a continuous reading system, the pressure differential must be verified and documented twice daily. | | Select |
| | The indicators for proper operation of any device (LAFW, CAI, BSC, CACI, ACD, etc.) must be verified every day, and data must be recorded in the general maintenance log. | | Select |
| | The temperature of controlled sterile compounding areas must be verified and documented at least once a day. | | Select |
| | Particle counts are taken under dynamic conditions as noted on the certification reports. Particles measured are greater than or equal to 0.5 micrometers. To achieve and maintain a particular ISO class for a clean room, all particle-generating sources must be controlled. ISO class area is certified to have appropriate counts. | | Select |
| | A written sampling plan for controlled areas and the PEC/C-PEC must be established. Sampling should be performed on all direct compounding areas, in each room, inside any pass-throughs and on any likely contaminated surfaces. | | Select |
| | Sampling must be obtained for three types of samples:<br>• non-viable particles per cubic metre of air;<br>• viable particles per cubic metre of air;<br>• viable surface particles.<br>Samples must be taken every 6 months and every time that the following conditions are present:<br>• during installation of new equipment or a new controlled area;<br>• during maintenance or repair of equipment (repair of PEC, ventilation system, etc.) or a controlled area (repair of hole in a wall);<br>• during investigation of a contamination problem or a problem involving non-compliance of personnel with aseptic processes. | | Select |
| | 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. | | Select |
| | For hazardous rooms - 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. | H | Select |

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| There is a quality assurance program in place that addresses the verification of equipment and facilities. | 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. | Select |
| | The general maintenance log includes all records or forms regarding the following activities:<br>• cleaning and disinfecting, certification and maintenance of the facility as a whole, certification and maintenance of the PEC and maintenance of other equipment;<br>• verification of proper operation of equipment and instruments (calibration, refrigerator temperatures, etc.).<br>All records must be retained as per standards of practice of the respective provincial regulatory authority and in accordance with the principles of confidentiality. | Select |
| | 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. The maintenance report must be saved in the general maintenance log. The general maintenance logs are complete, accurate and maintained as per standards of practice and NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous and/ or Hazardous Sterile Preparations. | Select |
| | 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.<br>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.<br>Temperature readings will include the actual temperature, the minimum temperature and the maximum temperature.<br>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. | Select |

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| | An investigation must be undertaken when a contamination or a problem involving non-compliance in the aseptic compounding process is discovered. | | Select |
| | Certification is according to Controlled Environment Testing Association (CETA) standard. Person/ parties responsible for overseeing the certification reports are familiar with the testing required and interpretation of results, and the reports have action levels identified. | | Select |
| | HEPA filter testing is performed in all ISO certified rooms. All HEPA filters were leak tested and leaks were identified if repaired. Hazardous in addition to above: the BSC/CACI exhaust HEPA filter are leak tested. | H | Select |
| | The HEPA filtered air changes per hour (ACPH) measured for the compounding rooms are acceptable. | | Select |
| | Smoke pattern testing is performed to analyze air pattern at:<br>1) critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions;<br>2) to confirm positive pressure (and negative pressure in hazardous compounding rooms) at all points around all openings, doorways and pass-throughs;<br>3) around particle generating equipment while equipment was in operation to confirm airflow. | | Select |
| | The equipment used by the certifier is calibrated and the calibration is in date. Each test has a clear indication of Pass or Fail. | | Select |
| | For compounding areas with no wall between the ante-area and clean area - there must be displacement airflow with a velocity of at least 40 feet per minute from clean area to ante-area. | | Select |

## Beyond use date (BUD) and dating methods

| Standard | Guidance | Response |
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| The pharmacy's operating procedures describe the risk assessment process used to establish the Beyond Use Date (BUD) and the storage conditions according to the NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations. | The BUD must not exceed the earliest of the dates established by the following two criteria:<br>1) expiration date based on chemical and physical stability according to reference texts;<br>2) storage time related to risk of microbial contamination. | Select |
| | 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 CAI/ CACI that meets the criteria specified when placed in environments with particle counts exceeding ISO Class 7. | Select |

