PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Members

- John Friel (Chair)
- Dr. Katherine (Katie) Gabriel-Cox
- Dr. Joe Gallagher
- Jose A. (Tony) Nuñez
- Marcus Pimentel

Special Closed Meeting Agenda

Wednesday, October 25, 2023 - 5:00 pm

Kathleen King Community Room - 85 Nielson Street, Watsonville

https://zoom.us/j/93443061917

Phone: +1 669 900 9128 WEBINAR ID: 934 4306 1917

Agenda documents are available for review in person at Watsonville Community Hospital, 75 Nielson Street, Hospital Main Lobby-Visitors Desk; and electronically on the Pajaro Valley Healthcare District's website, at: PVHCDHC.ORG. To view online, visit the Board's website at: **PVHCDHC.ORG** and select the meeting date to view the agenda and supporting documents. Written comments on agenda items may also be submitted to the Board by email or US Mail. Comments received after 4 p.m. on the day of the meeting and before the end of the meeting will be included in the official record.

Email: info@pvhcd.org

- Emailed documents may take up to 24 hours to be posted
- Please include the agenda item number

U.S. Mail:
PVHCD Board of Directors
75 Nielson Street
Watsonville, CA 95076

For additional information, call 831.763.6040 or email info@pvhcd.org

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The Pajaro Valley Health Care District Hospital Corporation does not discriminate on the basis of disability, and no person shall, by reason of a disability, be denied the benefits of its services, programs, or activities. If you are a person with a disability and wish to participate in the meeting and require special assistance in order to participate, please call (831)763-6040 or email info@pvhcd.org at least three business days in advance of the meeting to make arrangements. Persons with disabilities may request a copy of the agenda in an alternative format.

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Pajaro Valley Health Care District Hospital Corporation
Special Closed Meeting Agenda - Wednesday, October 25, 2023

Call to Order

Roll Call

Public Comment on Matters on the Agenda

Adjourn to Closed Session

1. **Conference with Labor Negotiators** (Government Code 54957.6)
   CNA, SEIU UHW S&M, Teamsters, CalTech
   Agency Negotiator: Allyson Hauck;
   Contact: Allyson Hauck, Chief Human Resources Officer

2. **Medical Executive Committees Report October 2023** (California Health & Safety Codes 32155 (2022) and 1461)
   Contact: Executive Sponsor-Dr. Angel, Chief of Staff, Medical Executive Committee

Adjournment

This agenda was posted in accordance with the California Brown Act. Any materials related to an item on this Agenda submitted to the Board after distribution of the agenda packet will be made available to the public in accordance with Government Section 54957.5.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Members

- John Friel (Chair)
- Dr. Katherine (Katie) Gabriel-Cox
- Dr. Joe Gallagher
- Jose A. (Tony) Nuñez
- Marcus Pimentel

Regular Meeting Agenda

Wednesday, October 25, 2023 - 5:15 pm

(Regular meeting immediately follows the PVHCDHC closed meeting.)

Zoom: https://zoom.us/j/93443061917

Phone: +1 669 900 9128 WEBINAR ID: 934 4306 1917

Kathleen King Community Room - 85 Nielson Street, Watsonville

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Pajaro Valley Health Care District Hospital Corporation
Regular Meeting Agenda - Wednesday, October 25, 2023

Call to Order

Roll Call

Closed Session Report

Agenda Modification Consideration

Public Comment on Matters Not on the Agenda

Time is set aside for members of the public to address the Board on any item not on the Board Agenda (not to exceed two minutes), which is within the subject matter jurisdiction of the Board.

Comments regarding items included on the Agenda will be heard before the item is discussed by the Board.

No action or discussion shall be taken on any item presented except that any Board Member may respond to statements made or questions asked or may ask questions for clarification. All matters of an administrative nature will be referred to staff. All matters relating to the Board will be noted in the minutes and may be scheduled for discussion at a future meeting or referred to staff for clarification and a report.

Comments from Board Members

Consent

All items listed under the Consent Calendar are considered and acted upon by one Motion. Members of the public must request that a Board Member pull an item from the Consent Agenda for discussion prior to the start of the meeting.

1. **Minute Approval: September 27, 2023**
   Recommendation: Pass a **Motion** approving the minutes for September 27, 2023.
   Contact: Rosie Brown, Clerk of the Board

2. **Policies/Policy Summary Approval: October 2023**
   Recommendation: Pass a **Motion** approving the Policies/Policy Summary.
   Contact: Sherri Torres, Chief Nursing Officer

3. **Short Term Loans Ratification**
   Recommendation: Pass a **Motion** ratifying Julie Peterson, CFO and Matko Vranjes, Interim CEO securing the short term loan arrangement from external partners, including potentially Salud Para La Gente, not to exceed $1.5 million dollars.
   Contact: Julie Peterson, Chief Financial Officer

4. **PVHCDHC Board and Committee Meeting Calendar Approval: 2024**
   Recommendation: Pass a **Motion** approving the 2024 Calendar.
   Contact: Rosie Brown, Clerk of the Board

Discussion

5. **Medical Executive Committees Report October 2023**
   Recommendation: Pass a **Motion** approving the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of October 2023.
   Contact: Executive Sponsor-Dr. Angel, Chief of Staff, Medical Executive Committee

6. **Watsonville Community Hospital (WCH) Food Market Pilot Program**
   Recommendation: Receive and file update on the Second Harvest Foodbank in conjunction with WCH as is done throughout the state to partner with healthcare providers to work upstream in addressing the social determinants of health.
   Contact: Matko Vranjes, Interim Chief Executive Officer

7. **Santa Cruz County Pediatrics Crisis Stabilization**
   Recommendation: Receive and file update from Matko Vranjes, Interim CEO on Watsonville County Hospital (WCH) partnership with the County of Santa Cruz Health Services Agency Behavioral Health Services division (Santa Cruz BHD) to accept minors detained on a §5585 hold, under EMTALA, until a designated receiving facility is completed.
   Contact: Matko Vranjes, Interim Chief Executive Officer.

8. **Chief Executive Officer Report**
   Recommendation: Receive and file.
   Contact: Matko Vranjes, Interim Chief Executive Officer

9. **Chief Financial Officer Monthly Financial Performance & Budget Update**
   Recommendation: Receive and file.
   Contact: Julie Peterson, Chief Financial Officer

10. **Pajaro Valley Health Care District and Pajaro Valley Health Care District Hospital Corporation Consolidated Audit Report**
    Recommendation: Pass a **Motion** approving the Pajaro Valley Health Care District Hospital Corporation and the Pajaro Valley Healthcare District audit findings for the period of September 01, 2022, through December 31, 2022.
    Contact: Julie Peterson, Chief Financial Officer

Adjourn

This agenda was posted in accordance with the California Brown Act. Any materials related to an item on this Agenda submitted to the Board after distribution of the agenda packet will be made available to the public in accordance with Government Section 54957.5.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: October 25, 2023
Report Type: Consent

Title: Minute Approval: September 27, 2023

Recommendation: Pass a **Motion** approving the minutes for September 27, 2023.

Contact: Rosie Brown, Clerk of the Board

Analysis

After each Board meeting, the Board Clerk composes the DRAFT minutes noting the action taken by the board. Those DRAFT minutes are presented to the Board Members for their approval as a permanent record of the meeting actions.

Financial Impact: None

Attachments:

A: September 27, 2023

Pajaro Valley Health Care District Hospital Corporation
Special Closed Meeting Minutes - Wednesday, September 27, 2023

Call to Order at 6:15 pm.

Roll Call
Present: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Public Comment on Matters on the Agenda

Adjourned to Closed Session at 6:16 pm.

1. **Conference with Labor Negotiators** (Government Code 54957.6)
   CNA, SEIU UHW S&M, Teamsters, CalTech
   Agency Negotiator: Allyson Hauck;
   Contact: Allyson Hauck, Chief Human Resources Officer

Pajaro Valley Health Care District Hospital Corporation
Regular Meeting Minutes - Wednesday, September 27, 2023

Call to Order at 5:00 pm.

Roll Call
Present: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Closed Session Report-None

Agenda Modification Consideration-None

Public Comment on Matters Not on the Agenda

a. Welcome Finance Manager-Chad Yerrick
b. Welcome Clerk of the Board-Rosalie (Rosie) Brown
c. Thank you to Directors Friel and Pimentel for CEO Recruitment-Jennifer Gavin

Comments from Board Members

a. Thank you to Matko Vranjes for serving as Interim Chief Executive Officer

Consent

All items listed under the Consent Calendar are considered and acted upon by one Motion unless otherwise noted.

Moved/Seconded: Nunez/Cox
Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

1. **Minute Approval: August 30, 2023**
   Action: Passed **Motion No. 052-2023** approving the minutes for August 30, 2023.
   Contact: Dawn Bullwinkel, Consultant Clerk of the Board

2. **Policies/Policy Summary Approval: September 2023**
   Action: Passed **Motion No. 054-2023** approving the Policies/Policy Summary.
   Contact: Sherri Torres, Chief Nursing Officer

Discussion

3. **Medical Executive Committees Report September 2023**
   Moved/Seconded: Nunez/Cox
   Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

   Action: Received the Quality Report and passed **Motion No. 054-2003** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of September 2023; and 2) addition of Fluoroscopy and Sedation Privilege to Gastroenterology Privilege Delineation List.
   Contact: Executive Sponsor-Dr. Angel, Chief of Staff, Medical Executive Committee

4. **Chief Executive Officer (CEO) Employment Agreement with Stephen Gray and Related Actions**
Moved/Seconded: Nunez/Pimentel
Yes: Directors Cox, Nunez, Pimentel and Chair Friel
No: Director Gallaher
Action: Passed **Resolution No. 006-2023**:1) approving the CEO Employment Agreement to appoint Stephen Gray as the CEO of Pajaro Valley Health Care District Hospital Corporation dba Watsonville Community Hospital (Hospital); 2) authorizing the Board Chair to executive the agreement and 3) approving the market study findings and confirming the reasonableness of Mr. Gray's compensation package.
Contact: Ad Hoc CEO Selection Committee (Board Chair John Friel and Director Pimentel); Staff Contact, Allyson Hauck, Chief Human Resources Officer.

5. **Chief Executive Officer Report**
Action: Received and filed.
Contact: Matko Vranjes, Interim Chief Executive Officer

6. **Chief Financial Officer Monthly Financial Performance & Budget Update**
Action: Received and filed.
Contact: Julie Peterson, Chief Financial Officer

7. **Santa Cruz County Bank Business Loan Agreement**
Moved/Seconded: Nunez/Gallagher
Yes: Directors Gallagher, Nunez and Chair Friel
Recused: Directors Cox and Pimentel

Action: Passed **Resolution No. 007-2023**: 1) authorizing the execution and delivery of a business loan agreement not to exceed up to $5 million with Santa Cruz County Bank and approving related documents and actions; 2) authorizing the interim Chief Executive Officer, Matko Vranjes and Chief Financial Officer, Julie Peterson (or any interim) or either of their designees (each, an "Authorized Officer") and directing them to execute and deliver the Loan Agreement, the related Security Agreement, and all other related documents on behalf of the Pajaro Valley Health Care District Hospital Corporation.
Contact: Julie Peterson, Chief Financial Officer

Adjourned at 6:07 pm.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: October 25, 2023

Report Type: Consent

Title: Policy/Summaries October 2023

Recommendation: Pass a **Motion** approving the Policies and Summary Report of October 2023.

Contact: Sherri Torres, Chief Nursing Officer, Sherri_StoutTorres@Watsonvillehospital.com

Analysis

As required under Title, 22, CMS and The Joint Commission (TJC), a list of regulatory required policies with a summary of changes are provided for your approval.

Financial Impact: None.

Attachment A:
Reports

Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: October 25, 2023

As required under Title, 22, CMS and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that request your approval.

Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Pharmacy (PHARM)				
Sterile Compounding Program Overview	PHARM2751	re-cleaned up wording to reflect our current state for our Segregated Compounding Area (vs Cleanroom) Previouly approved 08/2023)	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Designated Person for Sterile Compoinding	PHARMXXXX	re-cleaned up wording to reflect our current state for our Segregated Compounding Area (vs Cleanroom) Previouly approved 08/2023	Preparing for changes to USP 797	Author: Pharmacy Director 10-2023 CNO/Vp Sr leader/CEO:10-2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Respondsibilities of Sterile Compounding Personnel	PHARM2752	re-cleaned up wording to reflect our current state for our Segregated Compounding Area (vs Cleanroom) Previouly approved 08/2023	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Personel Trainning and Evaluation	PHARM2754	Policy#2754-replace with : USP Personel Trainning and Evaluation	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: October 25, 2023

As required under Title, 22, CMS and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that request your approval.

Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Compounded Sterile Products: Gloved Fingertip Sampling	PHARM2753	ARCHIVE/RETIRE: Incorporated into Policy 2754		Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Master Formula and Compounding Records	PHARMXXXX	re-cleaned up wording to reflect our current state for our Segregated Compounding Area (vs Cleanroom) Previouly approved 09/2023	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Labeling of Compounded Sterile Preparations	PHARM2205H	Policy#2205-H-replace with: USP Labeling of Compounded Sterile Preparations	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Beyond Use Dating and Stability Considerations	PHARM2728	re-cleaned up wording to reflect our current state for our Segregated Compounding Area (vs Cleanroom) Previouly approved 09/2023	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: October 25, 2023

As required under Title, 22, CMS and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that request your approval.

Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Workflow and Aseptic Technique for Sterile Compounding	PHARM2727	re-cleaned up wording to reflect our current state for our Segregated Compounding Area (vs Cleanroom) Previouly approved 09/2023	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC:10/17/2023 BOD:
Compounded Sterile Products: End Product (Final) Examination	PHARM2726	ARCHIVE/RETIRE: Incorporated into Policy 2727		Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Hand Hygiene and garbing for compounding in a Segregated compounding area	PHARM2724	re-cleaned up wording to reflect our current state for our Segregated Compounding Area (vs Cleanroom) Previouly approved 09/2023	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Cleaning and Disinfecting Sterile Compounding Areas	PHARM2222P	Policy#222P Replce with USP Cleaning and Disinfecting Sterile Compounding Areas	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: October 25, 2023

As required under Title, 22, CMS and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that request your approval.

Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Handling, Storage, Packaging, & Transport of CSPs	PHARM2724	re-cleaned up wording to reflect our current state for our Segregated Compounding Area (vs Cleanroom) Previouly approved 09/2023	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Immediate-Use Compounding	PHARMXXXX	New Policy	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Facilities and Engineering Controls for Sterile Compounding Areas	PHARM2725	Policy#2725 replace with USP Facilities and Engineering Controls for Sterile Compounding Areas	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Out of Specification Events Impacting Sterile Facilities, Environmental Controls, & Systems	PHARMXXXX	New Policy	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: October 25, 2023

As required under Title, 22, CMS and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that request your approval.

Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Equipment, Supplies, & Components for Sterile Compounding	PHARM2779	Policy#2779 replace with USP Equipment, Supplies, & Components for Sterile Compounding	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC:10/2023 MEC: 10/17/2023 BOD:
Certification and Recertification of Sterile Compounding Areas	PHARMXXXX	New Policy	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Microbiological Air and Surface Monitoring Program	PHARM0001	Policy#001 replace with USP Microbiological Air and Surface Monitoring Program	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Complaint, Adverse Drug Reaction, & Recall Handling	PHARMXXXX	New Policy	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOD

Reporting Period: October 25, 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Quality Assurance & Quality Control Program – Sterile Compounding	PHARMXXXX	New policy	Preparing for changes to USP 797	Author: Pharmacy Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC: 10/2023 MEC: 10/17/2023 BOD:
Patient Controlled Analgesia(PCA)	PHARM1820	=> Opioid Stewardship Sub-Committee reviewing policies; incorporating EndTidalCO2 monitoring and "sedation score" (patient safety and regulatory improvements to policy)		Author: Pharmacy/quality Director 10/2023 CNO/Vp Sr leader/CEO:10/2023 PTIC:10/2023 MEC: 10/17/2023 BOD:

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Sterile Compounding Program Overview	Policy #	PHARM2751
Responsible	Pharmacy Director	Revised/Reviewed	10/2023

I. PURPOSE

1. This policy provides an overview of Watsonville Community Hospital's Sterile Compounding Program which operates pursuant to the current version of USP <797>, related USP chapters, relevant Federal regulatory guidelines (e.g. FDA guidance), and in accordance with the California Board of Pharmacy State statutes governing sterile compounding practices. The Sterile Compounding Program outlines the following:
   - Type of healthcare organization or practice(s) engaged in sterile compounding
   - Type and location of compounding area(s) and ISO Class 5 hoods used
   - Categories of CSP compounded
   - Personnel performing sterile compounding
   - General types of sterile preparations compounded
   - Patient populations served
2. The overriding goal of the Sterile Compounding Program is to minimize harm, including death, to human patients that could result from:
   - Microbial contamination [non-sterility]
   - Excessive bacterial endotoxins
   - Variability from the intended strength of correct ingredients
   - Physical and chemical incompatibilities
   - Chemical and physical contaminants, and/or
   - Use of ingredients of inappropriate quality
3. Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication. While not an exhaustive list, the following CSPs are considered sterile preparations
   - Injections
   - Intravenous infusions
   - Irrigations for internal body cavities (i.e., any space that does not normally communicate with the environment outside of the body, such as the bladder cavity or peritoneal cavity). [Note-Irrigations for the mouth, rectal cavity, and sinus cavity are not required to be sterile.]
4. USP <797> defines CSP risk levels or categories of compounding that are primarily based on the state of environmental control under which the CSP is compounded, the probability for microbial growth during the time the CSP is stored, and the time period within which the CSP is to be used. USP <797> redefined CSP into the following categories:
   - **Immediate Use CSPs** – compounded in less than ISO Class 5 conditions (e.g. bedside or countertop), with 3 or fewer sterile products, and a maximum BUD of 4 hours after the initiation of compounding.

- **Category 1 CSPs** – compounded in ISO Class 5 PEC located in a segregated compounding area with a maximum BUD of 12 hours when stored at room temperature or 24 hours when refrigerated.
- **Category 2 CSPs** – compounded in an ISO Class 5 PEC located within a classified sterile compounding facility and adhering to USP BUDs based on storage conditions, administration of CSP sterility testing, sterilization method, and sterility of starting components.
- **Category 3 CSPs** – compounded in an ISO classified sterile compounding facility with increased garbing, environmental monitoring, compounding oversight requirements, and CSP sterility and endotoxin testing requirements allowing for extended BUD assignments.

5. Administration of medication, preparation of allergenic extract prescription sets, blood-derived and other biological material processing that occurs physically removed from sterile compounding activities, and sterile radiopharmaceuticals is not in the scope of the Sterile Compounding Program and USP <797>.

II. POLICY

1. The Sterile Compounding Program at Watsonville Community Hospital is summarized in Appendix One. The Program includes the following type(s) of facilities and sterile compounding areas where sterile compounding of Category 1 CSPs occurs:
   - Segregated Compounding Area (SCA)
2. Personnel who compound or have direct oversight of compounding personnel are required to successfully complete and remain current in all appropriate Sterile Compounding Core Competencies. These personnel include:
   - Pharmacy Technicians
   - Pharmacists
   - Nurses
3. Personnel supporting, but not directly compounding, are required to successfully complete and remain current in selected Sterile Core Compounding Competencies directly related to their limited role(s). These personnel include:
   - Environmental Services (i.e., Housekeeping)
4. Personnel not involved in sterile compounding or visitors are escorted and overseen by the Designated Person(s) or designee and expected to comply with all aspects of the Sterile Compounding Program (e.g. hand hygiene, garbing, conduct, etc.).
5. Patient populations served by CSPs prepared under the Sterile Compounding Program include:
   - Inpatients, Outpatients
   - Human
   - Adult, Neonate/Pediatric, Geriatric
6. General types of compounded sterile products prepared under the Sterile Compounding Program include:
   - Non-hazardous CSPs
   - Single patient, batched CSPs for single or multiple patients, repackaged CSPs
   - Sterile to sterile

- Single use CSPs, multi dose CSPs
- Other high risk CSPs including, but not limited to intrathecal, epidural CSPs
- Other CSPs not limited to parenteral nutrition

7. Types of primary engineering controls used to compound sterile products prepared under the Sterile Compounding Program include:
   - Restricted Access Barrier (RAB): CAI (Compounding Aseptic Isolator)

III. ROLES & RESPONSIBILITIES

The Designated Person(s) (DP): The DP is responsible for the Sterile Compounding Program and is accountable for the performance and operation of the sterile compounding facility and equipment; environmental monitoring and maintaining a state of microbial control within controlled areas; personnel competency qualification; and ongoing compliance with the Standard Operating Procedures.

IV. DEFINITIONS

1. **Biological safety cabinet (BSC):** A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
2. **Classified area:** An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class)
3. **Compounded sterile preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance
4. **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite, inside the perimeter of the SCA, or AECA)
5. **Compounding aseptic containment isolator (CACI):** A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
6. **Compounding aseptic isolator (CAI):** A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.
7. **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.
8. **Immediate-use CSP:** CSP aseptically compounded outside of ISO classified air for direct and immediate administration to a single patient with a maximum BUD of 4 hours after the initiation of compounding.
9. **Integrated vertical laminar flow zone (IVLFZ):** A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.
10. **Laminar airflow workbench (LAFW):** A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.
11. **Pharmaceutical isolator:** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer.

