CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

TEMPERATURE REQUIREMENTS AND MONITORING

CSHP
CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP<797>(2008) Requirements)

Temperature Description	**Degrees Centigrade**		**Degrees Fahrenheit**		**Comments/Explanations Requires NIST Certified Temperature Monitoring Devices (USP <1118>**	**USP 39 NF 34 (2016)** *(Used as a reference by the FDA for all package inserts)*	**CDC Vaccine Storage (May 2014) USP <797>**	**Board of Pharmacy January 1, 2017**
	Min	Max	Min	Max				
Controlled Freezer Temperature (USP and BOP)	-25º	-10º	-13º	14º	Check individual monographs for specific requirements outside this range	General Notices 10.20.10		No provision for excursions §1735.1 (i)
Freezer (CDC)	-50º	-15º	-58º	5º	Varicella and Zoster vaccines		See CDC Vaccine Storage and Handling Toolkit	
Controlled Cold Temperature –	2º 2.2º	8º 7.7º	35º	46º	• Transient excursions (0 ºC to 15 ºC) but the calculated MKT must be ≤ 8 ºC (46 ºF) • Transient spikes to 25 ºC (77 ºF), not to exceed 24 hours, if supported by the manufacturer's stability in writing	General Notices 10.30.40	See CDC Vaccine Storage and Handling Toolkit	No provision for excursions §1735.1 (h) Title 22 – 22 CCR § 70263 (q)(6)
Controlled Room Temperature	20º	25º	68º	77º	• Excursions allowed between 15 ºC to 30 ºC (59 ºF to 86 ºF) as long as the MKT is ≤ 25 ºC (77 ºF) • Spikes to 40 ºC (104 ºF) are permitted for less than 24 hours as long as the MKT is ≤ 25 ºC (77 ºF) • Check for specific drugs with narrow ranges	General Notices 10.30.60		No provision for excursions §1735.1 (j)
Clean Room Temperatures		20º or less		68º or less	In order to compensate for the additional layers of protective garb, this is the general recommendation.		USP <797> proposed language	
	20º	25º	68º	77º				Or lower required

WHAT IS MKT? Mean Kinetic Temperature approximates the effects of temperature on drug degradation. Higher temperatures result in faster degradation, lower temperatures result in less degradation. MKT calculations weight the various temperatures by their natural logs. Temperature spikes result in a greater increase in MKT than the average temperature, often by a critical 2-5 degrees. The MKT can be hand calculated, calculated by the temperature monitoring software vendor, or the manufacturer can be contacted and they have software to determine the MKT for every product.

N.B. Anytime a patient has received a vaccine or drug that is determined to have been out of range longer than allowed by the package insert, the manufacturer should be contacted immediately because all manufacturers have significant amounts of unpublished stability data by lot number, and the patient may not have to be re-dosed.

MONITORING REQUIREMENTS

Location	**Comment**	**USP 37 NF33**	**CDC (Vaccines) May 2014**	**BOP**
Freezers	Daily lapse time monitoring or continuous monitoring CDC vaccine toolkit on CDC website for more information. The vaccines for children program prohibits use of dorm refrigerators for vaccines.	Daily	Twice daily	Daily-§1735.5(c)(10) §1751.5(b)(5)(A,B,C)
Refrigerators		Daily	Twice daily	Daily-§1735.5(c)(10) §1751.5(b)(5)(A,B,C)
Rooms	Includes all drug storage location rooms: no specific requirements for monitoring inside ADCs	Daily		

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Rev. 9/17/18

COMPOUNDING FREQUENCY OF DOCUMENTATION AND CLEANING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP<797> (2008) Requirements

