Critical Environments Professionals, Inc.
Environmental Quality and Control
USP <797> Sterile Compounding Preparations & <800> Hazardous Drug Compliance Checklist

We at Critical Environments Professionals, Inc. are dedicated to serving Healthcare providing containment, contamination and infection control compliance consulting. This checklist is a work in progress and is a compilation of USP requirements per "USP40 NF35 Compounding Compendium" and current assessment practices performed. Focus has been placed on Environmental Quality and Control and Facility Design. This checklist is intended to aid in the assessment of USP <797> & <800>. Critical Environments Professionals (CEPro) is available to assist in interpreting these requirements and assess your specific operations.

Reference	Description	Compliant?			Notes
		Yes	No	Unsure	
	Getting Started				
	C-Suite sponsorship and involvement				
	Compliance team identified with roles/responsibilities assigned and ageed to (CNO/COO/CMO, Pharmacy, Facilities, Infection Control, Quality, Safety, USP Cleanroom Professionals, A&E)				
	Clear understanding of non-compliance implications and July 2018 mandate deadline				
	GAP analysis/assessment performed				
	Comprehensive compliance training				
	CMS, State, Joint Commission, AHJ survey dates known				
	CSP Microbial Contamination				
	Risk levels identified				
	Identify Hazardous Drug compounding volumes current/future				
	All BUD requirements identified				
	Based on risk level and use timing, determine storage requirements – controlled room, cold temperature or frozen state				

Reference	Description	Compliant?			Notes
		Yes	No	Unsure	
	Hazardous Drugs				
	HD's prepared in a C-SCA (Containment Segregated Compounding Area) or buffer area that is at a negative pressure of at least 0.01" WC to adjacent spaces and makes no allowance for both HD's and non-HD's to be prepared in the same area				
	Engineering Controls are in place to protect personnel and compounding from contamination by hazardous drugs				
	Hazardous drugs are received and stored separately from other inventory in a space that is negative pressure of at least 0.01" WC to adjacent spaces, is exhausted to the outside, and has at least 12 air changes per hour (ACH)				
	Sterile HD's are prepared in an ISO Class 5 environment with protective engineering controls in place and follows aseptic practices specified for the appropriate contamination risk levels				
	Access is limited to areas where hazardous drugs are stored and prepared				
	The ISO Class 5 Biological Safety Cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI) is placed in an ISO Class 7 area, physically separated and not less than 0.01-inch water column negative pressure to adjacent ISO Class 7 Ante-Room				
	The BSC or CACI is externally vented to the outside through HEPA filtration				
	A pressure indicator is installed that can be readily monitored for correct room pressurization				
	Environmental Quality and Control				
	Protection of critical sites by precluding physical contact and airborne contamination is given the highest priority in the sterile compounding practice				
	ISO Classes/Air Sources & Environment				
	Is Compliance Team familiar with ISO Classification of Particulate Matter in Room Air table adopted from ISO-14644-1 1999, "Cleanrooms and associated controlled environments – Classification of air cleanliness"				

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		Yes	No	Unsure	
	Source of ISO Class 5 air quality is provided by Primary Engineering Controls (PEC) = Laminar Air Flow Workbench (LAFW), Bio-Safety Cabinet (BSC), Compounding Aseptic Isolator (CAI) and Compounding Aseptic Containment Isolator (CACI)				
	The airflow in the PEC is unidirectional (laminar flow), and because of the particle collection efficiency of the filter, the "first air" at the face of the filter is, for the purposes of aseptic compounding, free from airborne particulate contamination				
	The PEC is located out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross-drafts. Supply air diffusers provide laminar flow, at least six feet from and are not directed into the face of the PEC				
	Primary engineering controls (PEC's) are operated continuously during compounding activity. When the blower is turned off and before other personnel enter to perform compounding activities, only one person enters the buffer area for the purposes of turning on the blower (for at least 30 minutes) and disinfecting the work surfaces				
	Cleanrooms (Compounding Areas and/or Buffer area) are supplied with the proper amount of HEPA-filtered air, have at least 30 ACH and meet ISO Class 7				
	Ante areas meet ISO Class 8 or 7 and have at least 30 ACH of HEPA filtered supply air				
	Environmental quality of air atmospheres and surfaces are verified by monitoring (*Viable and Nonviable Environmental Sampling (ES) Testing*).				
	Each compounding facility ensures that each source of ISO Class 5 environment is properly located, operated, maintained, monitored, and verified				
	Facility Design and Environmental Controls				
	Proper design and control strategies are in place to prevent turbulence and stagnant air in the critical area. Test/Balance and Certification documentation validates this operation				
	The principles of HEPA-filtered unidirectional airflow in the work environment are understood and provided in the compounding process in order to achieve the desired environmental conditions				