12. **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
13. **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

14. **Segregated compounding area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.

V. PROCEDURE

1. The Sterile Compounding Program is guided by policies and standard operating procedures, which are further outlined in this policy manual.
2. All Sterile Compounding Program policies and procedures are reviewed annually, at a minimum, by the Designated Person and relevant committees.
3. Any changes to Sterile Compounding Program policies and procedures are approved by the Designated Person and communicated to personnel in a manner commensurate with the degree of change.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

APPENDIX ONE: Watsonville Community Hospital's Sterile Compounding Program Overview

Healthcare Facility Type / Location	Description of Compounding Area(s)	Type of PECs Used	CSP Categories Compounded	Type of CSPs Prepared	Personnel Performing or Overseeing Compounding	Primary Patient Populations Served
Hospital: Inpatient Pharmacy	Segregated Compounding Area (SCA)	Compounding Aseptic Isolator (CAI)	Category 1, Immediate Use	Nonhazardous, sterile to sterile	Pharmacy technicians, Pharmacists	Inpatients, outpatients, human, adult, neonate/pediatric, geriatric
Hospital	Clinical practice sites where immediate use CSPs are prepared	N/A	Immediate Use		Nursing	

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Designated Person for Sterile Compounding	Policy #	PHARM797
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

This policy describes the primary roles and responsibilities for the Designated Person(s) (DP) responsible for the oversite of sterile compounding processes and compliance where Compounded Sterile Preparations (CSP) are prepared within Watsonville Community Hospital.

II. POLICY

1. Watsonville Community Hospital will designate one or more individuals (i.e., the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and all other functions pertaining to CSPs.
2. The DP for CSPs will have the following qualifications:
   - Completion of CE hours in the area of compounding
   - Recommended 3 years of experience preparing CSPs

III. DEFINITIONS

1. **Designated Person (DP):** One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.
2. **Compounded Sterile Preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

IV. ROLES & RESPONSIBILITIES

1. The Designated Person(s) for sterile compounding is the Director of Pharmacy.
   - DP may assign designee(s) to assist with Sterile Compounding Program.
   - Designee may be assigned by DP to assist with any of the procedures included in this policy.
2. The DP(s) is responsible for:
   - Overall compliance with USP <797>, applicable federal and state laws and regulations and accreditation standards.
   - Oversight of personnel training and competency for those involved in sterile compounding and handling and preparing CSPs
   - Selection of components
   - Monitoring and observing sterile compounding activities and taking immediate corrective action if deficient practices are observed.
   - Ensuring standard operating procedures (SOPs) and/or policies are fully implemented, and that follow-up is carried out if problems, deviations, or errors are identified.
   - Establishing, monitoring, and documenting procedures for the handling and storage of CSPs and/or components of CSPs.

3. Pharmacy Management is responsible for:
    - Ensuring adequate personnel resources for training and adherence to Watsonville Community Hospital's Sterile Compounding procedures,
    - Ensuring adequate equipment and facilities to comply with USP <797> standards,
    - Coordinating with the Designated Person for Sterile Compounding for local site implementation, monitoring, or concerns.

V. PROCEDURE

1. Training and Evaluation:
    - The DP creates, implements, and oversees training of all compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties. The DP ensures that all persons who enter the sterile compounding area and/or handles CSPs complete training and demonstrate competency in maintaining the quality of the sterile compounding environment.
    - The DP performs all training and observation associated with CSPs and/or designates an assigned trainer to complete these functions.
2. Personal Hygiene and Garbing:
    - The DP evaluates if individuals with certain conditions should be excluded from the sterile compounding environment. Conditions that have a higher risk of contaminating the CSP and the environment are personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.
    - The DP may permit individual personnel accommodations to hand hygiene and garbing as long as the quality of the CSP and the environment will not be affected; and will document accommodations as defined in the **Hand Hygiene and Garbing policy**.
3. Facility Design and Environmental Control:
    - The DP ensures that each area where CSPs are prepared meets the classified air quality standard appropriate for the activities conducted in that area.
    - The DP ensures that International Organization for Standardization (ISO) Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality.
    - The DP determines the dynamic operating conditions for the sterile compounding environment. The dynamic operating conditions are reproduced during dynamic room certification testing.
        - Dynamic operating conditions are the conditions in the sterile compounding area in which personnel are present and simulating or performing sterile compounding. These conditions will reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the DP.
    - The DP identifies and addresses other areas of risk related to placement and movement of materials within the compounding area to ensure the quality of the CSP and the environment will not be affected.
4. Certification and Recertification:
    - The DP reviews all certification and recertification records to ensure that the classified environments meet the minimum requirements outlined in USP <797>.
5. Components:
    - The DP assesses and selects acceptable and reliable sources if a component used in the compounding of CSPs cannot be obtained from a Food and Drug Administration (FDA)-registered facility.
6. Standard Operating Procedures (SOP)s:

- The DP ensures that SOPs are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function.
- The DP ensures that corrective actions are taken if problems, deviations, failures, or errors are identified, and documents corrective actions as necessary.
- The DP reviews SOPs at least every 12 months to ensure that they reflect current practices. The review is documented by DP.
- Any changes or alterations to an SOP are made only by a DP and must be documented.

7. Quality Assurance and Quality Control:
   - The DP ensures that Watsonville Community Hospital has a formal, written Quality Assurance (QA) and Quality Control (QC) program.
   - The written QA and QC program establishes a system of:
     - Adherence to procedures
     - Prevention and detection of errors and other quality problems
     - Evaluation of complaints and adverse events
     - Appropriate investigations and corrective action
   - The DP reviews the overall QA and QC program once every 12 months and the results of the review are documented and appropriate action taken if necessary.
8. Complaint Handling:
   - The DP reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.
9. Handling and storing CSPs:
   - If there is a known excursion to temperatures either below or above the storage temperature limits for the CSP, the DP determines (e.g., by consulting literature or analytical testing) whether the CSP is expected to retain its integrity or quality. If this cannot be determined, the CSP is discarded.

VI. REFERENCES

United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 proposed version.

VII. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Responsibilities of Sterile Compounding Personnel	Policy #	PHARM2752
Responsible	Pharmacy Director	Revised/Reviewed	10/2023

I. PURPOSE

1. This policy describes the responsibilities and procedures for Compounding Personnel and individuals entering sterile compounding areas where Compounded Sterile Preparations (CSP) are prepared within Watsonville Community Hospital.

2. Humans shed approximately 10^6 microbe-laden skin cells per hour and, as such, pose a significant risk to the cleanroom environment. Additionally, human touch contamination within the controlled areas is the most common cause of component and CSP contamination. Consequently, personal hygiene, proper hand washing and garbing, and appropriate conduct and work practices within a sterile environment help to reduce the introduction of contamination into the controlled environment and risk of touch contamination to sterile preparations.

3. Compounding personnel are essential in maintaining a state of control inside compounding areas and serve as the first line in the detection of deviations or failures of facilities, environmental controls, equipment, work processes, personnel conduct/behaviors, or entry of unauthorized personnel or visitors that could adversely impact the quality of the environment and, ultimately, patient safety. All compounding personnel have a responsibility to actively monitor the compounding environment and report any suspected or known issues in a timely manner to the Designated Person(s) (DP) and/or Designee.

II. POLICY

1. Compounding personnel are responsible to review, understand, and comply with all aspects of the Watsonville Community Hospital's sterile practice SOPs (Standard Operating Procedures) related to their job duties, including, but not limited to:
   - Hand Hygiene and Garbing
   - Personnel Training and Evaluations
   - Materials Movement into Controlled Areas
   - Aseptic Technique and Workflow
   - Beyond-use Date (BUD) Determination & Stability Considerations
   - Cleaning, Disinfecting, & Applying Sporicidal Agents
   - Labeling
   - Good Documentation Practices
2. All required sterile practice training, evaluations, and assessments are successfully completed:
   - Prior to compounding independently or overseeing compounding activities initially and
   - Per the required ongoing, role-based frequency as described in the Sterile Compounding Training and Competency Program and SOP

- Deviations from the required training and evaluation schedule and/or failures of any portion of an evaluation or assessment are reported to the Designated Person(s) and/or Designee as soon as known so appropriate accommodations, if appropriate, can be made and documented.

3. Illnesses, skin conditions, and noncompliant personal issues (e.g., unremovable jewelry) are reported to the Designated Person(s) (DP) and/or Designee prior to entering the compounding area at the beginning of each shift. The DP and/or Designee determines if accommodations are warranted and documents accommodations and/or reassignment of duties until the personal condition or situation is resolved (if possible).
4. Hand hygiene and garbing procedures are completed every time compounding personnel enter/reenter the compounding area.
5. Non-compounding personnel and visitors are observed and supervised when entering controlled areas and are required to perform hand hygiene and garbing. Deviations are reported to the DP and/or Designee immediately and unsupervised visitors are asked to exit the compounding area until proper oversight is available.
6. CSPs are labeled and assigned BUDs per policy. Reference appropriate resources, including but not limited to the USP-NF Monograph and MicroMedex to validate (and document, if needed) stability issues necessitating a shortened BUD.
7. Cleaning, disinfecting, and sporicidal application responsibilities within compounding areas is completed and documented according to the schedule, frequency, and task descriptions per policy.
8. Known or suspected issues impacting the quality of the compounding area; functioning of equipment, facilities, or processes; or quality of the components and/or final compounded preparations are reported to the DP and/or Designee in a timely manner.
9. State and Federal licensures and certifications required for sterile compounding are kept current and in good standing.

III. DEFINITIONS

- **Classified area:** An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).
- **Cleaning agent:** An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
- **Compounding area:** The area where compounding is occurring (i.e., inside the perimeter of the SCA).
- **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
- **IPA:** Isopropyl alcohol.
- **Low-lint wiper**: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.

IV. ROLES & RESPONSIBILITIES

1. Designated Person(s) (DP) (and/or Designee):

- Ensure Compounding Personnel have education and training in the foundational knowledge and skills needed to perform sterile compounding job duties successfully.

- Provide immediate access to the SOPs and compounding resources needed to perform sterile compounding job duties successfully, e.g., USP <797> and supporting Chapters, USP-NF Monographs and/or stability reference data.
- Evaluate personnel illness, health conditions, and personal garbing situations to assess the impact and/or potential risks to the quality of the compounding environment, CSPs, and coworkers. Determine and document accommodations or job reassignment, if appropriate.
- Ensure the compounding facilities, environmental controls, and equipment are in good working order.
- Provide timely communication and education to compounding personnel on new and updated policies, procedures, equipment, formulations, systems, supplies, available components, etc.
- In partnership with pharmacy leaders, address behavior and conduct issues inconsistent with safe compounding practices and that potentially impact the quality of the environment.

2. Compounding personnel:

- Remain current and in good standing on all required sterile compounding training, evaluations, and assessments.
- Report any health conditions, personal garbing issues, or other circumstances that could impact the quality of the compounding area to the DP and/or Designee prior to entry into the compounding area.
- Take an active role in ensuring the quality of the compounding environment and patient safety by reporting suspected or known concerns with sterile compounding facilities, environmental controls, equipment, systems, personnel, supplies, components, etc. in a timely and appropriate manner.
- Ensure all non-compounding personnel and visitors entering the compounding area are properly supervised and successfully complete hand hygiene, garbing, and cleaning of necessary tools and supplies brought into the compounding area. Report concerns immediately to DP and/or Designee.

V. PROCEDURE

1. Prior to entry into a classified compounding area
   - Wipe eyeglasses with a sanitizing agent that does not harm the lens or frames.
   - Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests) and store in appropriate area outside of segregated compounding area (SCA).
   - Remove all cosmetics including false eyelashes and nail polish, artificial nails, or extensions. Ensure nails are kept clean and trimmed to avoid puncturing gloves.
   - Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase the risk of contamination of the CSP
   - Leave drinks, food, gum, mints, personal electronics outside of controlled areas.
   - Attend to personal needs, such as visiting the restroom and fully hydrating, to minimize the need to exit and reenter the compounding area prior to assigned breaks or at the conclusion of compounding duties.
   - Report current respiratory infections, fevers, flaking skin conditions, fresh tattoos, fresh or oozing wounds, unremovable jewelry, or similar to the DP and/or Designee for

determination if compounding personnel should be reassigned to duties outside of the compounding area until the current health condition is resolved.

2. Upon entry into the compounding area
   - Follow the hand hygiene and garbing procedure and sequence when entering or reentering the compounding area.
   - Confirm all hair, including facial hair, is fully covered and hair and face coverings are positioned properly in mirror adjacent to the garbing area.
   - During hand hygiene, ensure proper use of the nail pick, full lathering and washing of hands and forearms (to the elbows), and continue washing for at least 30 seconds (after use of the nail pick) each time hands are washed. Pat dry arms with a low-lint towel to minimize skin shell shedding.
   - Following hand hygiene, immediately don compounding frock or gown without touching any other surfaces. Apply alcohol-based hand gel and allow to fully dry before donning sterile gloves, ensure ungloved hands do not touch any other surface during the process.
3. Conduct within compounding area
   - Limit access to compounding areas to trained and qualified compounding personnel or supervised non-compounding personnel or visitors.
   - Don and doff compounding gown immediately upon entry (just prior to exit) to minimize shedding from uncovered skin and scrubs. Store gown appropriately for reuse during same shift.
   - Minimize conversations to work-related communication only. Do not talk directly into a PEC, turn head away from PEC prior to speaking.
   - When coughing or sneezing occurs, replace mask and, at a minimum, sanitize gloves with sIPA prior to resuming activities. Turn head or step away from PEC if coughing or sneezing occurs while compounding.
   - Minimize touching of eyeglasses, face, or garb. Sanitize hands thoroughly with sIPA immediately and prior to resuming activities.
   - Move through the compounding areas in at a controlled and deliberate pace to minimize particle shedding. Avoid congregating in traffic pattern areas.
   - Do not eat, drink, chew gum or tobacco, spit, or similar in controlled areas.
   - Keep clean side carts within compounding area at all times. If a clean side cart crosses the Line of Demarcation (LOD), clean and disinfect the cart prior to reentry into the controlled area.
4. Conduct within the ISO Class 5 PEC
   - Prior to introducing items into the PEC:
     - Sanitize gloved hands and all components and supplies with sIPA just prior to introduction in the PEC. Use both mechanical/manual (i.e., wiping) and chemical (i.e., wet contact time) clean action to fully sanitize all surfaces.
     - Re-sanitize gloved hands throughout the compounding process and, when removed from the PEC, prior to reentry.
     - Components or supplies in a sterile outer wrap do not need to be cleaned if removed from the sterile wrap as the item crosses into the PEC.
   - Prior to compounding, wipe all critical sites with a sIPA wipe three times firmly in one direction or around the neck of an ampule. Allow the sIPA to fully dry prior to puncturing or entering the component.

- Perform compounding activities within the DCA (Direct Compounding Area) and use aseptic technique during all compounding manipulations while ensuring first air on critical sites.
- Conduct aseptic manipulations at least 6 inches from the front sash and 3 inches from the deck of the PEC to ensure unidirectional airflow and first air.
- Label CSPs outside of the PEC and place all used components, supplies, and finished CSPs in an individual bin for final verification and reduce the risk of mix ups.
- Do not allow bare skin (e.g., hands or face/neck) to enter a PEC.
- Adhere to require in-process quality control and release checks, as specified in the MFR, and document results appropriately

5. Managing Power Outages or Disruption
   - Allow PECs to run continuously. If PEC is turned off or if a power disruption occurs:
     - Stop compounding activities and restore power to the PEC(s) as soon as possible.
     - Allow the PEC to run for 30 minutes or for the timeframe stated by the manufacturer to restore the ISO Class 5 environment.
     - Fully clean and disinfect all interior surfaces of the PEC prior to resuming compounding activities and handle components and finished CSPs inside the hood at the time of the outage as follows:

<table>
<tr><th>Outage Timeframe</th><th>Cleaning of PEC Interior
30 minutes after Power Restored</th><th>Components</th><th>CSPs</th></tr>
<tr><td>< 1 Hour</td><td>One-step disinfectant cleaner followed by sIPA to remove residue: observe dwell times</td><td rowspan="3">Date, store, & use per component BUD policy

<u>Single use components</u>:
<u><</u> 12 Hour BUD

<u>Multi-dose components</u>:
<u><</u> 28 Days BUD</td><td rowspan="3">Completed: remove from hood and label; BUD unaffected

<u>Partially compounded individual CSPs: discard</u>

<u>Uncompounded batched CSPs (components):</u> move to another PEC or sanitize and compound after power is restored to PEC and it is cleaned</td></tr>
<tr><td>1 to 24 Hours</td><td>Sporicidal disinfectant followed by sIPA; observe dwell times</td></tr>
<tr><td>> 24 Hours</td><td>Triple clean followed by sIPA; observe dwell times</td></tr>
</table>

6. Materials Movement into Compounding Areas
   - Remove all supplies, medications, and components from corrugated cardboard and outer shipping containers prior to introduction into Segregated Compounding Area (SCA).
     - Smooth coated cardboard is allowed inside of the compounding area, however both the cardboard surface and contents (e.g., vials) are thoroughly cleaned and disinfected.
   - Clean and disinfect all materials (e.g., equipment, furniture, supplies, medications, components) introduced into Segregated Compounding Area (SCA) upon entry/crossing

the Line of Demarcation (LOD) with sterile 70% isopropyl alcohol (sIPA), EPA registered one step disinfecting cleaner, or sporicidal cleaner using both mechanical/manual (i.e., wiping motion) and chemical (e.g., dwell time or wet contact time) action.
    - Thoroughly "pre-clean" furniture and equipment (e.g., ladders, inspection equipment, etc.) visibly dirty or that have been used outside of the building prior to introduction into the compounding area with a hospital grade cleaner, one-step disinfectant cleaner, or sporicidal agent.
- Transport materials within the compounding area on a "clean-side" dedicated cart or bin. Do not allow "dirty side" carts to cross LOD without thorough cleaning of entire cart and wheels.

7. Cleaning, Disinfecting, & Applying Sporicidal Agents
    - Complete hand hygiene and don full garb prior to initiating cleaning activities.
        - Don appropriate protective eye gear and respiratory support (e.g., N-95, PAPR or full respirator) prior to and during use of sporicidal agents or other irritating cleaning solutions.
    - Clean, disinfect, and apply sporicidal agents to PECs according to the frequency and procedures described in the Cleaning & Disinfecting policy, including:
        - Conduct and sequence cleaning activities from cleanest to dirtiest areas and, generally, from top to bottom (e.g., ceiling to floor).
        - Observe dwell times for all cleaning agents; apply sIPA to remove cleaning agent residue inside PECs.
        - If surfaces inside the PECs are visibly soiled or have dried residue, remove debris with sterile water prior to initiating cleaning process.
        - Use only sterile cleaning agents and supplies inside of PECs.
        - Do not spray or squirt cleaning agents inside of PECs; apply cleaning solution to a sterile low-lint wipe or use pre-saturated sterile cleaning wipes inside the PEC.
    - Record completed cleaning activities in electronic system (e.g., Simplifi) prior to returning to work to ensure timely and accurate recording of these tasks.
    - Prior to returning to compounding activities, discard used garb and repeat the complete hand hygiene and garbing process with fresh garb.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding - Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health Care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Personnel Training and Evaluation**
Policy Number/ Version:	797-2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1 This policy serves as the written Sterile Compounding Training and Evaluation Program for Watsonville Community Hospital and describes the procedures for training and evaluating sterile practice knowledge and competencies of personnel involved in or having direct oversight of compounded sterile preparations (CSPs). **Refer to Appendix One for a summary of the Sterile Training and Competency Program.**

1.2 The Sterile Compounding Training & Competency Program equips compounding personnel with the didactic knowledge and practical training in the foundational principles of sterile compounding. Competency evaluations validate proficiency in the required skills necessary to perform related job functions and maintain the quality of the sterile environment. The Program consists of initial and ongoing training and evaluation in the following areas:

- **Sterile Compounding Core Competencies and Principles Knowledge** - demonstrates Compounding Personnel possess the knowledge of and proficiency in the skills necessary to perform sterile manipulations and achieve and maintain appropriate environmental conditions.
- **Hand Hygiene and Garbing Competency (including Gloved Fingertip and Thumb Sampling)** - ensures Compounding Personnel can safely and effectively complete hand hygiene, garbing, and donning of gloves without touch contamination.
- **Aseptic Manipulation Competency (including Media Fill)** - validates Compounding Personnel aseptic technique and related manipulations within an ISO 5 compounding environment.

1.3. The USP Expert Committee has recognized an effective sterile compounding practice involves personnel, vendors, and other visitors that are not directly compounding or performing compounding related activities. Consequently, training and evaluation requirements are defined based on role and potential risk for contaminating the sterile compounding areas.