The most stringent requirement will be required. BOP regulations for BOP requirements, and BOP and USP 797 regulation for CDPH requirements		
DAILY	LOW AND MEDIUM RISK	HIGH RISK
Room Temperature	X	X
Refrigerator temperature (Twice a day for vaccines)	X	X
Freezer temperature (Twice a day for vaccines)	X	X
Incubator temperature	X	X
Air pressure differentials or air velocity between adjoining ISO rooms (ambient room air vs. buffer area vs. ante area)	X	X
MiniHelix differentials for CAI, CACIs	X	X
Cleaning with germicidal cleaners and disinfected with suitable agent (sterile IPA) Counters + Cleanable Surfaces + Floors+ Carts	X	X
Cleaning within the ISO 5 environment (before each shift, every 30 minutes and before and after each batch) Facilities with IV robots will be required to petition the BOP for exception with documentation and description of an alternative cleaning schedule	X	X
Hazardous Drug 1) Deactivation with peroxide or bleach and Decontamination with sterile IPA, sterile water, peroxide or bleach 2) Cleaning with a germicidal 3) Disinfection with sterile 70% IPA	x	x
MONTHLY	LOW AND MEDIUM RISK	HIGH RISK
Cleaning with germicidal cleaners and disinfected with suitable agents (sterile IPA) Exterior workbench Walls/Ceiling Shelves/Storage Tables Stools	X	X
Sporicidal agent used for cleaning, all sites	X	X
Hazardous Drug Cleaning undertray of the BSC 1) Deactivation with peroxide or bleach and Decontamination with sterile IPA, sterile water, peroxide or bleach 2) Cleaning with a germicidal 3) Disinfection with sterile IPA	x	x
QUARTERLY	LOW AND MEDIUM RISK	HIGH RISK
Viable surface sampling, ALL CFUs identified to genus per USP <797>; facility-determined limits for BOP	NA	X
BIANNUAL	LOW AND MEDIUM RISK	HIGH RISK
Viable surface sampling, ALL CFUs identified to genus per USP <797>; facility-determined limits for BOP	X	NA
Volumetric air sampling Particle count CFUs, identified to genus. ALL CFUs identified to genus per USP <797>, only facility-determined limits for BOP	X	X
Hood and room certifications under dynamic conditions	X	X
Determination of CAI and CACI recovery times	X	X
Media fill/gloved fingertip testing for employees	NA	X
ANNUAL (at least every 12 months)	LOW AND MEDIUM RISK	HIGH RISK
Media fill/gloved fingertip testing for employees	X	NA
Competency testing Observation Written	X	NA
Review of compounding policies and procedures	X	X

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Last Revised September 17, 2018

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

Facilities and Engineering Controls: Hazardous Drugs

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP <800> Pending Requirements

CSHP CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

BOARD OF PHARMACY REGULATIONS CCR§1735 **Effective January 1, 2017**				
SECONDARY ENGINEERING CONTROL • **Temp 20-24C (68-75F)** • **Externally vented** • **HEPA filtered air** • **Negative pressure** • **Physically separate room**	**PRIMARY ENGINEERING CONTROL** • **PECs ISO Class 5 Negative Pressure unidirectional flow** • **HEPA filtered airflow** • **Non-turbulent** • **HEPA filtered exhausted air** • **External venting should be dedicated to one BSC or CACI**	**Beyond Use Dates** **LOW RISK** • **Sterile to sterile** • **=< 3 commercial packages** **=< 2 entries into 1 sterile container**	**MEDIUM RISK** • **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	**Comments**
• **ISO Class 7 or better** • Sink in ante area • At least 0.01”-0.03” w.c. negative relative to all adjacent space (rooms, above ceiling and corridors) • Minimum 30 Air Changes Per Hour (ACPH) • Ante-area ISO 7 or better CCR §1735.6(e)	• Biological Safety Cabinet, Class II Type A2 • Biological Safety Cabinet, Class II Type B2 • Compounding Aseptic Containment Isolators (CACI) with unidirectional flow. Air within the CACI shall not be recirculated or turbulent. CACI must meet requirements in 1751.4 (f) (1-3)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State ***	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State ***	• Document daily Pressure Differential or air velocity, or use continuous recording device, between adjoining ISO rooms. 1751.1(a)(8) • Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification by a CETA certified vendor at least every 6 months CCR §1751(b)(1), 1751.4(f) • Externally vented 1751.4(g), 1735.6(e) • All surfaces within the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4)
• **Segregated Compounding Area** • Sterile to sterile compounding only • Sink at least 3 ft from PEC • Minimum of at least 3 ft line of demarcation around PEC • Emergency eye wash station acceptable • At least 0.01”-0.03” w.c. negative relative to all adjacent space (rooms, above ceiling and corridors) • Minimum 12 ACPH 1735.6 (e) (1)	• Biological Safety Cabinet, Class II Type A2 • Biological Safety Cabinet, Class II Type B2 • Compounding Aseptic Containment Isolators (CACI) with unidirectional flow. Air within the CACI must not be recirculated or turbulent CACI must meet requirements in 1751.4 (f) (1-3)	12 hours	NA	• Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification by a CETA certified vendor at least q 6 months CCR §1751(b)(1), 1751.4(f)(g) • Externally vented 1751.4(g), 1735.6(e) • All surfaces within the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4) • Sink can be within 3 ft of CACI if CACI meets requirements in 1751.4 (f) (1-3)