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| | Low Risk preparations are prepared and must meet the beyond use dates;<br>• final product compounded using up to 3 “sterile units”,<br>• no more than 2 septum punctures at the injection site for each sterile unit,<br>• simple aseptic transfer technique;<br>• drug prepared for one patient (patient-specific dose) use the appropriate beyond use dates. | Select |
| | For low risk preparations, consider risk of contamination Low;<br>• At controlled room temperature, BUD must be no more than 48 hours,<br>• Refrigerator BUD must be no more than 14 days,<br>• Freezer BUD must be no more than 45 days. | Select |
| | Medium Risk preparations are prepared and must meet beyond-use dates;<br>• final product compounded using 4 or more “sterile units”,<br>• complex manipulations,<br>• prolonged preparation time,<br>• batch preparations (preparing more than one unit of the same composition during one compounding session). | Select |
| | For medium risk preparations, consider risk of contamination Medium;<br>• At controlled room temperature, BUD must be no more than 30 hours<br>• Refrigerator BUD must be no more than 9 days<br>• Freezer BUD must be no more than 45 days. | Select |
| | High Risk preparations are prepared and must meet beyond-use dates;<br>• non-sterile ingredients or equipment used before terminal sterilization,<br>• non-sterile preparations, containing water, stored for more than 6 hours before terminal sterilization,<br>• improper garbing or gloving by compounding personnel. | Select |
| | For high risk preparations, consider risk of contamination High;<br>• At controlled room temperature, BUD must be no more than 24 hours,<br>• Refrigerator BUD must be no more than 3 days,<br>• Freezer BUD must be no more than 45 days. | Select |

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| | Immediate use compounds are only being used for emergency purposes, aseptically compounded, include simple transfer of up to 3 commercially manufactured non-hazardous products and contain no greater than 2 entries / container. Administration of the preparation must begin within 1 hour after the start of compounding; otherwise, the preparation must be discarded. | Select |
| | The pharmacy must have a policy to specify the BUD of single-dose vials.<br>• If the vial is punctured in a CPEC/PEC that maintains ISO Class 5 air quality, the BUD is 6 hours.<br>• If the single-dose container is opened/ punctured in an environment with air quality worse than ISO Class 5, the BUD is 1 hour.<br>• Six hours after initial needle puncture, the vial can no longer be used. Once the vial is removed from the ISO Class 5 PEC, it must be discarded. To properly manage risk, a label must be affixed to the vial indicating the time of initial needle puncture.<br>No storage of an open ampoule is permitted; as such, no BUD applies. | Select |
| | The contents of a vial are not divided for the sole purpose of extending stability. | Select |
| | The pharmacy must have a policy in place to specify the BUDs of multi-dose vials. A multiple-dose container will be labelled as such by the manufacturer. Multiple-dose containers usually contain a preservative. 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. | Select |
| | 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. (See USP 71 for sterility testing standards.) | Select |

## Compounding procedures

| Standard | Guidance | Response |
|---|---|---|
| Sanitization and Decontamination | Disinfect non-powdered sterile gloves and critical sites with sterile 70% isopropyl alcohol and allow to dry before each entry into ISO Class 5 PEC. Must use a spray bottle (no open pour, spray bottle must be assembled in ISO 5 clean room) and non-linting/ non-shedding wipe. | Select |

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| | Where packaging allows, compounding equipment and products are disinfected with sterile 70% isopropyl alcohol just before being introduced into the clean room and ISO Class 5 PEC. Non-shedding wipes or swabs must be used for disinfection. The wipes or swabs must be changed regularly during disinfection of equipment and products. | Select |
| | Every CSP is visually inspected for thorough mixing and for the presence of particulate matter, evidence of incompatibility or other issues. | Select |
| | Appropriate sanitization processes are followed for vials and ampules prior to use. | Select |

## Compounding procedures - high risk preparations

| Standard | Guidance | Response |
|---|---|---|
| Compounding high risk sterile preparations. | Appropriate sterilization methods for high risk compounds are used and documented. | Select |
| | If the pharmacy uses non-sterile empty vials and vial stoppers or closures, the pharmacy terminally sterilizes them with an on-site autoclave. Autoclaves must be calibrated and maintained according to the manufacturer's recommendations. | Select |
| | Filter Sterilization: Documentation includes: that The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. Filtering is completed rapidly without filter replacement.<br>Confirmation of filter integrity (bubble testing) is performed for each filter used with each batch sterilized by filtration. Single use filters are only used once. The CSP and the CSP volume are appropriate for filter used. | Select |
| | Depyrogenation by Dry Heat: Documentation includes the dry heat sterilization has been validated (including external thermometer if applicable) for the exposure time and mass of the items to be sterilized (recommended annually) and heat mapping studies have been performed. Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes. The description of the cycle and duration for specific load items. The effectiveness of each cycle is verified using endotoxin challenge vials (ECVs). Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins. SOP shows how quickly depyrogentated items are used. SOP shows where the depyrogentated items are stored. | Select |