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	Ante area has continuous pressure monitoring and has calibration certification, has a line of demarcation, sink is hands free/wash and located on the clean side of demarcation, low level return air and gown storage is located on dirty side of demarcation				
	Non-HD Prep Room (Cleanroom, Buffer area, SCA's) has continuous pressure monitoring and has calibration certification, PEC certification current, no corrugated cardboard in room, low level return air				
	HD Prep Room (Cleanroom, Buffer area, SCA's) has continuous pressure monitoring with calibration records, PEC certification current, room for HD storage including refrigerator and Low Level exhaust air				
	Entry to HD Prep Room through positive pressure buffer (non-HD Prep) room				
	Semi-Annual documentation indicating room classification, temperature, humidity, supply airflow, Return/Exhaust airflow, room ft3 volume and ACH/calculations is available				
	All HEPA filters should be integrity/leak tested as part of the semi-annual certification process				
	A differential pressure of 0.02 to 0.05-inch water column is in place for positive rooms, and a differential pressure of 0.01 to 0.03 inch water column is in place for negative rooms and a physical separation through the use of walls, doors and/or pass-through is in place. Proper monitoring is provided and documented daily				
	Displacement airflow is used for separation of buffer areas from the Ante-room. (The principle of displacement airflow is a concept utilizing a low pressure differential, high airflow principle. requiring an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area.) The displacement concept is not used for high-risk compounding.				
	The segregated compounding area is not in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or in a location that is adjacent to construction sites, warehouse or food preparation				
	Policies and procedures for the PEC's are written and followed and are determined by the scope and risk levels of aseptic compounding activities utilized during the preparation of the CSPs				
	Recovery time to achieve ISO Class 5 air quality is documented and internal procedures in place where isolators are used for sterile compounding				

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	Surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in a classified area or in a segregated compounding area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants can accumulate				
	Walls must be constructed of durable material (e.g., heavygauge polymer) and panels must be locked together and sealed				
	Floors must be overlaid with wide, sheet vinyl flooring with heatwelded seams and flashed coving to the sidewall				
	Ceilings have gasketed ceiling grid system, vinyl laminated gyp board ceiling tiles, and calked perimeter. Ceiling is completely sealed to prevent infiltration of dirt/debris from above the ceiling space. All penetrations through the ceiling or walls are sealed				
	Lighting meets IES standards and the exterior lens surface of the ceiling lighting fixtures are smooth, mounted flush, gasketed and sealed				
	The buffer area does not contain sources of water (sinks) or floor drains				
	The plumbing system is free of defects that could contribute to contamination of any compounded preparation. Adequate hand and equipment washing facilities are easily accessible to the compounding areas. Facilities included, but are not limited to, hot and cold water, soap or detergent, and an air-drier				
	Door sweeps exist to aid in maintaining the required pressurization in the cleanrooms. (Use retractable, adjustable door sweeps)				
	Pass-throughs are equipped with interlocking doors to prevent both doors from opening simultaneously and compromising the integrity of the cleanroom. Pass-throughs to the negative pressure Containment Segregated Compounding Areas (C-SCA) are equipped with door seals				
	Viable and Non-Viable Environmental Sampling				
	The Environmental Sampling program provides information to staff and leadership to demonstrate that the PEC's including LAFWs, BSCs, CAIs, and Secondary Engineering Controls (SEC's)including buffer areas, ante-areas, and segregated compounding areas, are maintaining an environment that				

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	consistently ensures acceptably low viable and nonviable particle levels with certification implemented per the Controlled Environment Testing Association (CETA) guidelines				
	Facility has current certification that adequate HEPA filtered airflow is supplied as required by space classification and all filters pass operational/integrity testing				
	Environmental sampling shall occur as part a comprehensive quality management program and occurs minimally as part of the commissioning and certification of new facilities and equipment; following any servicing of facilities and equipment; as part of the re-certification of facilities and equipment (i.e., every 6 months); in response to identified problems with end products or staff technique; or in response to issues with CSPs, observed compounding personnel work practices, or patient-related infections (where the CSP is being considered as a potential source of the infection)				
	A CETA registered Cleanroom Certified Professional for Sterile Compounding Facilities and a NEBB/TABB certified Test & Balance Technician together provide certification services				
	A program to sample nonviable airborne particles is in place to directly measure the performance of the engineering controls PECs and SEC's used to create the various levels of air cleanliness				
	An appropriate environmental sampling plan is in place for airborne viable (microbial bioburden) particles based on a risk assessment of compounding activities performed and includes sample locations (sites of greatest risk of contamination), method of collection, frequency of sampling, volume of air sampled and time of day				
	Surface sampling is performed in all ISO classified areas on a periodic basis and at the conclusion of compounding. Locations to be sampled are defined on a sample plan				
	Sampling data is collected and reviewed, by the Compliance Team, on a periodic basis as a means of evaluating the overall control of the compounding environment				
	Action Levels of Microbial Contamination are agreed upon, by the Compliance Team, indicating elevated levels of microbial growth				

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	Source of contamination investigation processes are in place when sampling counts exceeds respective, agreed upon Action Levels immediately starting a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location				
	Certification records are maintained and reviewed by Compliance Team to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and ACPHs				
	Cleaning and Disinfecting				
	All cleaning and disinfecting practices and policies, agreed upon by the Compliance Team, for the compounding of CSPs are included in written SOPs and shall be followed by all compounding personnel including disinfectant products used and Minimum Frequencies of Cleaning and Disinfecting Compounding Areas				

Terminology/Definitions

CSP – Compounded Sterile Preparations. Mixed Drugs

BUD – Beyond Use Date. Drug stability/degradation

C-SCA - Containment Segregated Compounding Area. Cleanroom

CACI - Compounding Aseptic Containment Isolator: 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.

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

C-PEC - Containment Primary Engineering Control: 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.

C-SEC - Containment Secondary Engineering Control: 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).

C-SCA - Containment Segregated Compounding Area: A type of C-SEC with nominal airflow (12 ACPH) and room pressurization requirements (negative pressure between 0.01 – 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.

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. Line of demarcation separates the designated clean and dirty areas.

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.

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 CPEC 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, 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.