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Last Revised 9/17/2018

Facilities and Engineering Controls: Hazardous Drugs

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP <800> Pending Requirements

Non-Hazardous Drugs Prepared in a Hazardous Drug Primary Engineering Control (Chemo Hood)

All drugs prepared in a Hazardous Drug Primary Engineering Control (PEC) must be labeled with HD Cautions

HAZARDOUS DRUGS : USP <800> Pending Requirements

SECONDARY ENGINEERING CONTROL Externally vented	PRIMARY ENGINEERING CONTROL C-PECs ISO class 5 Negative Pressure unidirectional flow C-PECs externally vented	BEYOND USE DATES (July 1, 2018)		Comments
		Low Risk	Medium Risk	
• **HEPA filtered air in Negative Pressure Physically Separate Room** • **ISO Class 7 or better buffer room** • **0.01" to 0.03" w.c. negative pressure** • **Minimum 30 ACPH HEPA filtered air** • **Sink placed at least 1 meter from the entrance of buffer room**	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B1, B2 • ISO Class 5 Biological Safety Cabinet, Class III • Containment Aseptic Compounding Isolators (CACI) with unidirectional flow	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State ***	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State ***	• Requires negative pressure ISO 5 C-PEC • C-PEC and C-SEC externally vented • Eyewash readily available • Drug storage MUST be in a negative pressure space. Includes the refrigerator • Receiving of hazardous drugs must be in a negative or neutral pressure space. • May use the negative pressure room for non-sterile hazardous compounding BUT not at the same time. • Fixed walls
• **Containment Segregated Compounding Area (C-SCA)** • **Must be a negative pressure separate room** • **0.01" to 0.03" w.c. negative pressure** • **Unclassified room** • **Minimum 12 ACPH** • **Sink at least 1 meter from C-PEC**	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B1, B2 • ISO Class 5 Biological Safety Cabinet, Class III • Containment Aseptic Compounding Isolators (CACI) with unidirectional flow	12 hours	12 hours **(not allowed by BOP)**	

* Controlled Room Temp: 20 to 25 degrees C, 68 to 77 degrees F

**Controlled Cold Temp (Refrigerator): 2 to 8 degrees C, 35.6 to 46.4 degrees F

***Controlled Freezer Temp: (-25) to (-10) degrees C, (-13) to 14 degrees F

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FACILITIES AND ENGINEERING CONTROLS REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP <797> (2008) Requirements

BOARD OF PHARMACY REGULATIONS -- CCR§1735 and CCR §1751 -- NON-HAZARDOUS DRUGS (Low and Medium Risk)				
SECONDARY ENGINEERING CONTROL (Sterile Compounding Space)	**PRIMARY ENGINEERING CONTROL (PEC=Sterile Compounding Hoods)**	**Beyond Use Dates**		**Comments**
		LOW RISK • **Sterile to sterile** • **=< 3 commercial packages** • **=< 2 entries into 1 sterile container**	**MEDIUM RISK** • **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	**APPLIES TO ALL**
• **Temp 20-24C (68-75F)** • **HEPA-filtered air**	• **ISO 5 with unidirectional flow** • **HEPA-filtered first air** • **Non-turbulent**			
>ISO Class 7 clean room (clean area or buffer area) with ISO 8 or better ante-area • No sink in buffer area • Sink in ante-area • Minimum of 30 air changes per hour • 0.02-0.05" w.c. positive pressure differential relative to all adjacent spaces OR • Displacement airflow method: requires air velocity of >40 feet per minute from the clean area across the line of demarcation into the ante area, from floor to ceiling and wall to wall CCR §1735.1(m) & §1250.4 (1-4)	**Any ISO Class 5 PEC:** • Laminar Flow Hood OR • Biological Safety Cabinet with unidirectional flow OR • Compounding automated robots OR • Compounding Aseptic Isolators (CAI) with unidirectional flow. Air within the CAI shall not be recirculated or turbulent. CAI must meet requirements in 1751.4 (f) (1-3)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State *** CCR §1751.8 (a)	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (b)	• Each ISO environment requires certification at least every 6 months CCR §1751(b)(1), 1751.4(f) • Document **daily** pressure differential or air velocity, or use **continuous recording device**, between adjoining ISO rooms and spaces with immediate entry to ISO rooms. 1751.1(a)(8)
Segregated sterile compounding area • Any preparation area that is not ISO classed, exceeds ISO 7 limits, or does not meet pressure or air flow differentials • Sterile to sterile compounding only • PEC within demarcated area (at least 3 ft. perimeter) or separate room • Shall not have unsealed windows/doors that connect to outdoors • Not in high traffic area • Not adjacent to construction sites, warehouses or food preparation • Sink at least 3 ft. from PEC • Emergency eye wash station acceptable CCR §1735.1(af) & §1250.4 (1-4)	• CAI • Manufacturer of CAI must provide documentation for meeting requirements in 1751.4(f)(1-3) AND CAI must be certified as part of the certification process 1751.4(f)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (a)	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (b)	• Requires use of sterile gloves over isolator gloves 1751.4 (h) • PEC requires certification at least every 6 months CCR 1751.4(f) • Sink can be within 3 ft of CAI