- **Compounding Personnel** – individuals performing or directly overseeing compounding activities as well as the Designated Person(s) and/or Designee
- **Cleaning Personnel** – individuals performing cleaning and disinfecting activities and that do not directly or indirectly participate in compounding CSPs
- **In-Process & Final Verification Personnel** – typically pharmacists, who do not participate in compounding or the oversight of compounding activities
- **Other Personnel & Visitors** – individuals who have a need to enter compounding areas (under supervision) but do not participate in or support the compounding activities in any way

1.4. When performing aseptic manipulations according to the related USP standards and training and qualification requirements, personnel compounding the following types of sterile compounds are exempt from this policy:

- Immediate-use compounds
- Sterile drug preparation per approved manufacturer's labeling

- Proprietary bag and vial systems docked and activated for immediate administration to a single patient

1.5. This policy applies to compounding of only non-hazardous CSPs.
- NOTE: Watsonville Community Hospital does not compound hazardous drugs.

2. Policy

2.1. [USP 797] Compounding and supporting personnel successfully complete training and demonstrate knowledge of and proficiency in all of the skills and competencies necessary maintain the quality of the compounding environment and perform job-related functions ***before*** compounding CSPs, supervising, or performing support-related activities independently and complete refresher training and requalification as outlined below; adapted from USP <797> Tables 2 & 3.

Personnel Function	**Training & Competency in Maintaining Quality of Compounding Environment**	**Training & Competency in Sterile Compounding Principles & Practices**	**Hand Hygiene & Garbing Competency*** ***(Including GFT)***	**Aseptic Manipulation Competency*** ***(Including Media Fill, Post-GFT, and Surface Sample)***
Compounding Personnel: Personnel compounding or with direct oversight of compounding personnel & activities				
Compounder	Initially & Every *12* months	Initially & Every *12* months	Initially & Every 6 months	Initially & Every 6 months
Designated Person(s), Assigned Trainer(s)	Initially & Every *12* months	Initially & Every *12* months	Initially & Every *12* months	Initially & Every *12* months
Supporting Personnel: Personnel performing supporting roles that do not involve direct involvement in or oversight of compounding personnel or compounding activities				
Personnel Cleaning of Compounding Area(s) – e.g., Environmental Services (EVS)	Initially & Every *12* months	N/A	Initially & Every *12* months **Excluding GFT; performed in non-classified area*	N/A
Personnel performing Immediate Use Compounding	Initially	Initially	Initially **Excluding GFT; performed in non-classified area*	Initially **Excluding MF, GFT & SS; performed in non-classified area*
Other Personnel & Visitors (e.g., maintenance personnel, certifiers, contractors, inspectors, surveyors, students)	Not Required Must be supervised by DP(s) and/or Designee at all times and comply with Hand Hygiene, Garbing, Materials Movement, & Conduct policies			

Knowledge and Core Skill Competencies:

2.2 [USP 797] Compounding personnel involved in or having direct oversight of compounding CSPs ("Compounding Personnel") as well as the Designated Person(s) and Assigned Trainer(s) (AT) complete training and evaluation in core competencies, skills, and sterile practice principles including, but not limited to:

- Sterile core competencies and skills in maintaining the quality of the sterile compounding environment including, but not limited to:
  - Hand hygiene
  - Garbing
  - Cleaning and disinfection
  - Calculations, measuring, and mixing
  - Aseptic technique
  - Achieving and/or maintaining sterility
  - Use of equipment
  - Documentation of the compounding process (e.g., master formulation and compounding records)
  - Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
  - Proper use of primary engineering controls (PECs)
  - Principles of movement of materials and personnel within the compounding area

- Sterile compounding principles and practices including, but not limited to:
  - *USP <797> Pharmaceutical Compounding –Sterile Preparations*, other applicable standards, and relevant literature.
  - Watsonville Community Hospital policies and procedures related to sterile compounding and related job duties.
  - Beyond use dating, packaging, storage, and labeling of CSPs
  - Quality assurance and quality control procedures
  - Use of resources (e.g., Micromedex) and data base (e.g., Simplifi)

2.3 [USP 797] Personnel in supporting roles complete training and evaluation in job-related core competencies, skills, and sterile principles and practices including, at a minimum:

Core Skill	Cleaning Personnel
Hand Hygiene and Garbing	X
Cleaning/ Disinfecting	X
Principles of Materials Movement & Conduct within Controlled Areas	X

2.4 [USP 797] Refer to the **Immediate Use Compounding** policy for training and evaluation requirements. Personnel who perform both immediate use compounding and sterile compounding complete training and evaluation for both roles.

2.5 [USP 797] The Designated Person(s) assigns the role of Assigned Trainer (AT)/Designee to personnel who are responsible for or assist in training and evaluating competency of compounding personnel.

2.6 [USP 797] Core skills, competencies, and knowledge are assessed with hands-on demonstration of skill under direct observation by a DP or AT /Designee and sterile principles knowledge is assessed via written or electronic examination.

2.7 [USP 797] Successful or "passing" results for the Sterile Core Competencies and Knowledge Assessment are:

Observation	Validation	Initial Prior to Compounding Independently	Ongoing Every 12 Months
Competency-based checklist with 100% proficiency	USP <797> & Sterile Principles Knowledge Exam	>=80% cumulative score	>=80% cumulative score

2.8 **[CCR 1735.8] Quantitative** integrity shall be done annually.

- Potency of sample sent for independent (outside laboratory) review shall be expected to be 90 to 110%

Hand Hygiene and Garbing Competency:

2.9 [USP 797] Hand hygiene and garbing competencies are assessed with hands-on demonstration of skill under direct observation by a DP or AT/Designee and validated via the Gloved Fingertip and Thumb Sampling Assessment.

- **Initial Gloved Fingertip and Thumb Sampling Assessment (GFS):** successfully completed three separate times prior to compounding independently; each GFS is conducted separately after a completing the hand hygiene and garbing procedure
- **Ongoing Gloved Fingertip and Thumb Sampling Assessments:** successfully completed at least once every 6 months for Compounding Personnel requalification

2.10 Successful or "passing" results for the Hand Hygiene and Garbing Competency are:

Observation	Validation	Initial Prior to Compounding Independently	Ongoing Every 6 Months
Competency-based checklist with 100% proficiency	Gloved fingertip assessment	3 separate assessments • 6 total plates (1 plate per hand per assessment) 7-day incubation with zero (0) CFUs	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with zero (0) CFUs

Microbial identification of cultured CFU(s) is not required for Gloved Fingertip and Thumb Sampling.

Aseptic Manipulation Competency:

2.12 [USP 797] The Aseptic Manipulation Competency is administered, observed, and documented by the DP or AT/Designee and consists of four components:

- Media Fill Testing
- Direct visual observation of aseptic technique and manipulations
- Gloved Fingertip and Thumb Sampling of both hands *after* the media fill test
- Surface Sampling of the Direct Compounding Area (DCA) *after* the media fill test

2.13 [USP 797] The Media Fill Test(s) simulates the most difficult and challenging compounding procedure(s), compounding environments, and processing condition(s).

2.14 [USP 797] Successful or "passing" results for the Initial and Ongoing Aseptic Manipulations Competency is as follows:

Observation	Validation	Initial Prior to Compounding Independently	Ongoing Every 6 Months
Competency-based checklist with 100% proficiency	Media Fill	1 assessment 14-day incubation with no growth or turbidity	1 assessment 14-day incubation with no growth or turbidity
	Post Media Fill Gloved fingertip assessment	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with ≤ 3 CFU combined (total)	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with ≤ 3 CFU combined (total)
	Surface sample	1 sample of direct compounding area (DCA) 7-day incubation with ≤ 3 CFU	1 sample of DCA 7-day incubation with ≤ 3 CFU

2.11 [USP 797] If any portion of the Hand Hygiene and Garbing or Aseptic Manipulations Competency does not meet the minimum passing result, the respective Competency is repeated. Initial Hand Hygiene and Garbing (gloved fingertip tests) is complete when there are 3 successful evaluations in a succession. Failures in other Core Competencies are repeated individually. Documentation of the failure, corrective actions, and the repeated competency results is retained and readily accessible.

2.12 [BEST PRACTICE] In the event of a repeated, sequential failures of Core Competencies, Hand Hygiene and Garbing Competency, and/or Aseptic Manipulations Competency, corrective action plans are implemented that are consistent with Board of Pharmacy requirements and under the review and discretion of the DP. Patterns of competency failures over time are assessed on a case-by-case basis.

	Initial	Ongoing
1st Failure	• Coaching and retraining • Repeat failed competency ***STATUS:*** *Independent compounding not allowed until all competencies are successfully completed.*	• Coaching • Repeat failed competency ***STATUS:*** *Allowed to continue with compounding duties while results pending.*
2nd Failure	• Extensive skills and foundation knowledge retraining • Repeat failed competency ***STATUS:*** *Independent compounding is not allowed. If passed, consider increased competency assessment requirements (e.g. every month for 3 months).*	• Skills and foundational knowledge retraining • Repeat failed competency ***STATUS:*** *Independent compounding is not allowed; reassign to non-compounding duties while results pending.*

	Initial	Ongoing
3rd Failure	• Reassign to non-compounding role; consider referral to HR. ***STATUS:*** *Reassigned outside of sterile compounding practice.*	• Reassign to non-compounding role, consider referral to HR. ***STATUS:*** *Future sterile training requires completion of initial training and competency requirements and increased competency assessments.*

2.13 Other personnel or visitors who do not undergo training and evaluation in core competencies, skills, or knowledge required to maintain the quality of the sterile compounding environment, are required to, at a minimum:

- Adhere to all aspects of the **Hand Hygiene and Garbing** policy and procedure,
- Comply with proper materials movement and cleaning procedures
- Only enter a controlled compounding area under direct supervision of the DP or Designee
- Minimize movement within the controlled areas and contact with any surfaces

3. Roles & Responsibilities

3.1 [USP 797] The Designated Person(s) (DP):

- Oversees the Sterile Training and Evaluation Program for Compounding Personnel and supporting personnel involved in or supporting compounding activities.
- Reviews competency results, evaluation and determination of corrective actions, and monitors for longer-term trends with Compounding Personnel Competency performance.
- Ensures non-compounding personnel and visitors who enter the sterile compounding area and/or handle CSPs understand the expectations appropriate to their role or are directly observed to ensure compliance and minimize impact to the quality of the sterile environment.
- May designate and qualify an Assigned Trainer(s) (AT) (or Designee) to assist with the training, evaluation, and competency administration process.
- May define additional training and competency evaluation requirements for compounding personnel performing specialized roles or responsibilities.

3.2 [USP 797] Assigned Trainer(s) (AT) (or Designee):

- Responsible and accountable for directly providing the training, observation, and/or evaluation of personnel performing compounding related activities

3.3 Compounding personnel and supporting roles:

- Successfully complete assigned training and demonstrate proficiency via competency assessment on a timely basis and before the evaluation activities are past due.
- Uphold sterile practice and quality standards to help ensure the quality of the sterile compounding area.

4. Procedures

4.1 [USP 797] Sterile Compounding Knowledge, Skills and Core Competency Assessment

- DP or AT/Designee directly observes Compounding Personnel performing the Core Competencies and Skills (refer to Sections 2.2 and 2.3) and records results in the electronic compounding competency form (e.g., Simplifi documentation).
- Core competency evaluation can be completed in a single or multiple observed sessions. If the process is completed in separate sessions, documentation reflects the date, time, and initials of the DP or AT/Designee performing and evaluating the specific competencies.
- Competencies for hand hygiene, garbing, and aseptic technique can be conducted concurrently with the respective competency assessment. Observations and evaluations of each competency are clearly documented on the respective competency form.

4.2 [USP 797] Documentation of the Hand Hygiene and Garbing and Aseptic Manipulation Competencies includes, at a minimum:

- Name of person evaluated
- Evaluation date and time
- Media and component manufacturer, lot, and expiration date
- Incubation temperatures
- Dates of Incubation
- Competency results
- Name of competency observer and individual(s) reading and documenting results
- Corrective actions (if needed)

4.3 Garbing Competency and Gloved Fingertip and Thumb Sampling Assessment Procedure

- Remove sampling plates (or alternative sampling device) from refrigerator in manufacturer's overwrap and check expiration dates; do not use expired media.
- Collect other supplies needed (e.g., plates, permanent marker, tape), disinfect with sIPA, and move supplies to controlled environment.
- Allow sampling plates to come to room temperature just prior to sampling.
- Enter media lot numbers, expiration dates, and manufacturer on appropriate form.
- DP or AT/Designee labels the base (i.e. agar side) of the sampling plates legibly around the outer edge (or permanently affixed lid on slide or paddle). Label each sample plate with sample type (e.g. "GFS"), hand (e.g., "L" -left or "R" - right), sample number (e.g., 1, 2, or 3) for initial competency, date, and initials of individual.
- Complete hand hygiene and garbing under direct observation. See Policy 2.2 Hand Hygiene and Garbing.

For GFS – CAI:

- Apply sIPA to the disposable gloves donned upon entry into the control space.
- Transfer two labeled sampling plates and 2 pairs of sterile gloves into the antechamber of the compounding isolator.
- Place gloved hands inside isolator sleeves.
- Disinfect the isolator gloves and PEC, including the deck, with sIPA.
- Move both labeled sampling plates and 1 pair of gloves from the ante chamber to the main chamber. Leave the plates to the left of the DCA. Disinfect outer wrapping of gloves.

- Don the sterile gloves over the isolator gloves being careful not to touch the non-sterile surface of the glove wrapping.
- Carefully lift the sterile glove wrapping on the sterile (i.e., inner surface) side and use the wrapping to grab and move the two sample plates to the DCA.
- Carefully remove the lid of the plates and set the lid face down on the deck.
- On the corresponding plate for each hand, gently roll the pads of each gloved fingertip, one at a time, in an arch across the top of the agar surface ensuring not to overlap fingerprints. A thumb print is then gently in the middle of the plate.
- Replace the lids on both plates.
- Remove sterile gloves contaminated with growth media ensuring contaminated surfaces do not touch the isolator gloves, sleeves, or PEC.
- Apply sIPA to the isolator gloves and open the ante chamber door. Move both sample plates and all trash to the ante chamber.
- *During the Initial GFT competency assessment*, repeat this entire process twice more from hand hygiene through garbing with fresh garb and gloves.
- After all samples are collected, seal plates with wax or tape to ensure the lid is not dislodged during transit or incubation and results inspection.
- Prior to disinfecting the PEC and commencing compounding, retrieve the 2nd pair of sterile gloves from the ante chamber and don over the sanitized isolator gloves.

4.3 Aseptic Manipulation Competency Procedure (including Media Fill and Post Media Fill Gloved Fingertip and Surface Sampling)

- Collect supplies needed for the media fill testing, post media fill GFS (2 plates per media fill test), and surface sampling (1 plate per media fill test)
- [Best Practice] When more than one media fill test is to be completed, ensure all necessary media, supplies, and sampling plates for each media fill are collected and organized prior to initiating assessment.
- Check all growth media components for expiration date. Do not use expired media. Allow sampling plates to come to room temperature just prior to sampling.
- Inspect all sterile media fill components for cracks, leaks, or other potential factors that may have compromised product's sterility. Do not use media suspected of contamination or sterile container defects.
- Disinfect all media and supplies with sIPA, and move supplies to controlled environment.
- Enter media lot numbers, expiration dates, and manufacturers on the appropriate form.
- [Best Practice] When more than one media fill test is to be completed, record each media fill on a separate competency form.
- DP or AT/Designee labels the base (i.e. agar side) of the sampling plates legibly around the outer edge (or permanently affixed lid on slide or paddle) and the final dosage unit(s) for the media fill test. Label each sample with sample type (e.g. "MF", "PMF-GFS", or "SS"), hand (e.g., "L" -left or "R" - right), date, and initials of individual.
- Stage all media and supplies inside the ante chamber of the compounding isolator.
- Disinfect gloved hands and all components with sIPA prior to being moved into the ISO Class 5 area of the PEC.
- Perform media fill under direct observation per procedure
- sIPA is used throughout the media fill process to sanitize sterile gloves, critical sites, and the direct compounding area; however, do not apply sIPA to gloved hands or the DCA after the final step of the media fill procedure.

- Sterile media components are manipulated in a manner that simulates typical sterile-to-sterile compounding activities and the sterile soybean casein digest media is transferred into containers similar to those typically used. Soybean casein digest media is not diluted with water or another diluent unless specified by the manufacturer.
- Immediately following the final step of the media fill procedure and before sIPA is applied to gloved hands or the DCA:
  - Compounding Personnel completes the PMF-GFS and DCA surface sample ***inside*** the ISO 5 PEC under direct observation. GFS sampling is performed for both hands with one plate per hand. Refer to the GFS sampling procedures above in 4.1; note that gloves are contaminated with growth media and should be removed from the isolator gloves and replaced prior to commencing compounding activities.
- After all samples are collected and removed from the PEC, seal plates around outer edges with wax or tape to ensure the lid is not dislodged during transit or incubation and results inspection.
- Remove all other trash from the PEC and clean and disinfect PEC prior to commencing compounding.
- Remove and replace sterile gloves immediately without touching any other surfaces; gloves are contaminated with growth medium. Repeat hand hygiene and garbing prior to returning to compounding activities.

4.4 Selection, Incubation, & Interpretation of Media

Media Selection:

- [USP 797] Select a general microbial growth agar (plate, paddle, or slide) supporting both bacterial and fungal growth, such as trypticase soy agar (TSA), for gloved fingertip and surface sampling. Growth medium contains additives that neutralize residual cleaning solutions, such as lecithin and polysorbate 80.
- [USP 797] For media fill procedures, replace all CSP components with soybean–casein digest media components.
- Pharmacy uses commercial sterile microbial growth media: obtain a Certificate of Analysis (COA) from the growth media supplier or manufacturer. The DP and/or Designee reviews and retains the COA to ensure the culture media supports growth of microorganisms (as defined in Table 1 of USP <71>). Store media per manufacturer instructions and media is used in accordance with manufacturer instructions and before the expiration date of the media.

Media Incubation & Interpretation:

- Locate calibrated incubators monitored by NIST certified temperature gauge outside of the sterile compounding area. A minimum of two incubators are available:
  - Incubator 1: calibrated and maintained at 20 to 25°C
  - Incubator 2: calibrated and maintained at 30 to 35°C
- Invert gloved fingertip and surface sample agar plates during incubation to ensure moisture condensation does not collect and fall onto the agar surface which can contaminate and/or invalidate the results.

- Incubation temperatures and timeframes:

Competency	Media	1st Incubation	2nd Incubation	Total Incubation Timeframe
Gloved fingertip and surface samples	TSA agar plate, paddle or slide with polysorbate 80 & lecithin (neutralizers)	≥ 48 hours at 30°C - 35°C (85°F – 95°F)	≥ 5 Days at 20°C - 25°C (68°F – 77°F)	≥ 7 Days
Media fill test final dose unit(s)	Soybean casein digest (all components)	7 Days at 20°C - 25°C (68°F – 77°F)	7 Days at 30°C - 35°C (85°F – 95°F)	14 Days

- Only the DP and/or Designee who is qualified to manage, read, and interpret media places or moves media into and out of incubators.
- Record date, time, incubator temperature, and person(s) moving media into and between incubators on competency form(s).
- [Best Practice] Read and record CFU counts per sampling plate and examine media fill bags/units for visible changes daily or, at a minimum, when media are moved from the first to the second incubator. Record interim results on competency form(s).
- Read and record CFU counts per sampling plate at the conclusion of the full incubation; total CFU counts from all plates to determine the final CFU count results. Record results on the competency form(s).
- Examine the media fill bag/units for any visible turbidity or changes indicating growth at the conclusion of the full incubation against a white and black background in a well-lit area, record either a pass or failed result on the Media Fill form.

4.5 Corrective Action for Competency Failure

- [Best Practice] Any personnel failing to demonstrate competency during a foundational knowledge exam or hands-on skills assessment is coached and reinstructed on the applicable policy, technique(s), and foundational knowledge related to the skill; and subsequently re-evaluated by the DP or AT/Designee.
- [USP 797] Evaluation and corrective action for observed competencies is documented within the competency form. Corrective action records are used for long-term assessment of personnel competency and potential contributing factors to maintaining a state of microbial control within the sterile compounding environment.

4.6 Ongoing Training

- [Best Practice] The DP is responsible for assessing the training needs of personnel and the appropriate method for communication and delivery as new or updated equipment, components, recipes, or procedures are introduced.
- Ongoing training may be communicated in (e.g.,) a staff meeting, email, or formal program.
- Ongoing training will be documented in (e.g.,) meeting minutes, a training log, or formal competency.

5. Definitions

5.1 **Assigned Trainer (AT):** One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation and/or evaluation of personnel for the preparations of CSPs.

5.2 **CSP:** compounded sterile preparation

5.3 **Designated Person (DP):** is one ore more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CSPs.

5.4 **Direct Compounding Area (DCA):** A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air

5.5 **Laminar airflow workbench (LAFW):** An LAFW is a device that provides an ISO Class 5 or better environment for sterile compounding. The LAFW provides either horizontal or vertical unidirectional HEPA-filtered airflow.

5.6 **Integrated vertical laminar flow zone (IVLFZ):** An IVLFZ is a designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room.

5.7 **Media-fill test:** A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.

