Compounding Reference Chart – Physical Requirements

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

*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</th>
<th>Rooms Needed</th>
<th>Room Requirements</th>
<th>Garb Required</th>
<th>Necessary Equipment</th>
</tr>
</thead>
</table>
| **A** | Non-Sterile | 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 | ventilated containment device if compounding room is not adequately ventilated (i.e. an HVAC system installed within the room) |
|       | Simple and moderate compounds based on risk assessment of drugs being used |                       |               |                     |
| **B** | Non-Sterile | 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 appropriately 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 |                     |
<table>
<thead>
<tr>
<th>Non-Hazardous Sterile (Level A &amp; B Sterile)</th>
<th>Anteroom and Clean Room</th>
<th>Both:</th>
<th>Garb Required</th>
<th>Necessary Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>All sterile compounds not involving antineoplastic drugs</td>
<td></td>
<td>- 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>
</tr>
<tr>
<td>LEVEL C</td>
<td>Rooms Needed</td>
<td>Room Requirements</td>
<td>PPE Required</td>
<td>Necessary Equipment</td>
</tr>
<tr>
<td>---------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>---------------------</td>
</tr>
</tbody>
</table>
| 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) | - 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 |
<table>
<thead>
<tr>
<th>LEVEL C</th>
<th>Rooms Needed</th>
<th>Room Requirements</th>
<th>PPE Required</th>
<th>Necessary Equipment</th>
</tr>
</thead>
</table>
| Sterile | Compounds involving antineoplastic drugs | **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)  

**Anteroom:**  
*If Anteroom is shared between hazardous and non-hazardous sterile compounding Level C requirements must be in place for the shared room*  
- 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  

**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  

- 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  |

C-PEC installed in clean room:  
- Must be externally ventilated  
- Comply with ISO Class 5  
- Either Class II or III BSC or CACI
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
  - WHMIS - 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.