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FACILITIES AND ENGINEERING CONTROLS REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP <797> (2008) Requirements

SECONDARY ENGINEERING CONTROL (Sterile Compounding Space)	PRIMARY ENGINEERING CONTROL (PEC=Sterile Compounding Hoods)	Beyond Use Dates		Comments
		LOW RISK	MEDIUM RISK	
• **Temp 20-24C (68-75F)** • **HEPA-filtered air**	• **ISO 5 with unidirectional flow** • **HEPA-filtered first air** • **Non-turbulent**	• **Sterile to sterile** • **=< 3 commercial packages** • **=< 2 entries into 1 sterile container**	• **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	**APPLIES TO ALL**
	• Laminar Flow Hood • CAI where mfg not meeting requirements in 1751.4(f)(1-3)	12 hours CCR §1751.8 (d)	N/A	• 12 hours BUD for low-risk, non-hazardous preparations only 1751.8(d)(2) • PEC requires certification at least every 6 months CCR 1751.4(f)
Does not meet requirements for ISO Class 7 clean room or unclassified & Segregated Compounding area	• No PEC or outside ISO 5 PEC • Under conditions not meeting all requirements in any subdivision 1751.8 (a-d)	Labeled "Immediate Use" and shall be administered no later than 1 hour after mixing CCR §1751.8 (e)	N/A	Compounded only in limited situations where failure to administer could result in loss of life or intense suffering, and in quantity to meet immediate need

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REQUIRED ENVIRONMENTAL, PERSONNEL & END-PRODUCT TESTING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Environmental Testing Under Dynamic Conditions	Applicable Device, Room or Method	Frequency
Certification of PEC's	All BSC's, CAI's, CACI's, LAFW	Every 6 month (CCR) §1751
HEPA filter integrity testing	All BSC's, CAI's, CACI's, LAFW & ISO classified rooms	Every 6 months
Volumetric air sampling by impaction (non-viable particle counts)	All Buffer room/s and ante rooms. (Not required for segregated compounding rooms)	Every 6 months
Volumetric air sampling by impaction (non-viable particle counts)	All BSC's, LAFW	Every 6 months
Volumetric air sampling by impaction (non-viable particle counts) outside of an ISO 7 cleanroom	CAI and CACI's: ▪ Particle counts sampled 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during operations ▪ Not more than 3520 particles per cubic meter during material transfer where particle probe is located as near to the transfer door as possible w/o obstructing the transfer ▪ Recovery time to achieve ISO Class 5 air quality shall be documented	Every 6 months
Viable air sampling by volumetric impaction	▪ The volume sufficient for sampling is 400-1,000 liters ▪ All ISO classified rooms and PECs ▪ Identification of any colony forming unit (CFUs) to the genus level and action plan for CFUs exceeding USP action level thresholds**.	Every 6 months
Viable surface sampling	▪ Samples based on specified site map ▪ Identification of any (CFUs) to the genus level and action plan for CFUs exceeding USP action level thresholds**.	Low & medium risk compounding: Every 6 months High risk compounding: Quarterly
Air changes per hour (ACPH)	All Buffer room, Ante rooms, and segregated compounding rooms	Every 6 months
Video smoke study	▪ All BSC's, CAI's, CACI's, LAFW ▪ Unidirectional, non-turbulent airflow must be documented	Every 6 months

- Sampling locations, frequencies, and timing must be clearly described in the facility's report from the certification vendor
- Some tests may be performed by properly trained hospital staff if the CETA guidelines are followed
- Dynamic Conditions Definition: Routine staff activity during compounding-related processes must be simulated during certification
  Recertification of areas/equipment must occur is there are changes to the area such as redesign, construction, or replacement or relocation of the PEC, or alteration in the configuration of the room that could affect airflow or air quality