5.8 **Primary Engineering Control (PEC)**: A device or zone that provides an ISO Class 5 air quality environment for sterile compounding. (Ex: LAFW, BSC, RABS, CAI, CACI)

5.9 **sIPA:** sterile 70% isopropyl alcohol.

5.10 **Secondary Engineering Control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

5.11 **Segregated Compounding Area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.

6. Related Policies, Documents, References

6.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2 United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

6.3 United States Pharmacopeial Convention, Inc. <71> Sterility Tests, Culture Media, and Incubation Temperatures, Growth Promotion Test of Aerobes, Anaerobes, and Fungi. current version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval (10/2023)
Next review:	Month/year

7.1 Initial version published by Wolters Kluwer 2022.

7.2 *Revised/adapted by* {{Pharmacy/Organization Name}} *MM/YYYY*.

APPENDIX ONE: Watsonville Community Hospital

Sterile Compounding Training and Competency Program Description

DESIGNATED PERSON(S):	Director of Pharmacy, may appoint qualified Designee(s)
QUALIFIED TRAINER(S) / COMPETENCY EVALUATOR(S):	Pharmacists
DIDACTIC TRAINING RESOURCES:	Critical Point ASHP

COMPETENCY	TRAINING METHOD	ASSESSMENT METHOD	FREQUENCY	PASSING SCORE
1. Core Sterile Competencies: • Hand hygiene • Garbing • Cleaning and disinfection • Calculations, measuring, and mixing • Aseptic technique • Use of equipment, if appropriate • Documentation of the compounding process (e.g., master formulation and compounding records) • Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area • Proper use of primary engineering controls (PECs) • Principles of movement of materials and personnel within the compounding area	Didactic training program with video simulations Hands-on training program	Direct Observation	At least every 12 months	100% Competency & Compliance
2. Sterile Compounding Knowledge • Knowledge and understanding of principles behind the Core Competencies • USP 797 Guidelines	Didactic training Review of USP 797 Review of SOPs	Written / Electronic Knowledge Exam	At least every 12 months	≥ 80% composite score, as available
3. Garbing Competency • Hand Hygiene and Garbing Observation • Gloved Fingertip and Thumb Sampling Assessment	Didactic training Hands-On Training	Direct Observation & Evaluation Media Results	At least every 6 months	Observed Skills: 100% Competency Media Results Per USP 797
4. Aseptic Manipulations Competency • Aseptic Technique and Manipulations Observation • Media Fill Test(s) • Post Media Fill Gloved Fingertip and Thumb Sampling Assessment • Post Media Fill DCA Surface Sample Assessment		Direct Observation & Evaluation Media Results	At least every 6 months	Observed Skills: 100% Competency Media Results Per USP 797

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Personnel Training and Evaluation	Policy #	PHARM2754
Responsible	Pharmacy Director	Revised/Reviewed	10/2023

I. PURPOSE

1. This policy serves as the written Sterile Compounding Training and Evaluation Program for Watsonville Community Hospital and describes the procedures for training and evaluating sterile practice knowledge and competencies of personnel involved in or having direct oversight of compounded sterile preparations (CSPs). **Refer to Appendix One for a summary of the Sterile Training and Competency Program.**
2. The Sterile Compounding Training & Competency Program equips compounding personnel with the didactic knowledge and practical training in the foundational principles of sterile compounding. Competency evaluations validate proficiency in the required skills necessary to perform related job functions and maintain the quality of the sterile environment. The Program consists of initial and ongoing training and evaluation in the following areas:
   - **Sterile Compounding Core Competencies and Principles Knowledge -** demonstrates Compounding Personnel possess the knowledge of and proficiency in the skills necessary to perform sterile manipulations and achieve and maintain appropriate environmental conditions.
   - **Hand Hygiene and Garbing Competency (including Gloved Fingertip and Thumb Sampling) -** ensures Compounding Personnel can safely and effectively complete hand hygiene, garbing, and donning of gloves without touch contamination.
   - **Aseptic Manipulation Competency (including Media Fill) -** validates Compounding Personnel aseptic technique and related manipulations within an ISO 5 compounding environment.
3. The USP Expert Committee has recognized an effective sterile compounding practice involves personnel, vendors, and other visitors that are not directly compounding or performing compounding related activities. Consequently, training and evaluation requirements are defined based on role and potential risk for contaminating the sterile compounding areas.
   - **Compounding Personnel** – individuals performing or directly overseeing compounding activities as well as the Designated Person(s) and/or Designee
   - **Cleaning Personnel** – individuals performing cleaning and disinfecting activities and that do not directly or indirectly participate in compounding CSPs
   - **In-Process & Final Verification Personnel** – typically pharmacists, who do not participate in compounding or the oversight of compounding activities
   - **Other Personnel & Visitors** – individuals who have a need to enter compounding areas (under supervision) but do not participate in or support the compounding activities in any way
4. When performing aseptic manipulations according to the related USP standards and training and qualification requirements, personnel compounding the following types of sterile compounds are exempt from this policy:
   - Immediate-use compounds
   - Sterile drug preparation per approved manufacturer's labeling
   - Proprietary bag and vial systems docked and activated for immediate administration to a single patient

5. This policy applies to compounding of only non-hazardous CSPs.
   - NOTE: Watsonville Community Hospital does not compound hazardous drugs.

II. POLICY

Compounding and supporting personnel successfully complete training and demonstrate knowledge of and proficiency in all of the skills and competencies necessary maintain the quality of the compounding environment and perform job-related functions ***before*** compounding CSPs, supervising, or performing support-related activities independently and complete refresher training and requalification as outlined below; adapted from USP <797> Tables 2 & 3.

Personnel Function	**Training & Competency in Maintaining Quality of Compounding Environment**	**Training & Competency in Sterile Compounding Principles & Practices**	**Hand Hygiene & Garbing Competency*** ***(Including GFT)***	**Aseptic Manipulation Competency*** ***(Including Media Fill, Post-GFT, and Surface Sample)***
Compounding Personnel: Personnel compounding or with direct oversight of compounding personnel & activities				
Compounder	Initially & Every *12* months	Initially & Every *12* months	Initially & Every 6 months	Initially & Every 6 months
Designated Person(s), Assigned Trainer(s)	Initially & Every *12* months	Initially & Every *12* months	Initially & Every *12* months	Initially & Every *12* months
Supporting Personnel: Personnel performing supporting roles that do not involve direct involvement in or oversight of compounding personnel or compounding activities				
Personnel Cleaning of Compounding Area(s) – e.g., Environmental Services (EVS)	Initially & Every *12* months	N/A	Initially & Every *12* months **Excluding GFT; performed in non-classified area*	N/A
Personnel performing Immediate Use Compounding	Initially	Initially	Initially **Excluding GFT; performed in non-classified area*	Initially **Excluding MF, GFT & SS; performed in non-classified area*
Other Personnel & Visitors (e.g., maintenance personnel, certifiers, contractors, inspectors, surveyors, students)	Not Required Must be supervised by DP(s) and/or Designee at all times and comply with Hand Hygiene, Garbing, Materials Movement, & Conduct policies			

A. Knowledge and Core Skill Competencies:

1. Compounding personnel involved in or having direct oversight of compounding CSPs ("Compounding Personnel") as well as the Designated Person(s) and Assigned Trainer(s) (AT) complete training and evaluation in core competencies, skills, and sterile practice principles including, but not limited to:
   - Sterile core competencies and skills in maintaining the quality of the sterile compounding environment including, but not limited to:
     - Hand hygiene
     - Garbing
     - Cleaning and disinfection
     - Calculations, measuring, and mixing

- Aseptic technique
- Achieving and/or maintaining sterility
- Use of equipment
- Documentation of the compounding process (e.g., master formulation and compounding records)
- Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
- Proper use of primary engineering controls (PECs)
- Principles of movement of materials and personnel within the compounding area

- Sterile compounding principles and practices including, but not limited to:
  - *USP <797> Pharmaceutical Compounding –Sterile Preparations*, other applicable standards, and relevant literature.
  - Watsonville Community Hospital policies and procedures related to sterile compounding and related job duties.
  - Beyond use dating, packaging, storage, and labeling of CSPs
  - Quality assurance and quality control procedures
  - Use of resources (e.g., Micromedex) and data base (e.g., Simplifi)

2. Personnel in supporting roles complete training and evaluation in job-related core competencies, skills, and sterile principles and practices including, at a minimum:

Core Skill	Cleaning Personnel
Hand Hygiene and Garbing	X
Cleaning/ Disinfecting	X
Principles of Materials Movement & Conduct within Controlled Areas	X

3. Refer to the **Immediate Use Compounding** policy for training and evaluation requirements. Personnel who perform both immediate use compounding and sterile compounding complete training and evaluation for both roles.
4. The Designated Person(s) assigns the role of Assigned Trainer (AT)/Designee to personnel who are responsible for or assist in training and evaluating competency of compounding personnel.
5. Core skills, competencies, and knowledge are assessed with hands-on demonstration of skill under direct observation by a DP or AT /Designee and sterile principles knowledge is assessed via written or electronic examination.
6. Successful or "passing" results for the Sterile Core Competencies and Knowledge Assessment are:

Observation	Validation	Initial Prior to Compounding Independently	Ongoing Every 12 Months
Competency-based checklist with 100% proficiency	USP <797> & Sterile Principles Knowledge Exam	>=80% cumulative score	>=80% cumulative score

7. **[CCR 1735.8] Quantitative** integrity shall be done annually.
   - Potency of sample sent for independent (outside laboratory) review shall be expected to be 90 to 110%

B. Hand Hygiene and Garbing Competency:

1. Hand hygiene and garbing competencies are assessed with hands-on demonstration of skill under direct observation by a DP or AT/Designee and validated via the Gloved Fingertip and Thumb Sampling Assessment.

- **Initial Gloved Fingertip and Thumb Sampling Assessment (GFS):** successfully completed three separate times prior to compounding independently; each GFS is conducted separately after a completing the hand hygiene and garbing procedure
- **Ongoing Gloved Fingertip and Thumb Sampling Assessments:** successfully completed at least once every 6 months for Compounding Personnel requalification

Successful or "passing" results for the Hand Hygiene and Garbing Competency are:

Observation	Validation	Initial Prior to Compounding Independently	Ongoing Every 6 Months
Competency-based checklist with 100% proficiency	Gloved fingertip assessment	3 separate assessments • 6 total plates (1 plate per hand per assessment) 7-day incubation with zero (0) CFUs	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with zero (0) CFUs

Microbial identification of cultured CFU(s) is not required for Gloved Fingertip and Thumb Sampling.

C. Aseptic Manipulation Competency:

1. The Aseptic Manipulation Competency is administered, observed, and documented by the DP or AT/Designee and consists of four components:
   - Media Fill Testing
   - Direct visual observation of aseptic technique and manipulations
   - Gloved Fingertip and Thumb Sampling of both hands ***after*** the media fill test
   - Surface Sampling of the Direct Compounding Area (DCA) ***after*** the media fill test
2. The Media Fill Test(s) simulates the most difficult and challenging compounding procedure(s), compounding environments, and processing condition(s).
3. Successful or "passing" results for the Initial and Ongoing Aseptic Manipulations Competency is as follows:

Observation	Validation	Initial Prior to Compounding Independently	Ongoing Every 6 Months
Competency-based checklist with 100% proficiency	Media Fill	1 assessment 14-day incubation with no growth or turbidity	1 assessment 14-day incubation with no growth or turbidity
	Post Media Fill Gloved fingertip assessment	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with ≤ 3 CFU combined (total)	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with ≤ 3 CFU combined (total)
	Surface sample	1 sample of direct compounding area (DCA) 7-day incubation with ≤ 3 CFU	1 sample of DCA 7-day incubation with ≤ 3 CFU

4. If any portion of the Hand Hygiene and Garbing or Aseptic Manipulations Competency does not meet the minimum passing result, the respective Competency is repeated. Initial Hand Hygiene and Garbing (gloved fingertip tests) is complete when there are 3 successful evaluations in a succession. Failures in other Core Competencies are repeated individually. Documentation of the failure, corrective actions, and the repeated competency results is retained and readily accessible.
5. In the event of a repeated, sequential failures of Core Competencies, Hand Hygiene and Garbing Competency, and/or Aseptic Manipulations Competency, corrective action plans are implemented that are consistent with Board of Pharmacy requirements and under the review and discretion of the DP. Patterns of competency failures over time are assessed on a case-by-case basis.

	Initial	Ongoing
1st Failure	• Coaching and retraining • Repeat failed competency *STATUS: Independent compounding not allowed until all competencies are successfully completed.*	• Coaching • Repeat failed competency *STATUS: Allowed to continue with compounding duties while results pending.*
2nd Failure	• Extensive skills and foundation knowledge retraining • Repeat failed competency *STATUS: Independent compounding is not allowed. If passed, consider increased competency assessment requirements (e.g. every month for 3 months).*	• Skills and foundational knowledge retraining • Repeat failed competency *STATUS: Independent compounding is not allowed; reassign to non-compounding duties while results pending.*
3rd Failure	• Reassign to non-compounding role; consider referral to HR. *STATUS: Reassigned outside of sterile compounding practice.*	• Reassign to non-compounding role, consider referral to HR. *STATUS: Future sterile training requires completion of initial training and competency requirements and increased competency assessments.*

6. Other personnel or visitors who do not undergo training and evaluation in core competencies, skills, or knowledge required to maintain the quality of the sterile compounding environment, are required to, at a minimum:
   - Adhere to all aspects of the **Hand Hygiene and Garbing** policy and procedure,
   - Comply with proper materials movement and cleaning procedures
   - Only enter a controlled compounding area under direct supervision of the DP or Designee
   - Minimize movement within the controlled areas and contact with any surfaces

III. ROLES & RESPONSIBILITIES

A. The Designated Person(s) (DP):
- Oversees the Sterile Training and Evaluation Program for Compounding Personnel and supporting personnel involved in or supporting compounding activities.
- Reviews competency results, evaluation and determination of corrective actions, and monitors for longer-term trends with Compounding Personnel Competency performance.
- Ensures non-compounding personnel and visitors who enter the sterile compounding area and/or handle CSPs understand the expectations appropriate to their role or are directly observed to ensure compliance and minimize impact to the quality of the sterile environment.
- May designate and qualify an Assigned Trainer(s) (AT) (or Designee) to assist with the training, evaluation, and competency administration process.

- May define additional training and competency evaluation requirements for compounding personnel performing specialized roles or responsibilities.

B. Assigned Trainer(s) (AT) (or Designee):
- Responsible and accountable for directly providing the training, observation, and/or evaluation of personnel performing compounding related activities

C. Compounding personnel and supporting roles:
- Successfully complete assigned training and demonstrate proficiency via competency assessment on a timely basis and before the evaluation activities are past due.
- Uphold sterile practice and quality standards to help ensure the quality of the sterile compounding area.

IV. DEFINITIONS

1. **Assigned Trainer (AT):** One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation and/or evaluation of personnel for the preparations of CSPs.
2. **CSP:** compounded sterile preparation
3. **Designated Person (DP):** is one ore more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CSPs.
4. **Direct Compounding Area (DCA):** A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air
5. **Laminar airflow workbench (LAFW):** An LAFW is a device that provides an ISO Class 5 or better environment for sterile compounding. The LAFW provides either horizontal or vertical unidirectional HEPA-filtered airflow.
6. **Integrated vertical laminar flow zone (IVLFZ):** An IVLFZ is a designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room.
7. **Media-fill test:** A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.
8. **Primary Engineering Control (PEC)**: A device or zone that provides an ISO Class 5 air quality environment for sterile compounding. (Ex: LAFW, BSC, RABS, CAI, CACI)
9. **sIPA:** sterile 70% isopropyl alcohol.
10. **Secondary Engineering Control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
11. **Segregated Compounding Area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.

V. PROCEDURE

A. Sterile Compounding Knowledge, Skills and Core Competency Assessment

- DP or AT/Designee directly observes Compounding Personnel performing the Core Competencies and Skills (refer to Sections 2.2 and 2.3) and records results in the electronic compounding competency form (e.g., Simplifi documentation).
- Core competency evaluation can be completed in a single or multiple observed sessions. If the process is completed in separate sessions, documentation reflects the date, time, and initials of the DP or AT/Designee performing and evaluating the specific competencies.
- Competencies for hand hygiene, garbing, and aseptic technique can be conducted concurrently with the respective competency assessment. Observations and evaluations of each competency are clearly documented on the respective competency form.

B. Documentation of the Hand Hygiene and Garbing and Aseptic Manipulation Competencies includes, at a minimum:

- Name of person evaluated

- Evaluation date and time
- Media and component manufacturer, lot, and expiration date
- Incubation temperatures
- Dates of Incubation
- Competency results
- Name of competency observer and individual(s) reading and documenting results
- Corrective actions (if needed)

C. Garbing Competency and Gloved Fingertip and Thumb Sampling Assessment Procedure
- Remove sampling plates (or alternative sampling device) from refrigerator in manufacturer's overwrap and check expiration dates; do not use expired media.
- Collect other supplies needed (e.g., plates, permanent marker, tape), disinfect with sIPA, and move supplies to controlled environment.
- Allow sampling plates to come to room temperature just prior to sampling.
- Enter media lot numbers, expiration dates, and manufacturer on appropriate form.
- DP or AT/Designee labels the base (i.e. agar side) of the sampling plates legibly around the outer edge (or permanently affixed lid on slide or paddle). Label each sample plate with sample type (e.g. "GFS"), hand (e.g., "L" -left or "R" - right), sample number (e.g., 1, 2, or 3) for initial competency, date, and initials of individual.
- Complete hand hygiene and garbing under direct observation. See Policy 2.2 Hand Hygiene and Garbing.

D. For GFS – CAI:
- Apply sIPA to the disposable gloves donned upon entry into the control space.
- Transfer two labeled sampling plates and 2 pairs of sterile gloves into the antechamber of the compounding isolator.
- Place gloved hands inside isolator sleeves.
- Disinfect the isolator gloves and PEC, including the deck, with sIPA.
- Move both labeled sampling plates and 1 pair of gloves from the ante chamber to the main chamber. Leave the plates to the left of the DCA. Disinfect outer wrapping of gloves.
- Don the sterile gloves over the isolator gloves being careful not to touch the non-sterile surface of the glove wrapping.
- Carefully lift the sterile glove wrapping on the sterile (i.e., inner surface) side and use the wrapping to grab and move the two sample plates to the DCA.
- Carefully remove the lid of the plates and set the lid face down on the deck.
- On the corresponding plate for each hand, gently roll the pads of each gloved fingertip, one at a time, in an arch across the top of the agar surface ensuring not to overlap fingerprints. A thumb print is then gently in the middle of the plate.
- Replace the lids on both plates.
- Remove sterile gloves contaminated with growth media ensuring contaminated surfaces do not touch the isolator gloves, sleeves, or PEC.
- Apply sIPA to the isolator gloves and open the ante chamber door. Move both sample plates and all trash to the ante chamber.
- *During the Initial GFT competency assessment*, repeat this entire process twice more from hand hygiene through garbing with fresh garb and gloves.
- After all samples are collected, seal plates with wax or tape to ensure the lid is not dislodged during transit or incubation and results inspection.
- Prior to disinfecting the PEC and commencing compounding, retrieve the 2nd pair of sterile gloves from the ante chamber and don over the sanitized isolator gloves.

E. Aseptic Manipulation Competency Procedure (including Media Fill and Post Media Fill Gloved Fingertip and Surface Sampling)
- Collect supplies needed for the media fill testing, post media fill GFS (2 plates per media fill test), and surface sampling (1 plate per media fill test)

- When more than one media fill test is to be completed, ensure all necessary media, supplies, and sampling plates for each media fill are collected and organized prior to initiating assessment.
- Check all growth media components for expiration date. Do not use expired media. Allow sampling plates to come to room temperature just prior to sampling.
- Inspect all sterile media fill components for cracks, leaks, or other potential factors that may have compromised product's sterility. Do not use media suspected of contamination or sterile container defects.
- Disinfect all media and supplies with sIPA, and move supplies to controlled environment.
- Enter media lot numbers, expiration dates, and manufacturers on the appropriate form.
- When more than one media fill test is to be completed, record each media fill on a separate competency form.
- DP or AT/Designee labels the base (i.e. agar side) of the sampling plates legibly around the outer edge (or permanently affixed lid on slide or paddle) and the final dosage unit(s) for the media fill test. Label each sample with sample type (e.g. "MF", "PMF-GFS", or "SS"), hand (e.g., "L" -left or "R" - right), date, and initials of individual.
- Stage all media and supplies inside the ante chamber of the compounding isolator.
- Disinfect gloved hands and all components with sIPA prior to being moved into the ISO Class 5 area of the PEC.
- Perform media fill under direct observation per procedure
- sIPA is used throughout the media fill process to sanitize sterile gloves, critical sites, and the direct compounding area; however, do not apply sIPA to gloved hands or the DCA after the final step of the media fill procedure.
- Sterile media components are manipulated in a manner that simulates typical sterile-to-sterile compounding activities and the sterile soybean casein digest media is transferred into containers similar to those typically used. Soybean casein digest media is not diluted with water or another diluent unless specified by the manufacturer.
- Immediately following the final step of the media fill procedure and before sIPA is applied to gloved hands or the DCA:
  - Compounding Personnel completes the PMF-GFS and DCA surface sample ***inside*** the ISO 5 PEC under direct observation. GFS sampling is performed for both hands with one plate per hand. Refer to the GFS sampling procedures above in 4.1; note that gloves are contaminated with growth media and should be removed from the isolator gloves and replaced prior to commencing compounding activities.
- After all samples are collected and removed from the PEC, seal plates around outer edges with wax or tape to ensure the lid is not dislodged during transit or incubation and results inspection.
- Remove all other trash from the PEC and clean and disinfect PEC prior to commencing compounding.
- Remove and replace sterile gloves immediately without touching any other surfaces; gloves are contaminated with growth medium. Repeat hand hygiene and garbing prior to returning to compounding activities.

