Definitions:

PEC – Primary Engineering Control  
BSC – Biological Safety Cabinet  
C-PEC – Containment Primary Engineering Control  
CACI – Compounding Aseptic Containment Isolator  
CVE – Containment Ventilated Enclosure  
ACPH – Air Changes Per Hour  
ABHR – Alcohol Based Hand Rub  
PPE – Personal Protective Equipment  
LAFW – Laminar Airflow Workbench  
CAI – Compounding Aseptic Isolator  
ISO Class – International Organization for Standardization Classes of air cleanliness for airborne particulates in clean rooms and clean areas  

*Refer to Non-Hazardous Sterile Preparations document; Table 1, section 5.3.1, page 16 for particle allowances per ISO Class

<table>
<thead>
<tr>
<th>LEVEL A Non-Sterile</th>
<th>Rooms Needed</th>
<th>Room Requirements</th>
<th>Garb Required</th>
<th>Necessary Equipment</th>
</tr>
</thead>
</table>
| Simple and moderate compounds based on risk assessment of drugs being used | Separate Area | - designed and arranged to prevent cross contamination  
- away from high traffic areas in the pharmacy  
- large enough to work comfortably and to store equipment  
- sink with hot and cold running water and sewage disposal to complete proper hand hygiene  
- work surfaces and furniture constructed of smooth, impermeable, non-porous materials that are resistant to damage from cleaning and disinfecting products (i.e. stainless steel) | - disposable gown  
- gloves  
- surgical mask  
- hair net  
- short nails (no nail polish or artificial nails)  
- no jewelry on hands and wrists | |