****USP Action Level Threshold**

Location	Viable airborne	Viable surface
ISO-5 (PEC)	>1	>3
ISO-7 (Buffer)	>10	>5
ISO-8 (Anteroom)	>100	>100

Highly pathogenic microorganisms [e.g., G(-) rods, coag (+) Staph, molds and yeasts] must be immediately remedied, regardless of CFU count

CSHP and CHA
REQUIRED ENVIRONMENTAL, PERSONNEL & END-PRODUCT TESTING
CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Process validation: The individuals involved in the compounding of sterile drug preparation must successfully demonstrate competency on aseptic technique and aseptic area practices. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be as complicated as the most complex manipulations performed by staff with the same amount or greater amount of volume transferred during the compounding process.

Tests Required for Personnel (BOP and USP)	Risk Level	When Required
Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing, then 1x at least every 12 months thereafter.	Moderate and low risk compounding – initial competency	Prior to the first compound prepared for a patient
	Moderate and low risk compounding – ongoing competency	At least every 12 months as part of the competency testing process
Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing then at least every 6 months thereafter.	High risk compounding – initial competency	Prior to the first compound prepared for a patient
	High risk compounding – ongoing competency	At least every 6 months as part of the competency testing process

Facility policy should describe processes as determined by the PIC to assure accuracy of sterile compounding processes within the facility

End Product Testing: Requirement for Sterility and Potency Testing for Lots of Low/Med Risk CSPs	Comments	USP <797>	BOP
Beyond Use Date (BUD) is the lesser of the USP<797> or the manufacturer package insert/written communication	• Meets all PEC ISO 5 requirements • Low risk: 48 hour RT, 14 days refrigeration • Medium risk: 30 hour RT, 9 days refrigeration	As long as the shorter of the manufacturer insert stability and the USP <797> BUD is met, there is no batch sterility testing requirement.	None
Extended BUD (Greater than USP <797>)	• The USP <797> BUDs are an exemption from the USP <71> sterility testing. • BUD can only be extended if sterility tests according USP <71> are performed.	• No exemption for sterility testing for extended BUD. • Every batch of extended BUD requires sterility testing and sequestering. • In the revised USP <797> there is no extended BUD option.	BUD extension only allowable when supported by the following: Method suitability test, container closure integrity test, and stability studies. The compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality review, and packaging as the finished CSP.
Potency testing is the USP monograph described testing of potency	Products should have one of the following: • A manufacturer-sanctioned process • A published (refereed journal) method followed exactly • Lab data from testing of facility product	No requirements in USP <797>	Will require potency testing, schedule per the facility policy

Last Revised 9/17/18

COMPETENCY AND TRAINING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP<797> (2008) Requirements

Competency		
Low and Medium Risk: All training shall be completed and documented before any compounding personnel begin to prepare CSPs.		
Type of Competency	**Test**	**Frequency**
Written Test	Pharmaceutical calculations and terminology Aseptic technique Quality Assurance procedures Skills necessary to perform the assigned tasks	Initially, then at least every 12 months
Demonstration/ Observation	Hand hygiene & Garbing procedures, aseptic technique, achieving and maintaining ISO Class 5 environment, cleaning and disinfection procedure	Initially, then at least every 12 months
Process Validation	Media Fill testing	Initially, then at least every 12 months, or whenever the QA program yields an unacceptable result
	Gloved Fingertip Testing - Garbing: Immediately after donning all garb without disinfection gloves with 70% alcohol	3 sets initially, then one set at least every 12 months, or whenever the QA program yields an unacceptable result Action level - Greater than 0 CFU
	Gloved Fingertip Testing - Aseptic Technique: Immediately after completing the media-fill preparation	1 set initially, then at least every 12 months, or whenever the QA program yields an unacceptable result Action level - Greater than 3 CFU
High Risk: All training shall be completed and documented before any compounding personnel begin to prepare CSPs.		
Written Test	Pharmaceutical calculations and terminology Aseptic technique Quality Assurance procedures Skills necessary to perform the assigned tasks Sterilization technique	Initially, then at least every 12 months
Demonstration/ Observation	Hand hygiene & Garbing procedures, aseptic technique, achieving and maintaining ISO Class 5 environment, cleaning and disinfection procedure Sterilization techniques	Initially, then at least **every 6 months**
Process Validation	Media Fill Testing	Initially, then at least **every 6 months**, or whenever the QA program yields an unacceptable result
	Gloved Fingertip Testing - Garbing: Immediately after donning all garb without disinfection gloves with 70% alcohol	3 sets initially, then one set at least **every 6 months,** or whenever the QA program yields an unacceptable result Action level - Greater than 0 CFU
	Gloved Fingertip Testing - Aseptic Technique: Immediately after completing the media-fill preparation	1 set initially, then at least **every 6 months,** or whenever the QA program yields an unacceptable result Action level - Greater than 3 CFU