F. Selection, Incubation, & Interpretation of Media

Media Selection:

- Select a general microbial growth agar (plate, paddle, or slide) supporting both bacterial and fungal growth, such as trypticase soy agar (TSA), for gloved fingertip and surface sampling. Growth medium contains additives that neutralize residual cleaning solutions, such as lecithin and polysorbate 80.
- For media fill procedures, replace a**ll** CSP components with soybean–casein digest media components.
- Pharmacy uses commercial sterile microbial growth media: obtain a Certificate of Analysis (COA) from the growth media supplier or manufacturer. The DP and/or Designee reviews and retains the COA to ensure the culture media supports growth of microorganisms (as defined in Table 1 of USP <71>). Store media per manufacturer instructions and media is

used in accordance with manufacturer instructions and before the expiration date of the media.

Media Incubation & Interpretation:

- Locate calibrated incubators monitored by NIST certified temperature gauge outside of the sterile compounding area. A minimum of two incubators are available:
  - Incubator 1: calibrated and maintained at 20 to 25°C
  - Incubator 2: calibrated and maintained at 30 to 35°C
- Invert gloved fingertip and surface sample agar plates during incubation to ensure moisture condensation does not collect and fall onto the agar surface which can contaminate and/or invalidate the results.
- Incubation temperatures and timeframes:

Competency	Media	1st Incubation	2nd Incubation	Total Incubation Timeframe
Gloved fingertip and surface samples	TSA agar plate, paddle or slide with polysorbate 80 & lecithin (neutralizers)	≥ 48 hours at 30°C - 35°C (85°F – 95°F)	≥ 5 Days at 20°C - 25°C (68°F – 77°F)	≥ 7 Days
Media fill test final dose unit(s)	Soybean casein digest (all components)	7 Days at 20°C - 25°C (68°F – 77°F)	7 Days at 30°C - 35°C (85°F – 95°F)	14 Days

- Only the DP and/or Designee who is qualified to manage, read, and interpret media places or moves media into and out of incubators.
- Record date, time, incubator temperature, and person(s) moving media into and between incubators on competency form(s).
- Read and record CFU counts per sampling plate and examine media fill bags/units for visible changes daily or, at a minimum, when media are moved from the first to the second incubator. Record interim results on competency form(s).
- Read and record CFU counts per sampling plate at the conclusion of the full incubation; total CFU counts from all plates to determine the final CFU count results. Record results on the competency form(s).
- Examine the media fill bag/units for any visible turbidity or changes indicating growth at the conclusion of the full incubation against a white and black background in a well-lit area, record either a pass or failed result on the Media Fill form.

G. Corrective Action for Competency Failure

- Any personnel failing to demonstrate competency during a foundational knowledge exam or hands-on skills assessment is coached and reinstructed on the applicable policy, technique(s), and foundational knowledge related to the skill; and subsequently re-evaluated by the DP or AT/Designee.
- Evaluation and corrective action for observed competencies is documented within the competency form. Corrective action records are used for long-term assessment of personnel competency and potential contributing factors to maintaining a state of microbial control within the sterile compounding environment.

H. Ongoing Training

- The DP is responsible for assessing the training needs of personnel and the appropriate method for communication and delivery as new or updated equipment, components, recipes, or procedures are introduced.
- Ongoing training may be communicated in (e.g.,) a staff meeting, email, or formal program.

- Ongoing training will be documented in (e.g.,) meeting minutes, a training log, or formal competency.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding-Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.
- United States Pharmacopeial Convention, Inc. <71> Sterility Tests, Culture Media, and Incubation Temperatures, Growth Promotion Test of Aerobes, Anaerobes, and Fungi. current version.

VII. STAKEHOLDERS

N/A

APPENDIX ONE: Watsonville Community Hospital

Sterile Compounding Training and Competency Program Description

DESIGNATED PERSON(S):	Director of Pharmacy, may appoint qualified Designee(s)
QUALIFIED TRAINER(S) / COMPETENCY EVALUATOR(S):	Pharmacists
DIDACTIC TRAINING RESOURCES:	Critical Point ASHP

COMPETENCY	TRAINING METHOD	ASSESSMENT METHOD	FREQUENCY	PASSING SCORE
1. Core Sterile Competencies: • Hand hygiene • Garbing • Cleaning and disinfection • Calculations, measuring, and mixing • Aseptic technique • Use of equipment, if appropriate • Documentation of the compounding process (e.g., master formulation and compounding records) • Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area • Proper use of primary engineering controls (PECs) • Principles of movement of materials and personnel within the compounding area	Didactic training program with video simulations Hands-on training program	Direct Observation	At least every 12 months	100% Competency & Compliance
2. Sterile Compounding Knowledge • Knowledge and understanding of principles behind the Core Competencies • USP 797 Guidelines	Didactic training Review of USP 797 Review of SOPs	Written / Electronic Knowledge Exam	At least every 12 months	≥ 80% composite score, as available
3. Garbing Competency • Hand Hygiene and Garbing Observation • Gloved Fingertip and Thumb Sampling Assessment	Didactic training Hands-On Training	Direct Observation & Evaluation Media Results	At least every 6 months	Observed Skills: 100% Competency Media Results Per USP 797
4. Aseptic Manipulations Competency • Aseptic Technique and Manipulations Observation • Media Fill Test(s) • Post Media Fill Gloved Fingertip and Thumb Sampling Assessment • Post Media Fill DCA Surface Sample Assessment		Direct Observation & Evaluation Media Results	At least every 6 months	Observed Skills: 100% Competency Media Results Per USP 797

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Compounded Sterile Products: Personnel Aseptic Media Fill Testing and Process Verification	Policy #	PHARM2754
Responsible	Pharmacy Director	Revised/Reviewed	5/2021

I. PURPOSE

- To ensure that the quality of aseptic technique performed by individuals involved in compounding of sterile preparations as well as the capability of the compounding environment and processes used to prepare compounded sterile products (CSPs) for human use will be verified and continuously monitored.
- To ensure that a consistent process for employee aseptic media fill testing and media fill process verification evaluates production process techniques involved in the preparation of sterile preparations and can be used to detect and identify technical flaws or procedural concerns that could potentially compromise CSP integrity through microbial contamination.

II. POLICY

A. All new compounding personnel, except those who only prepare “Immediate Use” category CSPs, shall successfully complete three (3) initial media fill testing prior to compounding CSPs for human use.

1. Personnel generally requiring media fill testing are pharmacists and pharmacy technicians.
2. Professionals preparing only “Immediate Use” CSPs must prove competency in aseptic technique on an annual basis.

B. The competency of all compounding personnel will be evaluated by direct observation annually for low and medium risk levels using a competency, such as the *Competency Assessment for Aseptic Technique*.

C. Proper aseptic technique is evaluated by direct visual inspection by the Director of Pharmacy or designee, as well as media fill testing where a microbiological growth medium is used as a substitute for the usual components of an aseptically prepared CSP.

D. For low and medium risk compounding, a commercially available sterile fluid culture medium such as Soybean-Casein Digest Medium that is able to promote the colonization of bacteria most likely to be transmitted to CSPs from compounding personnel and the environment is likely.

E. The medium used must be accompanied by certification from the manufacturer that it is able to support microbial growth as a result of growth promotion tests.

F. All microbial growth study data will be maintained on file in a designated secured area.

G. The preparation of media fill units (MFUs) will not be performed during normal production hours. Routine media fills will be conducted after normal compounding activity has occurred to simulate a worst case scenario.

H. Initial Personnel Media Fill Testing

1. The Director of Pharmacy or designee is responsible to assure that compounding employees participate in a comprehensive and formal orientation and training program.
2. Compounding personnel must be knowledgeable about and able to perform the tasks associated with proper aseptic technique.
   a. Their ability to perform such tasks must be evaluated prior to beginning media-fill testing.
3. All compounding personnel must pass initial aseptic and media fill verification before beginning the preparation of CSPs.
   a. The verification must be completed at least annually for low and medium risk compounding.
4. Individual competency evaluation and objective testing will proceed in a logical manner with information and verification ordered in a manner whereby one step builds upon another.

Therefore, for initial competency evaluation, staff shall successfully complete three separate instances of the following:

a. Hand Hygiene and Garbing Competency
b. Gloved Fingertip Sampling
c. Competency Assessment: Aseptic Technique
d. Media fill Testing

5. Successful MFUs require that no observed growth occurs during the entire incubation period. The MFUs are observed every day for 14 days by checking for observable turbidity or cloudiness which indicates microbial contamination.

I. Ongoing Media Fill Testing of Compounding Employees

1. All compounding personnel shall successfully complete the ongoing aseptic media fill verification by preparing appropriate number of media fill units (MFUs), as determined by facility, at least semi-annually for high risk compounding or annually for low and medium risk levels.
2. The aseptic technique of compounding employees will be evaluated via a competency, such as the *Competency Assessment for Aseptic Technique* at least at each media fill testing occurrence.
3. Any compounding employee generating greater than two media fill positives in an ongoing media fill test where there is no assignable system cause must repeat the initial qualification procedure as outlined in Section H above.
4. Retraining shall consist of reviewing the appropriate policy and procedures, aseptic videos and learning tools as well as direct observation and completion of the following competencies:
   a. Hand hygiene and garbing
   b. Aseptic technique

J. Materials and Equipment

1. Hospital-specific procedures may be substituted if the method meets the current USP Chapter <797> standards and state regulations.
2. 1 - 100 ml bag of sterile Soybean-Casein Digest Medium for low and medium risk level compounding.
3. 1 - 20 ml vial of sterile Soybean-Casein Digest Medium for low and medium risk level compounding.
4. 1 – 3 ml media-filled ampule
5. 1 – 10 or 20 ml. vial of Sterile Water for Injection
6. Non-sterile Soybean-Casein Digest Medium must be used for high risk level compounding
7. 5 - Empty 10 ml Sterile Empty Vials
8. 5 Each - 3 ml and 5 ml syringes
9. 11 - 20 gauge x 1” or 1-1/2” needles
10. 1 – 5 micron filter needle and 1 – 5 micron filter straw
11. Sterilizing filters for high risk level media fill verification
12. A computer generated or hand written label containing spaces for the following information:
    a. Date prepared
    b. PEC number or location identification
    c. MFU number
    d. Initials of the person preparing the MFU
    e. The following statement: “NOT FOR HUMAN USE, DO NOT INFUSE”.

K. Initial Media Fill Testing and Compounding Processes

1. In order to verify the ability of an aseptic compounding process to produce sterile preparations, compounding personnel may prepare media fill units consisting of a planned

repetitive sequence of compounded units utilizing the specific equipment or methodology being tested.

2. The number of manipulations of each unit, and the number of units in each sequence should reflect the most complex and prolonged aseptic manipulations likely to be encountered during normal workload production.
3. The number of MFUs produced must be sufficient to ensure that the individual and the equipment are capable of replicating acceptable admixture sterility.

L. It is the responsibility of the Director of Pharmacy to determine the high volume, high risk compounding that requires qualification. This determination will occur after a sufficient period of operating time and will be made based on volume.

M. Equipment that may be considered for compounding process qualification is as follows:
1. High speed volumetric or gravimetric compounding pumps for parenteral nutrition (e.g., Baxter Automix, Baxa Repeater Pump, etc).
2. Depending on the complexity and frequency of the process verification media fill testing and a specific device or process, select equipment may be substitutable for an individual media fill testing exercise.
3. The following must be accomplished at the same time as the media fill testing processes:
   a. Hand hygiene and garbing competency
   b. Gloved fingertip sampling
   c. Competency assessment for aseptic technique
4. Initial media fill process testing is not appropriate for the initial personnel aseptic media fill testing of new employees.
5. Media fill process verification can be documented on the *Gloved Fingertip Sampling and Media Fill Results Log.*

N. Ongoing Media Fill Testing and Compounding Processes
1. A semi-annual re-qualification of all high volume compounding processes may be conducted based on the determination by the Director of Pharmacy or designee.

III. PROCEDURE:

A. Low and Medium Risk Level Compounding
1. Assemble all of the components used in the media fill testing procedure in the same manner as drug and solution components to simulate routine compounding practices.
2. All components will be visually inspected for in-date expiration, cracks, leaks, or any other potential breach of container integrity.
3. Lot numbers and expiration dates for all components can be recorded on the *Gloved Fingertip Sampling and Media Fill Results Log.*
4. All components will be sanitized with sterile 70% IPA prior to being placed in the ISO Class 5 compounding area.
5. No sterilizing (0.22 micron) filters, filter straws or filter membranes will be used at anytime during this process.
6. Follow manufacturer's directions.
7. Each completed MFU should be labeled with the following information:
   a. Date prepared
   b. PEC identification or location
   c. MFU number
   d. Initials of the person preparing the MFU
   e. Provide the following message on the label: "NOT FOR HUMAN USE, DO NOT INFUSE".
8. A separate *Gloved Fingertip Sampling and Media-Fill Results Log* should be completed for each day of testing.

B. Incubation and Inspection of the Media Fill Unit Compounding Exercise
   1. All MFUs are to be incubated for 14 days at 20 – 35 ° Celsius.
   2. Each MFU will be visually inspected daily through day 14, the final day of incubation. Any person, including the person who prepared the MFU may read the MFUs except on the last day of incubation.
   3. The Director of Pharmacy of designee will perform the final inspection for any signs of turbidity prior to proper disposal of MFUs. Results can be recorded on the *Gloved Fingertip Sampling and Media Fill Results Log.*

C. Actions in the Event of a Positive Media Fill Result
   1. Any positive result will immediately be brought to the attention of the Director of Pharmacy or designee and investigative action to determine the source of any contamination and appropriate corrective action will ensue.
   2. Actions will be documented on, for example, the Facility and Personnel Environmental Sampling Action Report.
   3. An evaluation should be made to verify that the employee performed the procedure correctly and that other issues did not trigger a positive result. All MFUs with growth must be carefully inspected for leaks. MFUs found to have leaks will be considered as NO TEST and not counted as a media fill with a positive result.
   4. The individual experiencing a positive MFU must perform the following:
      a. Repeat the entire media fill testing procedure if it was an initial media fill test.
      b. Repeat the single day of ongoing media fill testing preparation if less than three positive MFUs were prepared in the single day of MFUs prepared.
      c. If a compounding employee performing ongoing media fill test units has three or more units with growth, the employee must complete the initial media fill testing procedures outlined in this policy.
      d. The Director of Pharmacy may consider sending positive MUFs to an appropriately credentialed laboratory for identification of microorganisms at least to the genus level if organizational trends develop that require further investigation.

D. Documentation
   1. All MFU results shall be recorded on, for example, the *Gloved Fingertip Sampling and Media Fill Units Results Log*. These data sheets should be maintained in an easily retrievable area with a copy in each employee's personnel file.

I. REFERENCES

1. Joint Commission Standards: HR.01.04.01 EP 4, HR.01.05.03 EP 1, HR.01.06.01 EP 1 – 6, IC.02.01.01 EP 2

2. United States Pharmacopeial Convention; USP 35 NF 30 General Chapter <797>*Pharmaceutical Compounding – Sterile Compounding.*

II. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Compounded Sterile Products: Gloved Fingertip Sampling	Policy #	PHARM2753
Responsible	Pharmacy Director	Revised/Reviewed	05/2022

I. PURPOSE

To outline the procedures utilized to monitor and quantify possible viable living microorganism contaminants on personnel glove fingertip samples.

II. POLICY

A. Gloved Fingertip Sampling (GFS) is an integral part of insuring that the employee is aware of the microbiological bioburden on their gloves and that touch contamination is believed to be the primary source of CSP contamination.
B. Employee work practices and routine glove disinfection procedures are critical to minimizing or preventing CSP contamination.
C. All compounding personnel must receive training and proved competency regarding Hand Hygiene and Garbing prior to initiating the Gloved Fingertip Sampling (GFS).
D. All new compounding personnel must complete three (3) Gloved Fingertip Sampling occurrences prior to compounding CSPs for human use. Each of these three occurrences will occur prior to beginning of each of three days of media fill verification.
E. Subsequent GFS for tenured compounding personnel will occur annually or semi-annually during the media fill testing.
    1. Refer to Policy# 2754: Compounded Sterile Products: Personnel Aseptic Media Fill Testing and Process Validation.
F. The designated action level for GFS is dependent upon the location of the employee when the sample is taken.
    1. When the GFS is taken immediately after performing hand hygiene, garbing, and immediately after donning sterile gloves but before sanitizing gloved hands with sterile 70% IPA, the action level is 0 CFUs.
    2. On occasions that GFS are taken randomly when the employee is working within the ISO Class 5 PEC but not immediately after hand sanitization with 70% IPA, then the action level is greater than 3 CFUs.
    3. Action levels designate the number of CFUs on both gloves. Example: Total CFUs left hand plus total CFUs right hand equal greater than 0 CFUs in Section F.1 and greater than 3 CFUs in Section F.2.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. The following equipment and materials are necessary:

1. Incubator calibrated, NIST (National Institute of Standards and Technology) certified and has a certified monitoring device/thermometer as part of the incubator. The incubator should have a range of 30 to 35° Celsius.
2. Lint free towels
3. Sterile 70% IPA
4. Sterile gloves
5. Permanent ink pen
6. Two nutrient agar plates with neutralizing agents such as lecithin and polysorbate 80 that have been pre-incubated.

B. Preparation of plates for sampling
1. Upon receipt of plates, pre-incubate the plates at 30 to 35° C for at least 48 hours, but not greater than 72 hours prior to refrigerated storage for use to ensure that the plates are free from contamination before use.
2. Clean the work surface with sterile 70% IPA.
3. Remove 2 plates for each compounding employee to be tested.
4. Don sterile gloves.
5. Inspect the plates to ascertain they are free from growth or defect before use.
6. Record the manufacturer, lot number, and expiration date of the agar plates to be used on, for example, the Gloved Fingertip Sampling and Media Fill Results Log that is used to document each employee's results.
7. Using a lint free towel and sterile 70% IPA, wipe the exterior of the covered plates prior to bringing into the PEC.
8. With a permanent marking pen, label the bottom of each plate with the following:
   a. Employee's name
   b. Date
   c. Designation of "Left" on one plate and "Right" on the other plate.
9. Place the labeled plates into a bin to transport to the clean side of the anteroom where they will be administered.

C. Initial Gloved Fingertip Sampling procedure
1. The employee from whom the sample will be collected completes hand hygiene and garbing following the hospital's policy but will not complete the step to disinfect gloved hands with sterile 70% IPA.
2. The collector will perform hand hygiene and garb appropriate to the area where sampling is taking place.
3. Immediately after the compounding employee dons sterile gloves, the collector will remove the top from the contact plate designated for the left and right hand and place it on a counter top that has been disinfected with sterile 70% IPA.
4. The compounding employee will gently press each of four fingers and thumb from one hand onto the contact plate with sufficient force to make slight depressions in the agar.
5. The employee must avoid sliding or rotating the plate during the sampling.
6. Repeat the sampling process for the opposite hand on the second labeled plate.
7. After testing, the collector places the covers back onto each plate.
8. The compounding employee removes the gloves that were in place during the GFS, discards them and performs hand hygiene again prior to donning a clean pair of sterile gloves.
9. The collector will remove the covered plates from the anteroom and immediately tape the covers to prevent the plates from opening and becoming contaminated.

D. Subsequent Gloved Fingertip sampling for on-going employee media fill verification or process verification of equipment.
   1. The collector will observe the employee as they prepare to perform media fill verification within the ISO Class 5 area.
   2. The collector will ask the employee to remove hands from the ISO Class 5 PEC without disinfecting gloved hands.
   3. The collector will time this request so as to not coincide with a time immediately after hand sanitization has occurred with sterile 70% IPA.
   4. After the samples are taken, the compounding employee will remove their gloves, re-sanitize hands, don new sterile gloves, and re-sanitize the gloves with sterile 70% IPA prior to continuing media fill verification procedures.

E. Incubation
   1. Tape the cover of each plate in place in several locations.
   2. Record the necessary information on, for example, the Gloved Fingertip Sampling and Media Fill Results Log upon completing the collection of touch plates including the date and time the plates are placed in the incubator.
   3. Calculate the date and earliest time the plates may be removed from incubation which is 48 hours from the time they are placed into the incubator.
   4. Calculate the latest time and time the plates may be removed from the incubator which is up to 72 hours from the time they are placed into the incubator.
   5. Incubate the plates in an inverted position with the cover placed in a downward position and the media side upward at 30 to 35° C for at least 48 hours.
      a. Plates should not be incubated for more than 72 hours to prevent drying of agar plate media. Actual incubation temperature and times are dependent on the media used.
      b. Plates should be incubated with the covers down to prevent the formation of water droplets and dripping onto the agar.