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<thead>
<tr>
<th>LEVEL B Non-Sterile</th>
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<th>Necessary Equipment</th>
</tr>
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| Allergenic products or products that could have unintended effects (i.e. hormones) | Dedicated non-sterile, non-hazardous compounding room | - separate from the rest of the pharmacy  
- provides a larger workspace to store all materials and equipment  
- sink with hot and cold running water and sewage disposal to complete proper hand hygiene  
- uninterrupted workflow and greater protection from cross contamination  
- entirely closed off (doors and windows well sealed)  
- either ventilated outside or have a ventilated containment device | - disposable gown  
- gloves  
- surgical mask  
- hair net  
- short nails (no nail polish or artificial nails)  
- no jewelry on hands and wrists | ventilated containment device if compounding room is not adequately ventilated (i.e. an HVAC system installed within the room) |
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<th>Necessary Equipment</th>
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<tr>
<td><strong>Non-Hazardous Sterile</strong> (Level A &amp; B Sterile)</td>
<td><strong>Both:</strong> - ALL surfaces, fixtures and furniture must be constructed of smooth, impermeable, non-porous materials that are resistant to damage from cleaning and disinfecting products (i.e. stainless steel) - for low and medium risk compounding (sec 5.3.2.5 – Non-Hazardous Sterile Preparations) no wall separation is needed, but there must be displacement air flow with a velocity of 40 feet / minute from clean-area to ante-area <strong>Anteroom:</strong> - ISO Class 8 air quality must be maintained, unless it is a shared non-hazardous and hazardous drug anteroom, in which case ISO Class 7 must be maintained - separated into “dirty” area and “clean” area by a visible demarcation line - must have at least 20 ACPH - kept under positive pressure relative to non-controlled area (pharmacy) adjacent to anteroom - storage space for PPE - hands-free sink with hot and cold running water and sewage disposal (large enough to wash hands and fore-arms without touching sides) - soap dispenser - nail picks - ABHR - hand drying system - mirror to verify garbing - clock - waste container - eyewash station - pass-through for transferring products into clean room and/or cart reserved for use in “clean” area <strong>Clean Room:</strong> - PEC is installed in the clean room - kept under positive pressure relative to anteroom - ISO Class 7 air quality must be maintained - at least 30 ACPH or more</td>
<td>- disposable gown that has long sleeves, closed front, fitted cuffs - sterile gloves - surgical mask - hair net - beard cover - shoe covers -short nails (no nail polish or artificial nails) -jewelry removed from fingers, wrists, forearms, face, tongue, ears and neck</td>
<td>PEC installed in clean room is either: - LAFW - CAI</td>
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All sterile compounds not involving antineoplastic drugs
<table>
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<tr>
<th>LEVEL C</th>
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<th>PPE Required</th>
<th>Necessary Equipment</th>
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| Non-Sterile Compounds involving antineoplastic drugs | Room dedicated to hazardous drug/material compounding OR Separate room (non-hazardous compounding room) with assurances that it is meticulously cleaned so there is no risk of cross contamination with hazardous materials before compounding other preparations | - be under negative pressure  
- physically separate from other preparation rooms (if not having a shared hazardous and non-hazardous non-sterile compounding room)  
- have an appropriate air exchange of at least 12 ACPH  
- be externally vented through HEPA filtration  
- have a C-PEC  
- sink with hot and cold running water to complete proper hand hygiene as well as an eye wash station (water sources and drains must be at least 1 meter away from C-PEC)  
*If sharing a compounding room with non-hazardous non-sterile compounding Level C requirements must be in place for the shared room | - disposable gown that has long sleeves, closed front, fitted cuffs, resists permeability by hazardous products  
- double glove (chemo gloves)  
- mask (surgical masks do not provide respiratory protection. N95 or N100 will protect against airborne particles)  
- hair net  
- shoe covers  
- goggles and face shield, or a full-face respirator  
- short nails (no nail polish or artificial nails)  
- no jewelry on hands and wrist | C-PEC installed  
- Either a Class I BSC or a CVE  
- A Class II BSC or CACI may be used  
- For occasional non-sterile hazardous compounding, a C-PEC used for normal sterile compounding can be used but MUST be decontaminated, disinfected and cleaned before and after hazardous preparation |
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<tr>
<th>LEVEL C</th>
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<th>Room Requirements</th>
<th>PPE Required</th>
<th>Necessary Equipment</th>
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<tr>
<td>Sterile</td>
<td>Anteroom and Clean Room</td>
<td>Both: - maintain ISO Class 7 air quality - air into rooms must go through HEPA filtration - must have at least 30 ACPH - one or more observation windows installed for visual verification steps in compounding - ALL surfaces, fixtures and furniture must be constructed of smooth, impermeable, non-porous materials that are resistant to damage from cleaning and disinfecting products (i.e. stainless steel)</td>
<td>- non-shedding scrubs - disposable gown that has long sleeves, closed front, fitted cuffs, resists permeability by hazardous products - double glove (chemo gloves) - mask (surgical masks do not provide respiratory protection. N95 or N100 will protect against airborne particles) - hair net - shoe covers - goggles and face shield, or a full face respirator - beard cover - short nails (no nail polish or artificial nails) - jewelry removed from fingers, wrists, forearms, face, tongue, ears and neck</td>
<td>C-PEC installed in clean room: - Must be externally ventilated - Comply with ISO Class 5 - Either Class II or III BSC or CACI</td>
</tr>
<tr>
<td>Sterile</td>
<td>Anteroom and Clean Room</td>
<td>OR - if space limitations, an anteroom may be shared for hazardous and non-hazardous compounding</td>
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<tr>
<td>Sterile</td>
<td>Anteroom and Clean Room</td>
<td>Anteroom: &quot;If Anteroom is shared between hazardous and non-hazardous sterile compounding Level C requirements must be in place for the shared room&quot; - positive air pressure relative to main pharmacy area - separated into “dirty” area and “clean” area by a visible demarcation line - storage space for PPE - hands-free sink (large enough to wash hands and forearms without touching sides) - soap dispenser - nail picks - ABHR - hand drying system - mirror or other means to verify garbing - clock - cytotoxic waste container - eyewash station - pass-through for transferring products into clean room and/or cart reserved for use in “clean” area</td>
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<tr>
<td>Sterile</td>
<td>Anteroom and Clean Room</td>
<td>Cleanroom: - C-PEC is installed in the clean room - negative air pressure relative to anteroom - return air must be externally vented - return air exhausts at bottom of walls, forcing particles to flow downward - large enough to facilitate compounding, allow for proper cleaning and disinfecting and proper workflow</td>
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</tbody>
</table>
Hazardous drugs require a specified storage room that:
  • All air is exhausted outside
  • Negative air pressure relative to adjacent rooms
  • At least 12 ACPH (air changes per hour)
  • Proper signage (“Hazardous Products Present”)
  • Shelves with lips to prevent products from falling and breaking

Hazardous sterile preparations requiring refrigeration can be stored in a fridge kept in the hazardous clean room for this purpose only.

**Level A and B Risk Assessment:**
Factors to consider:
  • Concentration of ingredients in product
  • Physical characteristics of ingredients (liquid VS solid VS powders, water soluble VS lipid soluble)
  • Quality of ingredients being handled
  • Frequency of making the compound
  • Exposure to compounding personnel
  • Risk of microbial contamination
  • Availability of appropriate facilities and equipment
  • NIOSH/WHMIS classification of product

  NIOSH List of Hazardous Drugs - [https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf](https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf)
  WHMIS - [http://whmis.org/](http://whmis.org/)

Most simple or moderate non-sterile compounds can be made following Level A requirements. It would be possible to prepare a non-sterile simple preparation, which contains a drug categorized by NIOSH as hazardous (i.e. Clonazepam, Carbamazepine) and follow Level A if the hazardous drug is in a small quantity and has the physical characteristics conducive to minimizing contamination of the immediate area and risk to the compounding personnel.

Questions?
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