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TRAINING REQUIREMENTS	
Training	**Comments**
Hand hygiene and gloving	• Training includes theoretical principles and practical skills • Must complete didactic training, pass written competency and skills assessment (observation audit, GF testing, and media fill) before any compounding personnel begin to prepare/ handle CSPs • Media fill – simulates most challenging/ complicated condition/procedure actually encountered, and contains same amount of volume transferred. Verifies capability of compounding environment, aseptic technique and processes to produce sterile preparations
Procedure for Gloved Fingertip Sampling	
Order of Garbing procedures	
Aseptic work practices/technique (avoid touch contamination)	
Sterilization procedures for high risk compounding (if applicable)	
Pharmaceutical calculations & terminology	
Sterile compounding documentation (Compounding Log, Master Formula Record, Labelling, BUD, etc.)	
Quality assurance procedures	
Process validation using media fill tests	
General conduct in the controlled area	
Container, equipment and closure system selection	
Safe handling and compounding of CSPs (including hazardous drugs if applicable)	
Procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding	
Procedures for evaluating, maintaining, certifying, cleaning, disinfecting the facility/environment	
Achieving/maintaining ISO 5 (disinfect gloves and surfaces)	
Written training program	
Policy & Procedures	
Spill Management (pharmacy, nursing & other personnel)	
Train other support services (e.g. housekeeping) on hand hygiene, garbing, cleaning & disinfecting procedures	
Training documentation retained	

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HAZARDOUS GARBING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Compounding attire	Order	Order of garbing in the anteroom	Information
Double Shoe covers	1		Don the second pair upon entering the buffer area. Remove upon leaving.
Head cover	2		
Facial hair covers (if applicable)	2		
Face mask	3	(followed by washing of hands to the elbows x 30 seconds with soap and water and drying)	For spills/decontamination of the hood: see additional garbing requirements
*Face shields & goggles	3	*Required when working outside a C-PEC	
Non Shedding/Non Hazardous Gown			
Hand Cleansing	4	Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.	Clean under nails using one-time use disposable nail cleaning tool Note: Do not use scrub brushes
Non-shedding gown Disposable chemo gowns made of polypropylene or other laminate materials (should be glossy)	5	Must be changed every 2-3 hours or per manufacturer guidance. NEVER worn outside the HD handling area.	Must close in the back, long-sleeved, closed cuffs that are knit or elastic. No seams or closures that HDs could pass through.
Sterile Chemo gloves Must wear sterile gloves over any CAI gauntlet gloves	6	Chemo gloves must meet ASTM standard 6978 (or its successor). NO powder.	Tested for compatibility with sterile 70% isopropyl alcohol (SIPA). Change every 30 minutes or when torn, punctured or contaminated.
PROHIBITED ITEMS AND INDIVIDUALS			
Always prohibited • Wrist, hand, finger or visible jewelry • Piercing • Headphones • Earbuds • Personal electronic devices (including cell phones) • Cosmetics • Nail polish • Artificial nails			
Excluded from ISO 7 and ISO 5 spaces until resolved			
• Exposed rashes • Sunburn • Weeping sores • Conjunctivitis • Active respiratory infections • Communicable diseases			

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NON HAZARDOUS GARBING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Compounding attire	Order	Order of garbing in the anteroom	Information
Shoe covers	1		
Head cover (bouffant)	2		
Facial hair covers (if applicable)	2		
Face mask	3	(followed by washing of hands to the elbows x 30 seconds with soap and water and drying)	
Hand Cleansing	4	Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.	Clean under nails using one-time use disposable nail cleaning tool Note: Do not use scrub brushes
Non-shedding gown	5		
Sterile gloves Must wear sterile gloves over any CAI gauntlet gloves	6		Tested for compatibility with sterile 70% isopropyl alcohol (SIPA)
PROHIBITED ITEMS AND INDIVIDUALS			
Always prohibited • Wrist, hand, finger or visible jewelry • Piercing • Headphones • Earbuds • Personal electronic devices (including cell phones) • Cosmetics • Nail polish • Artificial nails			• These items should be removed before entering the gowning area • Sanitize eye glasses (with alcohol wipes) before entering the gowning area • Cosmetics include self-removable false eye lashes
Excluded from ISO 7 and ISO 5 spaces until resolved			
• Exposed rashes • Sunburn • Weeping sores • Conjunctivitis • Active respiratory infections • Communicable diseases			

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. The tool is not a fixed compliance assessment that must be followed and should not be construed as legal advice or used to resolve legal problems.