F. Reading of samples when incubation complete
   1. The person reading the plates must be one other than the compounding person being tested.
   2. After the total incubation period has elapsed, remove plates from the incubator and read the touch plates. Record the date and time the plates are removed for inspection in the space designated on, for example, the Fingertip Sampling and Media Fill Results Log.
   3. Record the number of CFUs on each plate in the space designated on, for example, the Fingertip Sampling and Media Fill Results Log.
   4. Record a zero on the results log if no CFUs are seen on the plate.
   5. Document the total number of CFUs by adding the results from the left hand and the right hand in the space provided.
   6. Person reading the plates must sign his/her name and indicate the time and date that the plates are read.
   7. Plates may be discarded after reading.

G. Actions taken when results exceed the action level
   1. Any GFS that exceeds the designated action level triggers a sequence of events designed to identify potential errors in the process, reinstruction of the employee and review of past data.
   2. The person reading the plates will inform the Director of Pharmacy immediately in the event the results of the GFS exceed the designated action level.
   3. A review of the following must occur with the compounding employee:
      a. Hand hygiene and garbing

   b. Glove re-sanitization
   c. Surface decontamination
   d. General aseptic work practices
4. The employee must validate the following competencies:
   a. Hand Hygiene and Garbing Competency
   b. Aseptic Technique Competency
5. An evaluation should be made to verify that the employee performed the procedure correctly and that other issues did not trigger a false positive result (e.g., defective media bag).
6. Documentation of all actions taken is accomplished on, for example, the Facility and Personnel Environmental Sampling Action Report.
7. The Director of Pharmacy may consider sending plates that have exceeded designated action levels to appropriately credentialed laboratory for identification of microorganisms at least to the genus level.

I. REFERENCES

1. Joint Commission Standards: HR.01.04.01 EP 4 HR.01.05.03 EP 1
   HR.01.06.01 EP 1 – 4 IC.02.01.01 EP 2
2. United States Pharmacopeial Convention; USP 35 NF 30 General Chapter <797> Pharmaceutical Compounding – Sterile Compounding.

II. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Master Formula & Compounding Records**
Policy Number/ Version:	797-2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the documentation elements and record keeping requirements for Master Formulation Records and Compounding Records for Compounded Sterile Preparations (CSPs) prepared at Watsonville Community Hospital.

1.2. In addition to *USP <797> Pharmaceutical Compounding – Sterile Preparations* requirements, Watsonville Community Hospital follows all regulations issued by the California State Board of Pharmacy, including record keeping and record retention.

1.3. Master Formula and Compounding Records create a detailed and reproduceable compounding procedure and historical record of each CSP compounded ensuring patients receive a consistent, high quality CSPs. The Compounding Record also provides the documentation framework to quickly implement a recall or patient review if needed.

- A **Master Formula Record (MFR)** is a detailed procedural record describing how a unique CSP is prepared, verified, packaged, and labeled. A MFR provides a precise roadmap allowing any compounder to, without assistance or interpretation, prepare a consistent and replicable CSP each time.

- A **Compounding Record (CR)** documents each instance of CSP compounding including specifics about the manufacturer, measurement, added substances, supplies, and dispensing devices in the preparation and quality control of the final dosing or yield unit(s).

2. Policy

2.1 [USP 797] A Master Formula Record (MFR) is created for each unique Category 1 and Immediate-Use CSP formulation when one or both of the following conditions exist:

- CSPs prepared for more than one patient (i.e. batch compounding or repackaging)

2.2 [USP 797] MFRs include at least the following per USP <797>:

- Name, strength or activity, and dosage form of the CSP
- Identities and amounts of all ingredients, active and inactive; if applicable, relevant characteristics of components (e.g. particle size, salt form, purity grade, solubility)
- Complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions
- Physical description of the final CSP
- Beyond use dating (BUD) and storage requirements
- If applicable, calculations or conversions to determine and verify quantities and/or concentrations of components and strength
- Stability reference source for the CSP
- Quality control (QC) procedures (e.g., visual inspection) and expected results

- Other information as needed to describe the compounding process and ensure repeatability, as appropriate
- [Best Practice] Labeling requirements

2.3 [Best Practice] Two (2) qualified compounding personnel including Designated Person and qualified designee(s) review and sign-off on all new or revised MFRs and associated calculations prior to initial use.

2.4 [USP 797] A Compounding Record (CR) is created for all Category 1 CSPs and for Immediate Use batched or repackaged CSPs intended for use in more than one patient and compounded according to an MFR.

2.5 [USP 797] CRs include at least the following per *USP <797>:*

- Name, strength or activity, and dosage form of the CSP
- Date and time of preparation of the CSP
- Assigned internal identification number (e.g., prescription, order, or lot number)
- A method to identify the individuals involved in the compounding process and individuals verifying the final CSP
- [Conditional: If pharmacy batches CSPs for use by more than one patient] Vendor, lot number, and expiration date for each component used in the preparation of CSPs (e.g. diluents or components)
- Weight or volume of each component
- Strength or activity of each component
- Total quantity compounded
- Final yield (e.g., quantity, containers, number of units)
- Assigned BUD and storage requirements
- Results of QC procedures (e.g., visual inspection)

If applicable:

- MFR reference (if retained separately)
- Calculations and conversions made to determine and verify quantities and/or concentrations of components, if applicable

2.6 [USP 797] MFRs and CRs are retained and readily accessible for review.

3. Roles & Responsibilities

3.1 [USP 797] The Designated Person (DP):

- Ensures MFRs are created, reviewed, and approved for each unique CSP formulation prepared for more than one patient (including repackaging).
- Provides education and communication for new or revised MFRs and CRs to compounding personnel.
- Ensures CRs are completed, retained, and readily accessible for required CSPs.
- Ensures MFRs and CRs meet minimum documentation standards.

3.2 Compounding Personnel:

- Follow the exact specifications and directions in the MFR and ensure complete and accurate documentation within the CR.

4. Procedures

4.1. Creation and Revisions of Master Formula Records (MFRs)

- Submit requests for new or revised MFRs to the Designated Person and/or designee.
- The Designated Person and/or qualified designee(s) reviews the request to determine the feasibility and viability the requested formulation including, but not limited to:
  - Supporting references for the formulation, CSP stability and BUD, and compounding methods and techniques
  - Availability and cost of needed ingredients, dispensing devices, equipment, and supplies
  - BUD assignment, storage, transport, and labeling requirements
  - Quality control procedures and tests based on the dosage form, route/location of administration, and drug stability
  - Impact to workflow and staffing
- If the request is approved, the DP or a qualified designee creates (or revises) the MFR.
- [BEST PRACTICE] An independent review of the MFR is conducted by two compounding personnel with the appropriate expertise. Both the MFR author and reviewer(s) sign off on the final MFR version prior to use.
- The DP or designee provides education and communication about the new/revised MFR with an effective date to Sterile Compounding Personnel.
- The DP and/or designee retains a revision history of the MFR.

4.2. Creation of Compounding Records (CRs)

- Compounding personnel creates a CR for all Category 1 CSPs and for immediate use compounds made for more than one patient.
- CRs are allowed in the following formats that are fully compliant with the CR documentation requirements stated above in section 2.5
  - MFR designed to allow for the manual entry of the information needed to complete the CR

4.3. Use of MFR and CR

- Prior to starting the compounding process, compounding personnel review the MFR and compounding procedure in detail; initiate the CR; complete and record all required calculations; and confirm necessary ingredients, devices, equipment, and supplies are readily available.
- Update the CR during the preparatory, compounding, and QC processes to ensure accurate and complete documentation of the compounding process.
- Ensure all components of the CR are complete and accurate including, but not limited to:
  - Formulation Name
  - Name/ID, manufacturer (or wholesaler), lot number, expiration, weight/volume, and strength of each added substance incorporated into the CSP
  - Calculations and conversions
  - Anticipated and actual final yield (including total quantity compounded and/or number of final dose units)
  - Anticipated and actual results of QC procedures and tests (e.g., final yield unit weight/volume) and verifying Pharmacist's initials.
- Validate the CSP label, prescription or med order and Master Formulation Records and Compounding record are consistent and conform with each other,

- Ensure signatures of the compounder(s) and verifying Pharmacist are indelibly written on each CR.
- Ensure compounding date, time compounding started, and assigned internal ID number are indelibly written on each CR.
- Submit final CR to the DP or qualified designee(s) for final review and approval prior to storage in a readily retrievable format.

5. Definitions

5.1 Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation, and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

5.2 Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms: inactive ingredient, excipient, and pharmaceutical ingredient.

5.3 Beyond-Use Date (BUD): The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.

5.4 Category 1 CSP: A CSP that is assigned a BUD of 12 hour or less at controlled room temperature or 24 hour or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in USP 797.

5.5 Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in USP 797.

5.6 Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in USP.

5.7 Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

5.8 Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication.

5.9 Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components if the latter are intended to provide additional protection.

5.10 Designated Person (DP) is one ore more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CSPs.

5.11 Final yield/Final yield unit: The total number of containers prepared at the end of the compounding process prior to release testing.

5.12 Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

5.13 Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.

5.14 Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.

5.15 Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation

5.16 Workflow management system: Technology comprised of hardware and software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

6. Related Policies, Documents, References

6.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2 United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval (10/2023)
Next review:	Month/year

7.1 Initial version published by Wolters Kluwer 2022.

7.2 *Revised/adapted by* Watsonville Community Hospital 9/2023.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Master Formula & Compounding Records	Policy #	PHARMXXXX
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

1. This policy describes the documentation elements and record keeping requirements for Master Formulation Records and Compounding Records for Compounded Sterile Preparations (CSPs) prepared for within Watsonville Community Hospital.

2. In addition to *USP <797> Pharmaceutical Compounding – Sterile Preparations* requirements, Watsonville Community Hospital follows all regulations issued by the California State Board of Pharmacy, including record keeping and record retention.

3. Master Formula and Compounding Records create a detailed and reproduceable compounding procedure and historical record of each CSP compounded ensuring patients receive a consistent, high quality CSPs. The Compounding Record also provides the documentation framework to quickly implement a recall or patient review if needed.
   - A **Master Formula Record (MFR)** is a detailed procedural record describing how a unique CSP is prepared, verified, packaged, and labeled. A MFR provides a precise roadmap allowing any compounder to, without assistance or interpretation, prepare a consistent and replicable CSP each time.
   - A **Compounding Record (CR)** documents each instance of CSP compounding including specifics about the manufacture, measurement, and use of Active Pharmaceutical Ingredients (APIs), added substances, supplies, and dispensing devices in the preparation and quality control of the final dosing or yield unit(s).

II. POLICY

A. A Master Formula Record (MFR) is created for each unique Category 1 and Immediate-Use CSP formulation when one or both of the following conditions exist:
   - CSPs prepared for more than one patient (i.e. batch compounding or repackaging)

B. MFRs include at least the following per USP <797>:
   - Name, strength or activity, and dosage form of the CSP
   - Identities and amounts of all ingredients, active and inactive; if applicable, relevant characteristics of components (e.g. particle size, salt form, purity grade, solubility)
   - Complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions (e.g., hazardous material handling instructions)
   - Physical description of the final CSP
   - Beyond use dating (BUD) and storage requirements
   - If applicable, calculations or conversions to determine and verify quantities and/or concentrations of components and strength or activity of API
   - Stability reference source for the CSP
   - Quality control (QC) procedures (e.g., visual inspection) and expected results
   - Other information as needed to describe the compounding process and ensure repeatability, as appropriate
   - Labeling requirements

C. Two (2) qualified compounding personnel including Designated Person and qualified designee(s) review and sign-off on all new or revised MFRs and associated calculations prior to initial use.

D. A Compounding Record (CR) is created for all Category 1 CSPs and for Immediate Use batched or repackaged CSPs intended for use in more than one patient and compounded according to an MFR.

E. CRs include at least the following per *USP <797>:*
- Name, strength or activity, and dosage form of the CSP
- Date and time of preparation of the CSP
- Assigned internal identification number (e.g., prescription, order, or lot number)
- A method to identify the individuals involved in the compounding process and individuals verifying the final CSP
- Vendor, lot number, and expiration date for each component used in the preparation of CSPs (e.g. diluents or components)
- Weight or volume of each component
- Strength or activity of each component
- Total quantity compounded
- Final yield (e.g., quantity, containers, number of units)
- Assigned BUD and storage requirements
- Results of QC procedures (e.g., visual inspection)

If applicable:
- MFR reference (if retained separately)
- Calculations and conversions made to determine and verify quantities and/or concentrations of components, if applicable

F. MFRs and CRs are retained and readily accessible for review.

III. ROLES & RESPONSIBILITIES

1. The Designated Person (DP):
   - Ensures MFRs are created, reviewed, and approved for each unique CSP formulation prepared for more than one patient (including repackaging).
   - Provides education and communication for new or revised MFRs and CRs to compounding personnel.
   - Ensures CRs are completed, retained, and readily accessible for required CSPs.
   - Ensures MFRs and CRs meet minimum documentation standards.
2. Compounding Personnel:
   - Follow the exact specifications and directions in the MFR and ensure complete and accurate documentation within the CR.

IV. DEFINITIONS

1. **Active pharmaceutical ingredient (API):** Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation, and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.
2. **Added substance:** An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms: inactive ingredient, excipient, and pharmaceutical ingredient.
3. **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.

4. **Category 1 CSP**: A CSP that is assigned a BUD of 12 hour or less at controlled room temperature or 24 hour or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in USP 797.
5. **Category 2 CSP:** A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in USP 797.
6. **Category 3 CSP:** A CSP that may be assigned a BUD exceeding the limits for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in USP.
7. **Compounded sterile preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
8. **Compounding:** The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication.
9. **Container closure system:** Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components if the latter are intended to provide additional protection.
10. **Designated Person (DP)** is one ore more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CSPs.
11. **Final yield/Final yield unit:** The total number of containers prepared at the end of the compounding process prior to release testing.
12. **Quality assurance (QA):** A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
13. **Quality control (QC):** The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
14. **Release inspection and testing:** Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
15. **Repackaging:** The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation
16. **Workflow management system:** Technology comprised of hardware and software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

V. PROCEDURE

A. Creation and Revisions of Master Formula Records (MFRs)

- Submit requests for new or revised MFRs to the Designated Person and/or designee
- The Designated Person and/or qualified designee(s) reviews the request to determine the feasibility and viability the requested formulation including, but not limited to:
  - Supporting references for the formulation, CSP stability and BUD, and compounding methods and techniques
  - Availability and cost of needed ingredients, dispensing devices, equipment, and supplies
  - BUD assignment, storage, transport, and labeling requirements
  - Quality control procedures and tests based on the dosage form, route/location of administration, and drug stability
  - Impact to workflow and staffing
- If the request is approved, the DP or a qualified designee creates (or revises) the MFR.

- An independent review of the MFR is conducted by two compounding personnel with the appropriate expertise. Both the MFR author and reviewer(s) sign off on the final MFR version prior to use.
- The DP or designee provides education and communication about the new/revised MFR with an effective date to Sterile Compounding Personnel.
- The DP and/or designee retains a revision history of the MFR.

B. Creation of Compounding Records (CRs)
- Compounding personnel creates a CR for all Category 1 CSPs and for immediate use compounds made for more than one patient.
- CRs are allowed in the following formats that are fully compliant with the CR documentation requirements stated above in section 2.5
  - MFR designed to allow for the manual entry of the information needed to complete the CR

C. Use of MFR and CR
- Prior to starting the compounding process, compounding personnel review the MFR and compounding procedure in detail; initiate the CR; complete and record all required calculations; and confirm necessary ingredients, devices, equipment, and supplies are readily available.
- Update the CR during the preparatory, compounding, and QC processes to ensure accurate and complete documentation of the compounding process.
- Ensure all components of the CR are complete and accurate including, but not limited to:
  - Formulation Name
  - Name/ID, manufacturer (or wholesaler), lot number, expiration, weight/volume, and strength of each added substance incorporated into the CSP
  - Calculations and conversions
  - Anticipated and actual final yield (including total quantity compounded and/or number of final dose units)
  - Anticipated and actual results of QC procedures and tests (e.g., final yield unit weight/volume) and verifying Pharmacist's initials.
- Validate the CSP label, prescription or med order and Master Formulation Records and Compounding record are consistent and conform with each other,
- Ensure signatures of the compounder(s) and verifying Pharmacist are indelibly written on each CR.
- Ensure compounding date, time compounding started, and assigned internal ID number are indelibly written on each CR.
- Submit final CR to the DP or qualified designee(s) for final review and approval prior to storage in a readily retrievable format.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Labeling of Compounded Sterile Preparations	Policy #	PHARM2205H
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

This policy describes the labeling requirements for Compounded Sterile Preparations (CSP) prepared at Watsonville Community Hospital.

Label and labelling represent distinct but important and legally required documentation affixed to (or surrounding) each CSP.

- The **label** designates the part of labeling that is on the immediate CSP container.
- **Labeling** refers to all of the labels (including auxiliary labels) - written, printed, or in graphical presentation - on the immediate container or on the inside of any package or wrapper (excluding shipping containers) in which the CSP in enclosed.

II. POLICY

A. All Category 1 CSPs dispensed are labeled with appropriate and legible identifying and administration information to prevent errors or CSP mix ups during storage, dispensing, and use. When possible, ISMP and FDA labeling recommendations (including tall man lettering, sound-alike look-alike distinctions, and abbreviations) are incorporated into labeling conventions.

B. All labeling complies with the laws and regulations of the applicable regulatory jurisdiction.

C. The label on each immediate CSP container prominently and legibly displays, at a minimum:

- Assigned internal identification number (e.g., barcode, prescription, order, or lot number / pharmacy reference number [CCR 1735.4])
- Active ingredients(s) and their amount(s), activity(ies), or concentration(s) [CCR 1735.4]
  - Name (brand or generic) and strength, volume or weight of each active ingredient.
  - For admixed intravenous (IV) solutions, the IV solutions utilized shall be included
- Dosage form
- Route(s) of administration
- Rate of administration
- Total amount or volume of the CSP unless it is obvious from the container
- Instructions for storage, handling, and administration. For admixed IV solutions, the rate of the infusion shall be included [CCR 1735.4]
- Warning statements
- Beyond-use date (BUD) or date and time
- The date compounded [CCR 1735.4]
- Any compounded drug preparation includes a statement that the drug preparation has been compounded by the pharmacy [CCR 1735.4 [c]]
- Compounding facility name and contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded

D. Prior to final release and dispensing, the label of each CSP is verified to ensure it conforms with the prescription or medication order, Master Formulation Record (MFR), and Compounding Record (CR) if required.

III. ROLES & RESPONSIBILITIES

1. Designated Person(s) (DP) and/or Designee:
   - Ensure label and labeling requirements for CSPs are met in available documentation system or manual label templates.
   - Ensure MFRs and CRs reflect additional label and labeling requirements per CSP, when applicable.
   - Educate compounding personnel on labeling requirements.
2. Compounding Personnel:
   - Comply with all of the labeling requirements for each CSP and notify the DP and/or Designee if suspected labeling elements are missing from the instructions (e.g. storage conditions or other important auxiliary labeling)
   - Affix appropriate labeling in a neat and professional manner that does not obstruct required manufacturer, product, or measurement annotations on the dispensing device
3. Verifying Pharmacist:
   - During final verification and before dispensing, ensure each CSP label and labeling meets all of the regulatory, legal, and organizational requirements per this policy.

IV. DEFINITIONS

- **Active Pharmaceutical Ingredient** is any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as Bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
- **Beyond Use Date (BUD)** is the date, or hour and the date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
- **Compounded stock solutions** are a sterile mixture of components that is used to compound additional CSPs.
- **Label** is the part of the labeling on the immediate container
- **Labeling** is all labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except any outer shipping container.

V. PROCEDURE

A. Labeling of Single Dose and Multi-dose CSPs

- For patient-specific preparations, the compounder affixes the label to the final container for dispensing once the volume or quantity has been prepared to ensure no mix up occurs. If labeling cannot occur immediately, place label(s) and CSP(s) in an individual basket or bin to reduce the risk of mixing up products and labels.
- Prior to placing label, verify the label, prescription or medication order, and CSP to be labeled match.
- Remove CSP from the PEC prior to labeling; place on an immediately adjacent table or cart and label the product immediately.
- Position label in a neat and well positioned manner so it has a professional appearance and does not cover critical dispensing container information such as manufacturer,

product name, and/or product ID (e.g., NDC, manufacturer's product id code), and/or measurement indicators.

B. Labeling of Multiple Single Doses of a CSP or Batched Preparations
   - During the compounding process, segregate all compounded dosage units, labels and components needed for final verification (e.g., vials, diluents, etc.) in a separate basket, bin, or container.
   - Immediately following the visual inspection of each dosage unit (e.g., syringes, bags, vials, cassettes, etc.), label the CSP.
   - Ensure labels affixed to smaller dispensing devices or container closure systems do not cover volume or dose markings.
   - If multiple single doses are prepared for a single patient, ensure all labels are consistent and labeling indicates total number of ordered doses.

