Last Updated: 6/1/2019

# USP <797> Readiness Checklist - Primary Engineering Controls

Protection for your patients and compounding personnel begins with selecting and implementing the right Primary Engineering Controls (PECs) for your pharmacy. Use this simple checklist as a review of your pharmacy's compliance readiness for new requirements per USP <797>, effective December 1st, 2019.

Have a specific question or concerns? Contact one of our pharmacy experts, or visit labconco.com for information on PECs and to access helpful articles on USP <797> and USP <800> compliance.

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## Appropriate PECs - Sterile Hazardous & Sterile Non-Hazardous Products

| Criteria | Comply? | Comment |
|---|---|---|
| Are PECs used for non-hazardous sterile compounding either Laminar Airflow Workstations (LAFWs) or Compounding Aseptic Isolators (CAIs)? | ☐ | |
| Are containment PECs (C-PECs) used for hazardous sterile compounding either Class II BSCs (Type C1, A2, or B2) or Compounding Aseptic Containment Isolators (CACIs)? Are Class II BSCs/CACIs externally vented? | ☐ | |
| Do PECs provide unidirectional ISO 5, HEPA-filtered airflow during dynamic conditions? Is airflow confirmed in smoke visualization studies? | ☐ | |
| If using a piece of equipment within the PEC (e.g. compounder, IV verification/gravimetric system, etc.), is uniform airflow maintained? | ☐ | |
| If using a CAI or CACI, has PEC's abiliity to maintain ISO 5 air quality under dynamic conditions been documented? | ☐ | |
| Are PECs constructed of materials that are compatible with cleaning/disinfection agents used in the pharmacy? Are polycarbonate/acrylic windows being cleaned with ammonia-free agents? | ☐ | |

## Location of PECs - Category 1 Compounded Sterile Products (CSPs)

| Criteria | Comply? | Comment |
|---|---|---|
| For non-hazardous Category 1 CSPs, are PECs located in a Segregated Compounding Area (SCA)? | ☐ | |
| For hazardous Category 1 CSPs, are C-PECs located in a Containment Segregated Compounding Area (C-SCA)? | ☐ | |

## Location of PECs - Category 1 Compounded Sterile Products (CSPs) (Continued)

| Criteria | Comply? | Comment |
|---|---|---|
| Is the C-SCA externally vented, with a minimum of 12 Air Changes Per Hour (ACPH) and negative pressure (between 0.01 and 0.03" of water column)? | ☐ | |
| Are PECs placed within a SCA or C-SCA located away from areas of turbulent airflow (e.g. doors)? | ☐ | |
| Is the SCA or C-SCA located away from sources of contamination (e.g. windows, high-traffic areas, restrooms, etc.)? | ☐ | |
| Is the PEC appropriately sized for the room? PECs should not cause excessive air currents within the SCA or C-SCA. | ☐ | |
| Are CSPs prepared in the SCA or C-SCA assigned BUD dates of 12 hours or less (24 hours or less if refrigerated)? | ☐ | |

## Location of PECs - Category 2 Compounded Sterile Products (CSPs)

| Criteria | Comply? | Comment |
|---|---|---|
| For non-hazardous Category 2 CSPs, are PECs (LAFWs, CAIs) placed in a (+) ISO 7 Buffer Room that is entered through an ISO 8 (or better) ante-room? | ☐ | |
| For hazardous Category 2 CSPs, are PECs (Class II BSCs, CACIs) placed in a (-) ISO 7 Buffer Room that is entered through an ISO 7 (or better) ante-room? | ☐ | |
| Do ISO 7 Rooms (both (+) and (-)) have a minimum of 30 ACPH? Do ISO 8 Rooms have a minimum of 20 ACPH? Are ACPH sufficient to maintain room classifications during dynamic conditions? | ☐ | |
| Are PECs placed within a (+) or (-) ISO 7 Buffer Room located away from areas of turbulent airflow (e.g. doors)? | ☐ | |
| If preparing Category 2 CSPs from non-sterile starting ingredients, are pre-sterilization procedures carried out in ISO 8 (or better) conditions? Are procedures carried out in a C-PEC? | ☐ | |

## Ventilation of C-PECs - Hazardous CSPs

| Criteria | Comply? | Comment |
|---|---|---|
| Are all C-PECs used to produce CSPs externally vented? | ☐ | |
| If Class II, Type A2 or C1 BSCs are used, are they canopy connected to the exhaust system, with a canopy alarm installed? | ☐ | |
| If Class II, Type B2 BSCs are used, are they connected to a exhaust system with redundant blowers? | ☐ | |
| If Class II, Type B2 BSCs are used, are they connected to a single exhaust blower and single duct run per each B2 BSC? | ☐ | |
| If a hard-ducted Class II, Type A/3B3 BSC is used, does a plan exist to remove the BSC per USP <800> and NSF/ANSI Standard 49? | ☐ | |
| If using a CACI, are (3) pairs of gloves being used? Glove liner, gloves on sleeves/gauntlets, gloves over top of sleeve/gauntlet gloves. | ☐ | |
| If a PEC(s) is providing a portion of a room's minimum air changes (C-SCA = 12 ACPH, ISO 7 Buffer Room = 30 ACPH), is it left on continuously? | ☐ | |
| If a PEC(s) is providing a portion of the minimum 30 ACPH, is the room HVAC providing at least 15 of the ACPH? | ☐ | |

## Certification of PECs

| Criteria | Comply? | Comment |
|---|---|---|
| Is the certification professional(s) servicing your cleanroom properly trained? CETA Sterile Cleanroom Certified, NSF Accredited, etc? | ☐ | |
| Do all PECs used to prepare CSPs have a current certification within the last 6 months? | ☐ | |
| Are PECs used to prepare CSPs scheduled to receive a certification every 6 months after initial certification? | ☐ | |

## Certification of PECs (Continued)

| Criteria | | Comply? | Comment |
|---|---|---|---|
| Are PECs missing any parts (diffusers, bolts, etc.)? | | ☐ | |
| Do HEPA filter(s) within the PECs have any visual discoloration or damage? If yes, does a plan exist to have the filter(s) replaced and re-certified? | | ☐ | |
| For older PECs, does the manufacturer still have available replacement parts? | | ☐ | |
| Do programs exist for the monitoring of total airbone particles, viable airbone particles, and surfaces within all PECs used for CSPs? | | ☐ | |
| Do certification reports for your PECs include: | | | |
| Certification Testing Components | Airflow Testing (Face Velocity (LAFW, CAI, CACI) or Inflow/Downflow (Class II BSC)? | ☐ | |
| | HEPA Filter Integrity Testing? | ☐ | |
| | Total Particle Count Testing? | ☐ | |
| | Dynamic Airflow Smoke Pattern Testing? | ☐ | |
| Are certification reports for PECs understood by the Pharmacy Director/Pharmacist-In-Charge? Compounding Personnel? | | ☐ | |

## PEC Personnel Training

| Criteria | Comply? | Comment |
|---|---|---|
| Do formal SOPs exist for all compounding activities involving PECs? Compounding, cleaning, certification, etc. | ☐ | |
| Do compounding personnel have a basic understanding of how each PEC used in the pharmacy works? Controls, airflow, etc. | ☐ | |
| Have all compounding personnel that prepare CSPs performed a media fill test within the last 12 months? | ☐ | |