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| | The pharmacy must have a written risk assessment process to establish BUD's in their operating procedures. Sterility tests and risk assessments must be performed for a given preparation or batch to establish a longer BUD. Preparations must be quarantined while awaiting the results of sterility tests. | Select |
| | If high risk CSPs are: compounded in batches of over 25 identical units; exposed for more than 12 hours at a temperature between 2°C and 8°C before sterilization; exposed for more than 6 hours at a temperature above 8°C before sterilization then sterility testing and bacterial endotoxin testing are performed. | Select |
| | The pharmacy has a policies and procedures in regards to:<br>1) daily observation of media,<br>2) immediate recall upon evidence of growth,<br>3) notification of prescribing practitioners and patients for potential risk to a contaminated CSP. | Select |
| | A sterility test via membrane filtration must be performed for high-risk sterile preparations in the following situations:<br>• when sterile preparations are compounded in batches of over 25 identical units;<br>• when there has been more than 12 hours of exposure time at a temperature between 2°C and 8°C before sterilization;<br>• when there has been more than 6 hours of exposure time at a temperature above 8°C before sterilization. | Select |
| | Bacterial Endotoxin tests are being performed for all high risk level CSP's:<br>1) prepared in batches >25, or<br>2) exposed longer than 12 hours at 2-8C, or<br>3) longer than 6 hours at warmer than 8C before sterilization | Select |

## Labelling

| Standard | Guidance | Response |
|---|---|---|
| Labelling of the final compounded sterile preparation meets NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous and/ or Hazardous Sterile Preparations and provincial requirements. | Each container for a compounded sterile preparation must be labelled. | Select |
| | 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, storage method; date when the sterile preparation was compounded; BUD; preparation batch number. | Select |

## Recall of sterile products of final compounded sterile preparations

| Standard | Guidance | Response |
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| There is a process in place when a 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. | Select |

## Receipt, transport, and delivery

| Standard | Guidance | Response |
|---|---|---|
| The pharmacy has policies and procedures in place to ensure safe receipt, transport and delivery of compounded non-hazardous sterile preparations. | Space must be provided for unpacking supplies. | Select |
| | 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. | Select |
| | 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. | Select |
| | Policies and procedures must be developed and implemented for the transport of compounded sterile preparations and their delivery to patient care units, pharmacists, patients and other hospitals. | Select |
| 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. H | Select |
| | 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. Damaged hazardous drugs must be unpacked in a C-PEC used for compounding of non-sterile hazardous preparations. H | Select |
| | If a shipping container for hazardous drugs appears damaged upon receipt, appropriate procedures must be followed. H | Select |
| | 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. H | Select |
| | 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. H | Select |

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

## Incident and accident management

| Standard | Guidance | Reponse |
|---|---|---|
| The pharmacy has policies and procedures in place to address incident and accident management with respect to non-hazardous sterile compounding. | Each organization must have a process for incidents and accidents and must maintain a log. The information in the log is used to investigate deviations from protocol and to improve processes. | Select |
| | When an incident or accident involving a compounded sterile preparation occurs, an event report and explanation form must be completed. | Select |
| 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. | H Select |
| | Policies, procedures and training for managing spills must be in place for employees who clean up spills. | H Select |
| | When an incident or accident involving a hazardous compounded sterile preparation occurs, an event report and explanation form must be completed. | H Select |

## Waste management

| Standard | Guidance | Response |
|---|---|---|
| The pharmacy has a non-hazardous waste management process in place. | The pharmacy must have 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. | Select |
| | 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. | Select |

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| | The pharmacist and pharmacy technician must ensure that medications to be destroyed are safely stored in a location separate from other medications in inventory. | | Select |
| | There must be a procedure developed and implemented for the destruction of pharmaceutical waste. | | Select |
| 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. | H | Select |
| | The pharmacist and pharmacy technician must ensure that medications to be destroyed are safely stored in a location separate from other medications in inventory. | H | Select |
| | 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. | H | Select |