C. Immediate use CSPs are labeled with the following information unless directly administered by or the preparation remains in possession of, and administration is witnessed by the preparer of the CSP:
   - Names and amounts of all active ingredients
   - Name or initials of the person who compounded the preparation
   - The specific 4-hour timeframe during which the drug administration must begin (from the time the compounding process was initiated)

D. Special Labeling Considerations:
   - CSPs intended for use in dialysis, hemofiltration, or irrigation should be labeled to indicated contents are not to be administered intravenously or intra-arterially.
   - Concentrations of electrolytes given for replacement therapy should be stated on the label in milliequivalents per volume (mEq/volume); phosphorus containing CSPs should be expressed in milliMoles per volume (mM/volume). The label of electrolyte containing CSPs also should contain the quantity of ingredient in terms weight or percentage concentration.
   - Abbreviations for common salts of drugs are allowed when abbreviating names of the salts of organic acids, but are not allowed at the beginning of an official title (e.g., Phenobarbital NA is acceptable, but NA Salicylate is not). The abbreviations for the following commonly known salts are allowed:
     - HCl for hydrochloride
     - HBr for hydrobromide
     - Na for sodium
     - K for potassium
   - The use of "white-out", paper correction fluid or crossovers is not permitted at any time on prescription labels.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding - Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <7> Labeling. Current version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

- Institute for Safe Medication Practice (ISMP). List of Error Prone Abbreviations, Symbols, and Dose Designations. 2012
- ISMP. Draft Guidelines for Safe Electronic Communication of Medication Orders. Medication Safety Alert. 2003.
- Food and Drug Administration (FDA). Center for Drug Evaluation and Research (CDER). Name Differentiation Project. 2009.
- California Board of Pharmacy: CCR 1735.4

VII. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Compounded Sterile Products: Labels	Policy #	PHARM2205H
Responsible	Pharmacy Director	Revised/Reviewed	5/2021

I. PURPOSE

To promote medication safety by ensuring compounded sterile products are labeled using a standardized format and process.

II. POLICY

- A supplementary label shall be affixed to the container when drugs are added to parenteral or other sterile preparations.
- Labels of sterile products shall accurately reflect the contents.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. **Pharmacy Compounded Sterile Product Label Contents:**

1. Parenteral product label shall be distinctive and shall contain at least:
   - Patient's name and location, if applicable
   - Name and amount of drug(s) added
   - Name and volume of basic parenteral solution
   - Total Volume
   - Name or identifying code (e.g., initials) of the person who prepared the product
   - Date and time prepared
   - Date and time to be administered
   - Rate of administration
   - Actual expiration date of the product
   - Appropriate accessory and supplemental labels (e.g., Refrigerate)
   - Name or identifying code (e.g., initials) of the pharmacist performing the final check of the product

B. If sequential numbers are assigned to parenteral solutions, the numbers shall be placed on the label and the patient's IV profile.

C. **Labeling Sterile Products Compounded in Patient Care Areas:**

1. Labels should contain at least the following information:
   a. Patient's name and location, if applicable, unless the primary container already has this information

   Name and amount of drug(s) added

   b. Date and time prepared

c. Actual expiration date and time of the compounded product
d. Name or identifying code (e.g., initials) of the person who prepared the product

D. **Affixing labels:**

1. Labels should be affixed to containers so that they may be read while the container is hanging.
2. Labels shall be placed so that visual inspection of the infusion contents is possible. The name, type of solution, and the manufacturer's lot number shall be visible.

E. **Removing HIPAA Specific Information on labels:**

1. Prior to a patient specific CSP (compounded sterile product) being discarded in the trash, a de-identifying (cover-up) label or sufficient mark-over with a permanent marker should be placed over the patient's identifiers (name, admission number, room number, etc.) printed on the label.

REFERENCES

- Joint Commission Standards: MM.03.01.01 EP7 MM.05.01.07 EP 2-4 MM.05.01.09 EP1-12
- ASHP, Compounding Sterile Preparations, 2nd edition, 2005, pp. 97.

STAKEHOLDERS

N/A

Watsonville Community Hospital	**Beyond Use Dating and Stability Considerations**
Policy Number/ Version:	797-2022 Version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the procedures for the determination and assignment of beyond use dating (BUD) for Compounded Sterile Preparations (CSP) prepared at Watsonville Community Hospital.

1.2. [USP 797] BUD limits are intended to help prevent patient harm resulting from microbial proliferation and contamination of CSPs. BUDs are determined by evaluating the chemical stability of the CSP components or formulation, storage conditions, starting components, sterile processing approach, and type of sterile compounding area where the CSP is prepared.

1.3. [USP 797] Expiration dates and BUDs are not interchangeable terms or concepts and medication administration terms cause confusion around the definition and application of BUDs assigned to compounded sterile preparations.

- **Expiration date** is the time during which a manufactured product can be expected to meet the requirements of the USP–NF monograph, if one exists, or maintain expected quality provided it is kept under the specified storage conditions; applies to all conventionally manufactured products and added substances.
- **BUD** is the date, or hour and date, after which the administration of a CSP cannot begin. BUDs are not intended to limit administration time; applies to all CSPs and stock solutions made by Compounding Personnel.
- **Hang time or administration time** refers to the amount of time during which a CSP or conventionally manufactured product (e.g. pre-mix, large volume parenteral solution) may by be infused before which the tubing or medications needs to be changed due to stability considerations. Hang time is not determined by USP <797> and is considered out of scope for this policy.

1.4. This policy denotes the BUD assignment for all Category 1 CSPs compounded at Watsonville Community Hospital.

- Refer to **Immediate Use Compounding** policy for the procedures pertaining further information about the requirements and definition of Immediate Use Compounding

2. Policy

2.1. [USP 797] Every CSP is labeled with a date, or date and hour, after which administration of the medication cannot begin/occur (i.e., BUD). BUDs are:

- Based on anticipated storage conditions
- Determined from the time compounding begins
- Not allowed to exceed the shortest remaining expiration date of any of the commercially available or compounded components used in the preparation of the CSP.
- Consider one day equivalent to 24 hours

2.2. [USP 797] Maximum BUDs differ for Immediate Use and Category 1 CSPs and, at no times, are extended beyond those stated in USP <797>; adapted from Tables 12 and 13 of USP <797>.

- Watsonville Community Hospital has a Segregated Compounding Area (SCA), not a cleanroom suite.

	Controlled Room Temperature [20°C to 25°C] (68°F - 77°F)	Refrigerated Temperature [2°C to 8°C] (36.8°F – 46.4°F)	Frozen Temperature [-25°C to -10°C]
Immediate Use CSPs			
Aseptically processed CSPs from only sterile starting components	≤ 4 hours	≤ 4 hours	Not Applicable
Category 1 CSPs			
Aseptically processed CSPs from only sterile starting components	≤ 12 hours	≤ 24 hours	Not Applicable

2.3. [USP 797] BUDs are assigned by Compounding Personnel with consideration for factors that could impact the CSP quality or sterility including, but not limited to:

- Chemical and physical stability of the components and/or formulation
- Compounding environment in which the CSP is prepared
- Storage conditions

2.4. [USP 797] When the chemical or physical stability of the CSP is shorter than the maximum BUD, the most conservative dating becomes the BUD.

- Chemical stability is based on available manufacturer's data, published literature, and industry references.

2.5. [USP 797] Packaging is selected for the CSP to preserve sterility, chemical stability, and potency.

2.6. [USP 797] CSPs stored under or moved to different storage conditions before they are used assume the new shorter BUD of the storage condition(s) which does not to exceed the original BUD placed on the CSP at the time of preparation

- BUDs are not additive; administration is initiated before the BUD is exceeded or the CSP is promptly and appropriately discarded
- Once a CSP has been stored under a new storage condition requiring a shorter BUD, the CSP is used within the shortened timeframe

2.7. [USP 797] Storage conditions per **USP <659> Packaging and Storage Requirements**:

- Controlled Room Temperature: 20°C to 25°C (68°F - 77°F)
- Refrigerated: 2°C to 8°C (36.8°F – 46.4°F)

2.8. [USP 797] Conventionally manufactured sterile products or components used in the preparation of CSPs adhere to the following BUDs, use and storage requirements:

Conventionally Manufactured Products & Components		
	Expiration Date	Use and Storage Conditions
Single-dose containers	12 hours	• Punctured and entered within an ISO Class 5 PEC • Stored per labeled storage conditions
Ampule (or open plastic luer lock vials)	Discard immediately after use	• Punctured and entered within an ISO Class 5 PEC
Multi-dose containers	28 days (unless otherwise specified by manufacturer's labeling)	• Punctured and entered within an ISO Class 5 PEC • Stored per labeled storage conditions
Pharmacy bulk packages	Per manufacturers labeling	• Punctured and entered within an ISO Class 5 PEC • When manufacturer provides a shorter expiration time after puncture or entry, use the shorter dating and clearly label on packaging
Proprietary bag & vial systems	• Docking and activation for immediate use – is NOT considered compounding (no BUD assignment required) and can be performed in a non-classified area. • Docking for future activation and use – performed in an ISO Class 5 PEC and assigned a BUD that does not exceed the BUD specified in the manufacturer's labeling.	

2.9. [USP 797] CSPs compounded as components for use in other CSPs are initially assigned BUDs per USP <797> (see Section 2.2) and adhere to the following BUDs, use, and storage conditions once entered or punctured for use in a Final CSP; the BUD of the Final CSP is not impacted by the component CSP.

CSPs Compounded as a Component in a Final CSP			
	BUD of Component CSP Once Punctured	BUD of Final CSP Using Component	Use and Storage Conditions of Component
Preserved multi-dose Component CSP	No longer than 28 Days or the Component BUD (whichever is shorter)	Per USP <797> (not impacted by the Component BUD)	• Punctured and entered within an ISO Class 5 PEC • Stored per conditions intended for the initial BUD
Single-Dose & CSP Stock Solutions	≤ 12 Hours or the Component BUD (whichever is shorter)	Per USP <797> (not impacted by the Component BUD)	• Punctured and entered within an ISO Class 5 PEC • Stored per conditions intended for the initial BUD • Remainder is discarded

3. Roles & Responsibilities

3.1. The Designated Person(s) and/or Designee:

- Ensures all CSPs compounded at Watsonville Community Hospital are assigned the correct and appropriate BUD by careful consideration and research pertaining to component and final CSP stability, sterility of components ancontainer closure system, and compounding conditions
- Ensures Master Formula Records (MFRs) have the correct BUD, CSP storage, and drug stability information and instructions
- Ensures Compounding Personnel are educated on how to accurately determine and document BUDs and storage conditions for CSPs and conventionally manufactured and compounded components used in compounding Final CSPs
- Ensures individuals (e.g., practitioners, patients, caregivers, other support staff) transporting, storing, or administering mediations understand how to interpret and/or adjust BUDs if conditions warrant

3.2. Compounding Personnel

- Determine and properly record the BUD on the immediate product label and affix all appropriate auxiliary labels confirming required storage conditions
- Conduct all aseptic manipulations in an ISO 5 and store CSPs and components appropriately

4. Procedures

4.1. [USP 797] **Immediate Use Compounds**

- See **Immediate-Use Compounding** policy for the conditions that must be met to utilize immediate use dating

4.2. [USP 797] **Category 1 Compounded Sterile Preparations**

- Determine the appropriate BUD for Category 1 CSPs (refer to Section 2.2 adapted from Table 12 of USP <797>). Category 1 CSPs meet the following criteria:
    - Compounded in a Segregated Compounding Area (SCA)
    - Compounded in a certified ISO Class 5 Primary Engineering Control (PEC)
    - Compounded aseptically by qualified Compounding Personnel
    - Compounded using only sterile starting components
    - Stored in conditions associated with the assigned BUD
- Sterility and endotoxin testing is not required for Category 1 CSPs

4.3 **Proprietary bag and vial systems**:

- Docking of proprietary bag and systems for FUTURE activation and administration is considered compounding and is compounded in an ISO Class 5 PEC. BUD assignment does not exceed the BUD stated in the manufacturer's labeling.
- Docking and activation of proprietary bag and vial systems for IMMEDIATE administration is not considered sterile compounding and is not assigned a BUD.

4.4. **Conventionally Manufactured Products and Components used in CSPs**

- BUDs for entered or punctured commercially manufactured products used to compound a CSP do not exceed the values listed in Section 2.9.
- Inspect for damage or visible defects to the packaging or the product prior to use.
- Puncture or enter in an ISO Class 5 PEC.
- Commercially manufactured products are stored per the labeled instructions. When storage temperature and/or condition deviations are known or suspected, consult with the Designated Person(s) and/or Designee or the manufacturer's healthcare support line. Discard the product if data validating the safety and stability of the medication under the excursion conditions cannot be attained.

5. Definitions

5.1. **Administration:** The direct application of a sterile medication to a single patient by injecting, infusing, or otherwise providing a sterile medication in its final form.

5.2. **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.

5.3. **Category 1 CSP**: A CSP that is assigned a BUD of 12 h or less at controlled room temperature or 24 h or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.

5.4. **Category 2 CSP**: A CSP that may be assigned a BUD of greater than 12 h at controlled room temperature or greater than 24 h refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.

5.5. **Category 3 CSP**: A CSP that may be assigned a BUD exceeding the limits in Table 13 for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.

5.6. **Component:** Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

5.7. **Compounded sterile preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

5.8. **Conventionally manufactured product:** A pharmaceutical dosage form, usually the subject of an FDA approved application, and manufactured under current good manufacturing practice conditions.

5.9. **Immediate Use CSP:** CSP aseptically compounded outside of ISO classified air for direct and immediate administration to a single patient with a maximum BUD of 4 hours from the initiation of compounding.

5.10. **Stability:** The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.

6. Related Policies, Documents, References

6.1. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2. United States Pharmacopeial Convention, Inc. <7> Labels and Labeling for Products in Other Categories, Expiration Date and Beyond Use Date. Current version.

6.3. United States Pharmacopeial Convention, Inc. <51> Antimicrobial Effectiveness Testing. Current version.

6.4. United States Pharmacopeial Convention, Inc. <71> Sterility Testing. Current version.

6.5. United States Pharmacopeial Convention, Inc. <85> Bacterial Endotoxin Testing. Current version.

6.6. United States Pharmacopeial Convention, Inc. <659> Packaging and Storage Requirements. Current version.

6.7. United States Pharmacopeial Convention, Inc. <788> Particulate Matter in Injections. Current version.

6.8. United States Pharmacopeial Convention, Inc. <789> Particulate Matter in Ophthalmic Solutions. Current version.

6.9. United States Pharmacopeial Convention, Inc. <1163> Quality Assurance in Pharmaceutical Compounding. Current version.

6.10. United States Pharmacopeial Convention, Inc. <1207> Package Integrity Evaluation – Sterile Products. Current version.

6.11. United States Pharmacopeial Convention, Inc. <1225> Validation of Compendial Procedures. Current version.

7. Approval and Review Summary

Approved by/date:	PTIC, Date of approval (10/2023)
Next review:	Month/year

7.1. Initial version published by Wolters Kluwer 2022.

7.2. Revised MM/YYY with the following key changes…OR…with no changes.

Watsonville Community Hospital	**Workflow and Aseptic Technique for Sterile Compounding**
Policy Number/ Version:	797-2022 Version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1 This policy describes the procedures for Sterile Compounding Workflow and materials handling within a Segregated Compounding Area (SCA) to maintain the quality of the compounding environment and minimize the risk of contamination to Compounded Sterile Preparations (CSPs) prepared within Watsonville Community Hospital.

1.2 This policy describes the procedures for Aseptic Technique of CSPs within an SCA where CSPs are prepared within Watsonville Community Hospital.

- Aseptic technique is set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count as an irreducible medium.

1.3 Sterile compounding workflow includes all the movement of materials within the designated compounding area. It is critical to control transfer of materials between areas of lower quality air to higher quality air to minimize the influx of contaminants, especially activities such as:

- Entering and exiting SCA
- Entering and exiting Restricted-access Barrier System (RABS)
- Use of pass-through chambers
- Aseptic technique during compounding

1.4 This policy is not intended to describe the requirements and procedures for aseptic technique of CSPs for Immediate Use within Watsonville Community Hospital.

- Policies and procedures for immediate use CSPs can be found in the **Immediate Use Compounding policy**.

1.5 [Conditional] This policy outlines the steps for workflow and aseptic technique for compounding non-hazardous sterile preparations.

- Watsonville Community Hospital does not compound hazardous drug CSPs.

2. Policy

2.1 [USP 797] It is the policy that compounding personnel maintain sterility of CSPs prepared within Watsonville Community Hospital by ensuring aseptic technique is followed in the entirety of the compounding process.

2.2 [USP 797] All furniture, equipment and other materials necessary for performing sterile compounding activities that is moved into the SCA is low-shedding and easily cleaned and disinfected.

2.3 [USP 797] All furniture, equipment and other materials necessary for performing sterile compounding activities that is moved into the SCA is cleaned per this policy.

2.4 [USP 797] Corrugated cardboard and other outside shipping containers are not allowed into the SCA

2.5 [USP 797] Personnel who compound CSPs within Watsonville Community Hospital independently have successfully completed all required sterile compounding training and competency programs.

2.6 [USP 797] All aseptic manipulations and processes occur inside an ISO Class 5 Primary Engineering Control (PEC).

2.7 [USP 797] All personnel who compound CSPs within Watsonville Community Hospital follow all procedures in the Hand Hygiene and Garbing policy including personnel conduct in the sterile compounding area(s).[USP 797] All supplies, medications, fluids and equipment are cleaned upon entry/crossing the Line of Demarcation (LOD) with sIPA at a minimum

3. Roles & Responsibilities

3.1 [USP 797] The Designated Person(s) (DP) (and/or Designee):

- Ensure all furniture, equipment and materials necessary for sterile compounding is low shedding and easily cleaned and disinfected
- Ensure all personnel involved in sterile compounding move materials, medications, fluids, and supplies into sterile compounding locations and ISO classified areas per this policy in order to maintain the sterility of the CSPs
- Ensure all personnel who compound CSPs are following aseptic technique throughout the entirety of the sterile compounding
- Ensure technology supporting sterile compounding workflow is maintained and consistent with organizational policies and procedures
- Communicate changes in workflow, procedures and systems to compounding staff.

3.2 [USP 797] Compounding personnel:

- Follow all policies and procedures for moving materials, medications, fluids, and supplies into and out of the sterile compounding locations per this policy
- Follow aseptic technique throughout the entirety of sterile compounding

3.3 [USP 797] Pharmacist:

- Provide direct oversight of compounding personnel and procedures to ensure compliance.
- Perform in-process checks and final verification checks of CSPs per policy.
- Perform all CSP storage and/or dispensing processes per policy.

4. Procedures

Movement of Materials: Segregated Compounding Area (SCA):

4.1 [USP 797] Remove all materials moving into the SCA from outer shipping containers and corrugated cardboard. Move these containers and cardboard away from the immediate vicinity of the SCA and/or before crossing the line of demarcation (LOD) or perimeter line.

4.2 [USP 797] Disinfect all materials that are introduced inside the perimeter of an SCA by wiping with a low-lint wipe saturated with EPA-registered disinfectant or sterile 70% isopropyl alcohol (sIPA) prior to moving into the perimeter of the SCA.

- Wear gloves when wiping down materials.
- Ensure the integrity of all materials is not affected by wiping.

- [Conditional] EPA-registered disinfectant remain on the materials for the proper contact time.
- [Conditional] sIPA remains on the materials until it dries.

4.3 Disinfect all carts moving into the perimeter line of the SCA by wiping with a low-lint wipe saturated with EPA-registered disinfectant or sterile 70% isopropyl alcohol (sIPA) prior to moving into the perimeter line of the SCA. Ensure castors are also wiped down thoroughly.

4.4 [USP 797] Only introduce materials needed for sterile compounding activities inside the perimeter of the SCA.

4.5 [USP 797] Move materials into their storage location within the SCA or use materials for compounding CSPs.

Sterile Compounding Procedure:

4.6 [USP 797] Personnel follow all policies and procedures outlined in **Hand Hygiene and Garbing for Sterile Compounding** policy prior to compounding CSPs and/or working in the SCA.

4.7 [USP 797] Gather all materials needed for compounding CSPs prior to initiating compounding.

4.8 [USP 797] Check expiration date on all vials, ampules, and fluids being used for sterile compounding.

4.9 [USP 797] Check each vial, ampule, bag for:
- Changes in color
- Particles floating in the fluid
- Cloudiness
- Leakage or packaging defects that could impact the integrity of the sterile component
  - If any of these present, do not use for compounding CSPs

4.10 [USP 797] All items necessary for compounding CSPs are wiped down with sIPA and a low-lint wiper and allowed to dry before moving materials into the Primary Engineering Control (PEC).
- The wiping procedure does not render the product label unreadable.
- Sterile supplies in sealed containers moving into the PEC may be removed from the outer covering as the supplies are introduced into the PEC without needing to be wiped with sIPA

4.11 [Conditional] Movement of Materials – RABS (CAI):
- Spray gloved hands with sIPA
- Transfer all materials that have been wiped down into the ante chamber of the compounding isolator.
- Place gloved hands inside isolator sleeves and disinfect the isolator gloves and PEC, including the deck, with sIPA.
- Move materials from the antechamber to the main chamber. Disinfect outer wrapping of gloves.
- Don the sterile gloves over the isolator gloves being careful not to touch the non-sterile surface of the glove wrapping.

