USP 800 Cheat Sheet

Goes into effect 2/1/2016 and facilities have until 7/1/2018 to become compliant.

DEFINITIONS

Anteroom: Transition area between the general area and the room containing the C-PEC. Hand hygiene, garbing, staging of components, order entry, and other particle-generating activities are performed in the anteroom. For sterile compounding, the anteroom shall meet ISO Class 7 and also provides assurance that pressure relationships between rooms are constantly maintained.

Beyond-Use Date (BUD): The date or time after which a compounded preparation shall not be used, stored, or transported.

Buffer Room: Part of the HD compounding area under negative pressure where the C-PEC is physically located. Activities that occur in this area are limited to the preparation and staging of components and supplies used when compounding HDs.

Compounding Aseptic Containment Isolator (CACI): A specific type of CAI that is designed for compounding of sterile HDs. Exhaust air from the isolator shall be appropriately removed by properly designed building ventilation.

Compounding Aseptic Isolator (CAI): An isolator specifically designed for compounding sterile, non-hazardous pharmaceutical ingredients or preparations. A CAI shall not be used for the manipulation of HDs.

Containment Primary Engineering Control (C-PEC): A ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants. Examples of C-PECs include Class I, II, or III BSCs, CACIs, and CVE (e.g., powder hood). C-PECs used for nonsterile compounding do not need to have ISO Class 5 air quality. C-PECs used for sterile compounding shall have ISO Class 5 air quality.

Containment Secondary Engineering Control (C-SEC): The C-SEC is the room in which the C-PEC is placed. It incorporates specific design and operational parameters required to contain the potential hazard within the compounding room (e.g., restricted access, barriers, special construction technique, ventilation, and room pressurization are components of the secondary control strategy).

Containment Segregated Compounding Area (C-SCA): A type of C-SEC with nominal airflow (12 ACPH) and room pressurization requirements (negative pressure between 0.01 ï 0.03 inches of water column) as they pertain to HD compounding. The C-SCA is limited for use with a BSC or CACI when preparing low or medium-risk level CSPs with 12-hour or less BUDs or preparing nonsterile HDs in a C-PEC.

Containment Ventilated Enclosure (CVE): A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants (through HEPA filtration) and prevent their release into the work environment (e.g., powder hood).

NOTES

Nonsterile Compounding

*Nonsterile HD compounding must be performed in a C-PEC that provides personnel and environmental protection, such as a Class I BSC or CVE. A Class II BSC or a CACI may also be used. For occasional nonsterile HD compounding, a C-PEC used for sterile compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated, cleaned and disinfected before resuming sterile compounding in that C-PEC.