Last Revised 9/17/18

Donning, Hand Hygiene & Doffing for HAZARDOUS Sterile Compounding

DONNING SEQUENCE

Step 1: Removal of Jewelry and Cosmetics

Outside the ante-room or outside the perimeter line of the Segregated Compounding Area (SCA):

1) **Remove and store in a safe place:**
   a. **Jewelry: wrist, hand and finger (including watches)**
   b. **All other visible jewelry, piercings, headphones, earbuds and personal electronic device(s)**
2) **Remove any nail polish/artificial nails**
3) **Remove all cosmetics**

Before entering the sterile compounding area, let your manager know if you are experiencing: Exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease.

Step 2: Shoe Covers

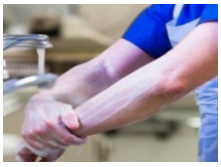
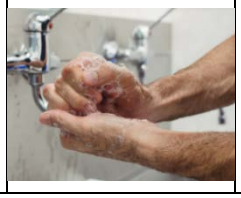
1) **Put on TWO pairs of shoe covers on the foot closest to the line of demarcation (LOD) and place the covered foot onto the clean side of the LOD**
2) **Repeat for 2nd foot**

Step 3: Hair Cover & Face Mask

Inside DIRTY side of the Ante Room or outside the perimeter line of the Segregated Compounding Area (SCA)

1) **Put on Hair Cover: Cover entire head and ears**
2) **Put on beard cover (if necessary)**
3) **Put on Face Mask (over nose and pulled all the way beneath the chin. If the mask has ties to secure: put on hair cover first then the face mask)**
4) **Validate sufficient coverage (including coverage of all facial and head hair coverage)**

Step 4: Hand Hygiene Sequence

 **Using warm water, wet hands and arms to the elbow. Apply appropriate cleaning agent. Shut off water in a hands-free manner.**	**Clean under nails using a one-time use disposable nail cleaning tool. Note: Do NOT use scrub brushes** 	 **Using appropriate cleaning agent, vigorously wash hands and arms (up to the elbow) for 30 seconds**	**Use warm water to rinse hands and arms to the elbow** 	 **Use non-shedding wipes to dry hands and arms.**

Step 5: Gowning

1)Don a non-HD long-sleeved gown
2)Don a second long-sleeved HD gown (polypropylene or low-shedding) with sleeves that fit snuggly around the wrist, closes in the back and covers all the way to the neck.

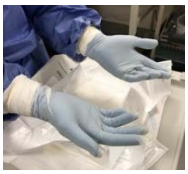
NOTE: HD-gowns must be changed, at a minimum, every 3 hours OR immediately after a spill or splash

Donning, Hand Hygiene & Doffing for HAZARDOUS Sterile Compounding

STEP 6: Hand Hygiene Inside Ante Room or Buffer Area OR within the LOD if the SCA

1) **Disinfect using alcohol based product with persistent activity**
2) **Allow to dry before wearing gloves.**

STEP 7: Sterile Gloves



1) **For HD compounding, put on 2 PAIRS of sterile chemo tested gloves (ASTM 6978-05)**
   - **First pair of gloves: wear underneath the cuffs of the HD gown**
   - **Second pair of gloves: wear over the cuff of the HD gown**
2) **Prior to entry into the PEC, apply sterile isopropyl alcohol to gloves and allow to dry**

Reusing PPEs used for Hazardous Compounding?

The only PPE that can be re-used: **non-HD Gown** if stored for reuse on the CLEAN side of the Ante room, where possible, at least 3 feet from the sink. Reuse restricted to single user, and for the duration of the shift

DOFFING SEQUENCE

DOFFING STEP 1:

Inside the BSC or CACI, remove the outer pair of sterile gloves and discard as hazardous waste

DOFFING STEP 2:

For facilities with HD-buffer room: perform the following steps within the HD-Buffer room doffing area. For facilities with HD-SCA: perform the following steps within the LOD of HD-SCA.
Remove and discard as hazardous waste:

1) **The outer shoe covers**
2) **The outer HD gown AND**
3) **The inner pair of sterile gloves**

DOFFING STEP 3:

Inside CLEAN Side of the Ante Room OR outside the LOD of the SCA:

1) **Remove the non-HD gown. If non-HD gown is not soiled, hang (where possible at least 3 feet from the sink) to reuse gown for the rest of the shift.**

DOFFING STEP 4:

Cross the LOD into the DIRTY Side of the Ante Room and remove and discard into the waste bin:

1) **Non-HD gown – if not reused**
2) **Shoe covers**
3) **Head and face covers**

EXIT THE ANTEROOM

Donning, Hand Hygiene & Doffing for NON-HAZARDOUS Sterile Compounding

DONNING SEQUENCE

Step 1: Removal of Jewelry and Cosmetics

Outside the ante-room or outside the perimeter line of the Segregated Compounding Area (SCA):

1) **Remove and store in a safe place:**
   a. **Jewelry: wrist, hand and finger (including watches)**
   b. **All other visible jewelry, piercings, headphones, earbuds and personal electronic device(s)**
2) **Remove any nail polish/artificial nails**
3) **Remove all cosmetics**

Do NOT enter sterile compounding area if you are experiencing: Exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease.

Step 2: Shoe Covers

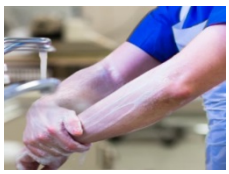
1) **Put on shoe cover on the foot closest to the line of demarcation (LOD) and place the covered foot onto the clean side of the LOD.**
2) **Repeat for 2nd foot**

Step 3: Hair Cover & Face Mask

Inside DIRTY Side of the Ante Room or outside the perimeter line of the Segregated Compounding Area (SCA)

1) **Put on Hair Cover: Cover entire head and ears**
2) **Put on beard cover (if necessary)**
3) **Put on Face Mask (over the nose and pulled all the way beneath the chin. If the mask has ties to secure: put on hair cover first then the face mask)**
4) **Validate sufficient coverage (including coverage of all facial and head hair coverage)**

Step 4: Hand Hygiene Sequence

 **Using warm water, wet hands and arms to the elbow. Apply appropriate cleaning agent. Shut off water in a hands-free manner.**	**Clean under nails using a one-time use disposable nail cleaning tool. Note: Do NOT use scrub brushes** 	 **Using appropriate cleaning agent, vigorously wash hands and arms (up to the elbow) for 30 seconds**	**Use warm water to rinse hands and arms to the elbow** 	 **Use non-shedding wipes to dry hands and arms**

Donning, Hand Hygiene & Doffing for NON-HAZARDOUS Sterile Compounding

Step 5: Gowning

1) **Don a non-HD long-sleeved gown with sleeves that fit snuggly around the wrist**

STEP 6: Hand Hygiene Ante Room or Inside Buffer Area OR within the LOD if the SCA

1) **Disinfect using alcohol based product with persistent activity**
2) **Allow to dry before wearing gloves.**

STEP 7: Sterile Gloves

1) **Don sterile gloves - cuff overlapping the gown sleeve**
2) **Prior to entry into the PEC, apply sterile isopropyl alcohol to gloves and allow to dry**

What PPEs may be re-used for Non-Hazardous Sterile Compounding?

A. Booties and Hair Net: **NO.** Discard once you cross the LOD into the dirty side of the Ante Room or outside of the LOD for SCA
B. Face Mask: **NO.** Change at least every 2 hours OR whenever the mask gets wet. Discard once you cross the LOD into the dirty side of the Ante Room or outside the LOD for SCA
C. Gown: **YES,** if stored for reuse on the CLEAN side of the Ante room, where possible, at least 3 feet from the sink. Reuse restricted to single user, and for the duration of a single shift
D. Gloves: **NO**. Discard once you cross the LOD into the dirty side of the Ante Room or outside the LOD for SCA

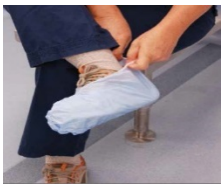
DOFFING SEQUENCE

DOFFING STEP 1:

Inside CLEAN Side of the Ante Room OR outside the LOD of the SCA:

1) **Discard the gloves**
2) **Remove the gown. Hang (where possible at least 3 feet from the sink) to reuse gown for the rest of the shift if gown is not soiled.**

DOFFING STEP 2:



Cross the LOD into the DIRTY Side of the Ante Room and remove and discard into the waste bin:

1) **Gown – if not soiled or not needed for the rest of the shift**
2) **Shoe covers**
3) **Head and face covers**

EXIT THE ANTEROOM