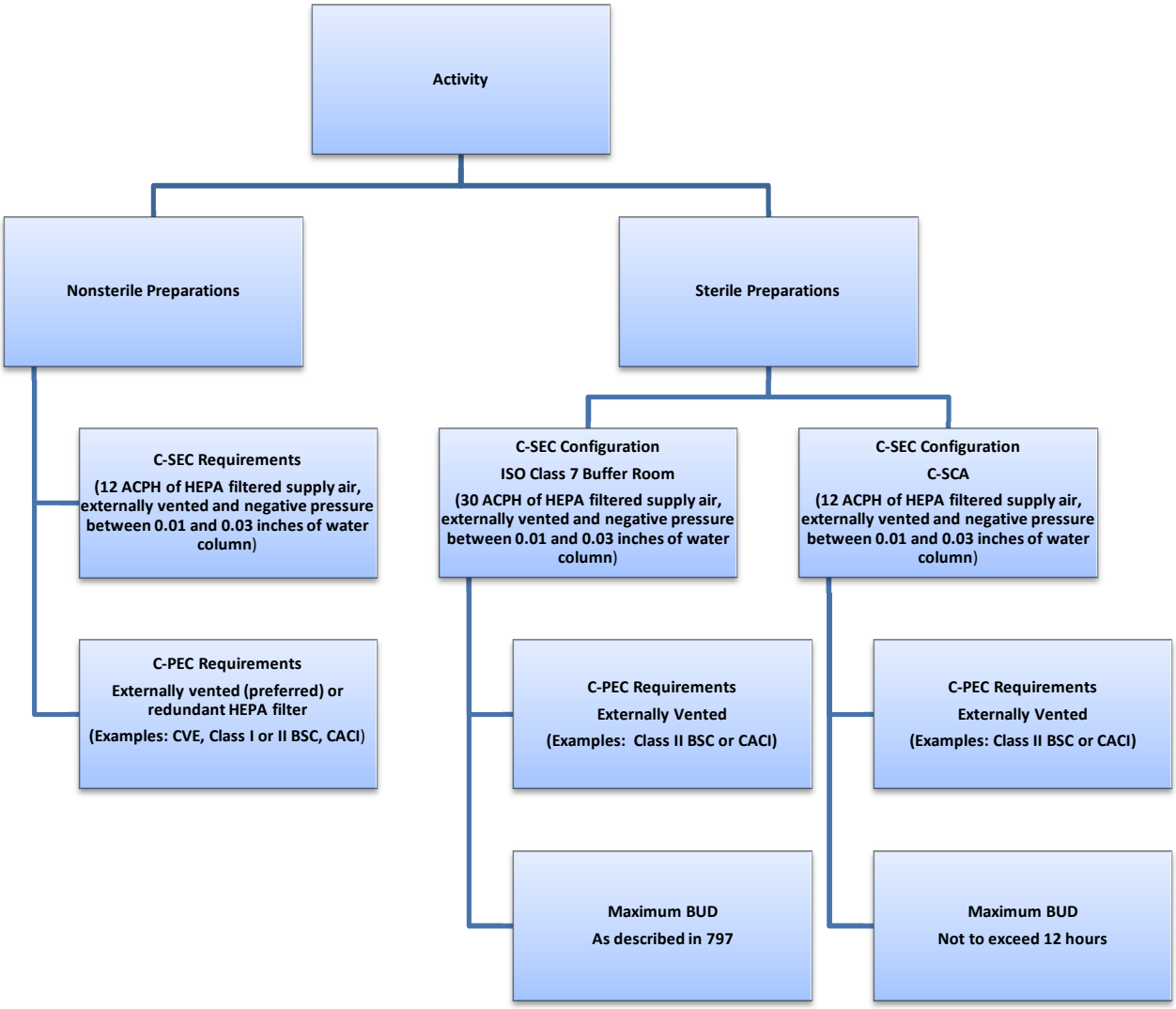
Sterile Compounding

*All C-PECs used for manipulation of sterile HDs must be externally vented. Sterile HD compounding must be performed in a C-PEC that provides Class 5 or better air quality, such as a Class II or III BSC, or CACI. Class II BSC types A2, B1 or B2 are all acceptable. For most known HDs, type A2 cabinets offer a simple and reliable integration with the ventilation and pressurization requirements of the C-SEC. Class II type B2 BSCs are typically reserved for use with volatile components.

*The C-PEC must be located in a C-SEC, which may either be an ISO Class 7 buffer room (preferred) or an unclassified containment segregated compounding area (C-SCA). If the C-PEC is placed in a C-SCA, the beyond-use date (BUD) of all compounded sterile preparations (CSPs) prepared must be limited to 12 hours or less.

*The C-PEC may be placed in an ISO Class 7 buffer room that has a negative pressure between 0.01 and 0.03 inches of water column and has a minimum of 30 ACPH of HEPA-filtered supply air. HD CSPs prepared in an ISO Class 7 buffer room may use the BUDs described in <797>, based on the categories of CSP, sterility testing and storage temperature.

*The C-PEC may be placed in an unclassified C-SCA that has a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent spaces and has a minimum of 12 ACPH of HEPA-filtered supply air. Only low and medium risk HD CSPs may be prepared in a C-SCA.


Activity
Nonsterile Preparations
Sterile Preparations
C-SEC Requirements
(12 ACPH of HEPA filtered supply air, externally vented and negative pressure between 0.01 and 0.03 inches of water column)
C-PEC Requirements
Externally vented (preferred) or redundant HEPA filter
(Examples: CVE, Class I or II BSC, CACI)
C-SEC Configuration
ISO Class 7 Buffer Room
(30 ACPH of HEPA filtered supply air, externally vented and negative pressure between 0.01 and 0.03 inches of water column)
C-SEC Configuration
C-SCA
(12 ACPH of HEPA filtered supply air, externally vented and negative pressure between 0.01 and 0.03 inches of water column)
C-PEC Requirements
Externally Vented
(Examples: Class II BSC or CACI)
C-PEC Requirements
Externally Vented
(Examples: Class II BSC or CACI)
Maximum BUD
As described in 797
Maximum BUD
Not to exceed 12 hours