4.12 [USP 797] Spray gloved hands with sIPA prior to beginning any CSP manipulations. Gloved hands remain in the ISO 5 PEC for the entire sterile compounding process. When hands removed from PEC, spray gloved hands with sIPA prior to putting them back into the PEC.

4.13 [USP 797] Items used for compounding are arranged inside the PEC so that all items are receiving first air.

- Like items are arranged together to organize the direct compounding area (DCA) inside the PEC.

[Best Practice] **Aseptic Technique:**

4.14 Flip dust covers off vials, disinfect vial septum by wiping with an individual sIPA wipe three times firmly in a single direction and allow to dry.
- Critical sites always receive first air after disinfection with sIPA. If first air is interrupted, wipe the vial septum again with sIPA.

4.15 Wipe ampule necks with individual sIPA wipes and allow to dry prior to manipulation. The individual sIPA wipes are used only once.
- Ensure all liquid is in the body of the ampule; lightly tap the head of the ampule, causing liquid to drip down into the body of the ampule.
- Open ampule by wrapping a sIPA wipe around the neck of the ampule and snapping the neck at the scored line if available, away from hands and body, and towards the side of the PEC.
- The ampule is never opened toward the HEPA filter of the PEC.

4.16 Assemble needle and syringe:
- Remove appropriately sized syringe for volume being drawn up from outer packaging. Do not push syringe through paper backing, if present. Gently peel back the two sides of the packaging without touching any of the critical sites. Place packaging trash off to the side. Maintain first air across the luer lock of the syringe, as this is the critical site. Hold syringe in hand as needle is opened.
- Remove outer packaging of appropriately sized needle and twist needle onto the syringe. Do not push needle through paper backing, if present. Gently peel back the two sides of the packaging without touching critical sites. Care is taken to avoid twisting the needle cap off needle; instead pull straight back in a single movement to avoid finger sticks.

4.17 Withdraw required volume from a vial:
- Pull back on the syringe to fill the syringe with air equal to the volume of fluid being removed from the vial
- Hold syringe so that the needle shaft is at a 45^{o} angle to the middle of the vial septum and needle bevel is up. Pierce vial septum with tip of the needle, rotate the needle to 90^{o} the vial septum and push down through the vial septum in one fluid motion. To avoid vial septum coring, do not twist the needle into the vial septum.
- Push air into the air space of the vial, invert vial and hold vial so as to not block first air to the critical site. Ensure needle is now in the fluid space in the vial.
- Pulling back on the plunger flange, withdraw required volume from vial, taking care only to touch the plunger flange and not the plunger shaft.
- Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.
- Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe. Push air into the vial into the air space, move needle to the fluid space and withdraw to required volume markings on syringe.
- Withdraw needle from the vial and ensure required volume is still within the syringe.

- If required volume not in the syringe, disinfect vial septum with sIPA wipe and follow all above steps. Do not enter the vial septum in the same location, always utilize an unpierced area on the vial septum to avoid coring.

- Follow all the above steps to reconstitute other vials or withdraw volumes from more than one syringe.
- Needles should not be used more than five (5) times, as this dulls the needle and contributes to coring.
- Remove needle and replace with an unused needle if further manipulations need to be performed with that syringe.

4.18 Withdraw required volume from ampule:

- Ensure needle used in only one direction is a filter needle. The filter needle can be used to withdraw contents from an ampule or push syringe contents into final dose. [Best Practice] Use filter needle or filter straw to withdraw contents from ampule.
- Insert filter needle or filter straw into the contents of the ampule
- Pulling back on the plunger flange, withdraw more than the required volume from the ampule, taking care only to touch the plunger flange and not the plunger shaft.
- Remove the filter straw or filter needle from ampule and turn the syringe upward.
- Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe.
- Remove filter straw or filter needle from the syringe and replace with a new appropriately sized needle.
- Push the plunger flange upward to expel air bubbles and extra volume. Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.

4.19 Withdrawing or adding required volume from or into IV bag:

- Disinfect drug additive port of IV bag by wiping three times firmly in a single direction with sIPA wipe and allow to dry
- With needle at a 90^{o} angle to the drug additive port, push needle into drug additive port through the center of the port. To avoid coring, do not twist the needle into the IV bag port.
- Pulling back on the plunger flange, withdraw required volume from IV bag, taking care only to touch the plunger flange and not the plunger shaft.
- Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.
- Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe. Push air into the bag then pull back to withdraw required volume to markings on syringe.
- Pull back on the syringe to remove needle from the IV bag.

4.20 Medication reconstitution:

- Withdraw the required amount of diluent from a bag or vial; following steps above for piercing bags and vials.
- Inject the required diluent into the medication vial; verifying with medication package insert for the instructions for reconstitution (into the powder cake or into the side of the vial).
- Withdraw air from the vial equal to the amount of diluent injected then withdraw needle.
- Follow medication package insert for instructions on the method for ensuring the medication goes into solution (e.g., can the medication be shaken or only swirled).

4.21 The following limits should be followed:

- The maximum number of times a needle is used is five (5) times
- The maximum needle gauge for a multiple dose vial is recommended to be 21 gauge
- The selection of syringe size to use is based on volume being measured

4.22 When recapping needle, always utilize the one-handed scoop technique to avoid finger sticks:

- With the syringe in dominant hand and needle cap laying on the DCA, scoop up the needle cap with the needle. Once cap resting over needle, press needle cap completely onto the needle.

4.23 [Conditional: Best Practice when not using an IV Workflow system] All ingredients and measured volumes are checked by a pharmacist prior to being injected or mixed into the final dose.

4.24 [USP 797] Continuously inspect gloves during sterile compounding for holes, punctures, or tears. Gloves are replaced immediately upon discovery of these defects.

- Do not don or doff gloves inside the PEC.
- To replace gloves:
  - Step away from PEC when in a SCA
  - Remove torn, punctured, or soiled gloves
  - Reapply hand sanitizer to hands/wrists and allow to dry
  - Don new pair of gloves

4.25 Cover critical sites of completed CSPs with a tamper evident seal, cover, or cap.

4.26 [USP 797] Compounding personnel inspect completed CSPs for cores, visible particles, discoloration, or other defects and removed from the PEC.

4.27 Move completed CSPs from the PEC to a cart in the buffer room, accumulate all trash in the PEC and discard, and place sharps into a hard-sided sharps container.

4.28 [USP 797] Wipe the DCA of the PEC with sIPA and allow to dry prior to beginning the next CSP.

4.29 Move completed CSPs from the SCA through pass-throughs or doors.

[USP 797] **Conclusion of Compounding: Visual Inspection:**

4.30 Pharmacists check completed CSPs in person and in/on appropriate logs. Items checked include:

- Correct ingredients: medication, diluents, and fluids are used
- Correct measured volumes are removed from vials and/or fluid bags
- Correct measured volumes are injected into vials and/or fluid bags
- Correct/required supplies were used (e.g., filter needle/filter straw)
- All required steps are completed, including but not limited not, lot number/expiration date

4.31 Pharmacist visually checks final CSPs for inappropriate physical appearance including:

- Particles [Best Practice]: by holding CSP up to white light and black box, when available
- Foreign matter such as vial coring pieces
- Discoloration
- Cloudiness
- Other defects

4.32 Pharmacist visually inspects the final CSP to ensure the label matches the medication order or prescription.

4.33 Pharmacist ensures correct Beyond Use Date (BUD) is located on the label of the final CSP.

- BUD is determined by Category of CSP and facility conditions during compounding. Refer to **Establishing Beyond-use Dates policy** for additional criteria**.**

4.34 Pharmacist signs completed CSP dose to indicate all checks have been completed
- Signature is printed on the CSP label or hand written

4.35 Any CSP found to have unacceptable quality; the CSP is not signed and immediately rejected.
- The CSP is clearly denoted by the pharmacist as rejected
- The CSP is removed immediately and segregated, then appropriately destroyed

4.36 Move completed, verified, and checked CSPs to the proper storage location and storage conditions within the facility for future dispensation or dispense to the patient.

5. Definitions

5.1 **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.

5.2 **Critical Site:** A location that includes and component or fluid pathway surfaces (e.g., vial septum, injection port, and beakers) or openings (e.g., opened ampules and needle hubs) that are exposed and at risk of direct contact whit air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.

5.3 **Designated Person(s) (DP):** One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.

5.4 **Direct Compounding Area (DCA):** A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

5.5 **EPA:** Environmental Protection Agency

5.6 **First Air:** The air exiting the HEPA filter in a unidirectional air stream

5.7 **Hazardous Drug (HD):** Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, orang toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.

5.8 **High-efficiency particulate air (HEPA) filtration:** Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.

5.9 **Line of Demarcation (LOD):** A visible line on the floor that separates the clean and dirty side of the anteroom

5.10 **Low-lint:** Material that exhibits few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from the material in a dry condition

5.11 **Pass-through:** An enclosure with sealed doors on both sides that should be interlocked. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.

5.12 **Primary Engineering Control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.

5.13 **Restricted-access Barrier System (RABS):** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings

that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include Compounding Aseptic Isolators (CAIs) and Compounding Aseptic Containment Isolators (CACIs).

6. Related Policies, Documents, References

6.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2 United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

7. Approval and Review Summary

Approved by/date:	PTIC, Date of approval (10/2023)
Next review:	Month/year

Initial version published by Wolters Kluwer 2022.

Revised MM/YYY with the following key changes…OR…with no changes.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Work and Aseptic Technique for Sterile Compounding	Policy #	PHARM2727
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

1. This policy describes the procedures for Sterile Compounding Workflow and materials handling within a Segregated Compounding Area (SCA) to maintain the quality of the compounding environment and minimize the risk of contamination to Compounded Sterile Preparations (CSPs) prepared within Watsonville Community Hospital.
2. This policy describes the procedures for Aseptic Technique of CSPs within an SCA where CSPs are prepared within Watsonville Community Hospital.
    - Aseptic technique is set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count as an irreducible medium.
3. Sterile compounding workflow includes all the movement of materials within the designated compounding area. It is critical to control transfer of materials between areas of lower quality air to higher quality air to minimize the influx of contaminants, especially activities such as**:**
    - Entering and exiting SCA
    - Entering and exiting Restricted-access Barrier System (RABS)
    - Use of pass-through chambers
    - Aseptic technique during compounding
4. This policy is not intended to describe the requirements and procedures for aseptic technique of CSPs for Immediate Use within Watsonville Community Hospital.
    - Policies and procedures for immediate use CSPs can be found in the **Immediate Use Compounding policy**.
5. This policy outlines the steps for workflow and aseptic technique for compounding non-hazardous sterile preparations.
    - Watsonville Community Hospital does not compound hazardous drug CSPs.

II. POLICY

A. It is the policy that compounding personnel maintain sterility of CSPs prepared within Watsonville Community Hospital by ensuring aseptic technique is followed in the entirety of the compounding process.
B. All furniture, equipment and other materials necessary for performing sterile compounding activities that is moved into the SCA is low-shedding and easily cleaned and disinfected.
C. All furniture, equipment and other materials necessary for performing sterile compounding activities that is moved into the SCA is cleaned per this policy.
D. Corrugated cardboard and other outside shipping containers are not allowed into the SCA
E. Personnel who compound CSPs within Watsonville Community Hospital independently have successfully completed all required sterile compounding training and competency programs.
F. All aseptic manipulations and processes occur inside an ISO Class 5 Primary Engineering Control (PEC).
G. All personnel who compound CSPs within Watsonville Community Hospital follow all procedures in the Hand Hygiene and Garbing policy including personnel conduct in the sterile

compounding area(s). All supplies, medications, fluids and equipment are cleaned upon entry/crossing the Line of Demarcation (LOD) with sIPA at a minimum

III. ROLES & RESPONSIBILITIES

1. The Designated Person(s) (DP):
   - Ensure all furniture, equipment and materials necessary for sterile compounding is low shedding and easily cleaned and disinfected
   - Ensure all personnel involved in sterile compounding move materials, medications, fluids, and supplies into sterile compounding locations and ISO classified areas per this policy in order to maintain the sterility of the CSPs
   - Ensure all personnel who compound CSPs are following aseptic technique throughout the entirety of the sterile compounding
   - Ensure technology supporting sterile compounding workflow is maintained and consistent with organizational policies and procedures
   - Communicate changes in workflow, procedures and systems to compounding staff.
2. Compounding personnel:
   - Follow all policies and procedures for moving materials, medications, fluids, and supplies into and out of the sterile compounding locations per this policy
   - Follow aseptic technique throughout the entirety of sterile compounding
3. Pharmacist:
   - Provide direct oversight of compounding personnel and procedures to ensure compliance.
   - Perform in-process checks and final verification checks of CSPs per policy.
   - Perform all CSP storage and/or dispensing processes per policy.

IV. DEFINITIONS

1. **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
2. **Critical Site:** A location that includes and component or fluid pathway surfaces (e.g., vial septum, injection port, and beakers) or openings (e.g., opened ampules and needle hubs) that are exposed and at risk of direct contact whit air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.
3. **Designated Person(s) (DP):** One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.
4. **Direct Compounding Area (DCA):** A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
5. **EPA:** Environmental Protection Agency
6. **First Air:** The air exiting the HEPA filter in a unidirectional air stream
7. **Hazardous Drug (HD):** Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, orang toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.
8. **High-efficiency particulate air (HEPA) filtration:** Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
9. **Line of Demarcation (LOD):** A visible line on the floor that separates the clean and dirty side of the anteroom
10. **Low-lint:** Material that exhibits few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from the material in a dry condition

11. **Pass-through:** An enclosure with sealed doors on both sides that should be interlocked. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
12. **Primary Engineering Control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
13. **Restricted-access Barrier System (RABS):** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include Compounding Aseptic Isolators (CAIs) and Compounding Aseptic Containment Isolators (CACIs).

V. PROCEDURE

A. Movement of Materials: Segregated Compounding Area (SCA):

1. Remove all materials moving into the SCA from outer shipping containers and corrugated cardboard. Move these containers and carboard away from the immediate vicinity of the SCA and/or before crossing the line of demarcation (LOD) or perimeter line.
2. Disinfect all materials that are introduced inside the perimeter of an SCA by wiping with a low-lint wipe saturated with EPA-registered disinfectant or sterile 70% isopropyl alcohol (sIPA) prior to moving into the perimeter of the SCA.
   - Wear gloves when wiping down materials.
   - Ensure the integrity of all materials is not affected by wiping.
   - EPA-registered disinfectant remain on the materials for the proper contact time.
   - sIPA remains on the materials until it dries.
3. Disinfect all carts moving into the perimeter line of the SCA by wiping with a low-lint wipe saturated with EPA-registered disinfectant or sterile 70% isopropyl alcohol (sIPA) prior to moving into the perimeter line of the SCA. Ensure castors are also wiped down thoroughly.
4. Only introduce materials needed for sterile compounding activities inside the perimeter of the SCA.
5. Move materials into their storage location within the SCA or use materials for compounding CSPs.

B. Sterile Compounding Procedure:

1. Personnel follow all policies and procedures outlined in **Hand Hygiene and Garbing for Sterile Compounding** policy prior to compounding CSPs and/or working in the SCA.
2. Gather all materials needed for compounding CSPs prior to initiating compounding.
3. Check expiration date on all vials, ampules, and fluids being used for sterile compounding.
4. Check each vial, ampule, bag for:
   - Changes in color
   - Particles floating in the fluid
   - Cloudiness
   - Leakage or packaging defects that could impact the integrity of the sterile component
     - If any of these present, do not use for compounding CSPs
5. All items necessary for compounding CSPs are wiped down with sIPA and a low-lint wiper and allowed to dry before moving materials into the Primary Engineering Control (PEC).
   - The wiping procedure does not render the product label unreadable.
   - Sterile supplies in sealed containers moving into the PEC may be removed from the outer covering as the supplies are introduced into the PEC without needing to be wiped with sIPA

6. Movement of Materials – RABS (CAI):
   - Spray gloved hands with sIPA
   - Transfer all materials that have been wiped down into the ante chamber of the compounding isolator.
   - Place gloved hands inside isolator sleeves and disinfect the isolator gloves and PEC, including the deck, with sIPA.
   - Move materials from the antechamber to the main chamber. Disinfect outer wrapping of gloves.
   - Don the sterile gloves over the isolator gloves being careful not to touch the non-sterile surface of the glove wrapping.
7. Spray gloved hands with sIPA prior to beginning any CSP manipulations. Gloved hands remain in the ISO 5 PEC for the entire sterile compounding process. When hands removed from PEC, spray gloved hands with sIPA prior to putting them back into the PEC.
8. Items used for compounding are arranged inside the PEC so that all items are receiving first air.
   - Like items are arranged together to organize the direct compounding area (DCA) inside the PEC.

C. Aseptic Technique:

1. Flip dust covers off vials, disinfect vial septum by wiping with an individual sIPA wipe three times firmly in a single direction and allow to dry.
   - Critical sites always receive first air after disinfection with sIPA. If first air is interrupted, wipe the vial septum again with sIPA.
2. Wipe ampule necks with individual sIPA wipes and allow to dry prior to manipulation. The individual sIPA wipes are used only once.
   - Ensure all liquid is in the body of the ampule; lightly tap the head of the ampule, causing liquid to drip down into the body of the ampule.
   - Open ampule by wrapping a sIPA wipe around the neck of the ampule and snapping the neck at the scored line if available, away from hands and body, and towards the side of the PEC.
   - The ampule is never opened toward the HEPA filter of the PEC.
3. Assemble needle and syringe:
   - Remove appropriately sized syringe for volume being drawn up from outer packaging. Do not push syringe through paper backing, if present. Gently peel back the two sides of the packaging without touching any of the critical sites. Place packaging trash off to the side. Maintain first air across the luer lock of the syringe, as this is the critical site. Hold syringe in hand as needle is opened.
   - Remove outer packaging of appropriately sized needle and twist needle onto the syringe. Do not push needle through paper backing, if present. Gently peel back the two sides of the packaging without touching critical sites. Care is taken to avoid twisting the needle cap off needle; instead pull straight back in a single movement to avoid finger sticks.
4. Withdraw required volume from a vial:
   - Pull back on the syringe to fill the syringe with air equal to the volume of fluid being removed from the vial
   - Hold syringe so that the needle shaft is at a 45^{o} angle to the middle of the vial septum and needle bevel is up. Pierce vial septum with tip of the needle, rotate the needle to 90^{o} the vial septum and push down through the vial septum in one fluid motion. To avoid vial septum coring, do not twist the needle into the vial septum.
   - Push air into the air space of the vial, invert vial and hold vial so as to not block first air to the critical site. Ensure needle is now in the fluid space in the vial.

- Pulling back on the plunger flange, withdraw required volume from vial, taking care only to touch the plunger flange and not the plunger shaft.
- Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.
- Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe. Push air into the vial into the air space, move needle to the fluid space and withdraw to required volume markings on syringe.
- Withdraw needle from the vial and ensure required volume is still within the syringe.
  - If required volume not in the syringe, disinfect vial septum with sIPA wipe and follow all above steps. Do not enter the vial septum in the same location, always utilize an unpierced area on the vial septum to avoid coring.
- Follow all the above steps to reconstitute other vials or withdraw volumes from more than one syringe.
- Needles should not be used more than five (5) times, as this dulls the needle and contributes to coring.
- Remove needle and replace with an unused needle if further manipulations need to be performed with that syringe.

5. Withdraw required volume from ampule:
   - Ensure needle used in only one direction is a filter needle. The filter needle can be used to withdraw contents from an ampule or push syringe contents into final dose. Use filter needle or filter straw to withdraw contents from ampule.
   - Insert filter needle or filter straw into the contents of the ampule
   - Pulling back on the plunger flange, withdraw more than the required volume from the ampule, taking care only to touch the plunger flange and not the plunger shaft.
   - Remove the filter straw or filter needle from ampule and turn the syringe upward.
   - Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe.
   - Remove filter straw or filter needle from the syringe and replace with a new appropriately sized needle.
   - Push the plunger flange upward to expel air bubbles and extra volume. Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.
6. Withdrawing or adding required volume from or into IV bag:
   - Disinfect drug additive port of IV bag by wiping three times firmly in a single direction with sIPA wipe and allow to dry
   - With needle at a 90^{o} angle to the drug additive port, push needle into drug additive port through the center of the port. To avoid coring, do not twist the needle into the IV bag port.
   - Pulling back on the plunger flange, withdraw required volume from IV bag, taking care only to touch the plunger flange and not the plunger shaft.
   - Ensure plunger seal is in-line with the correct volume markings on the barrel of the syringe to confirm correct volume withdrawn.
   - Check for air bubbles in the syringe barrel. If bubbles are present, flick the barrel of the syringe with fingers to move air bubbles to the top of the syringe. Push air into the bag then pull back to withdraw required volume to markings on syringe.
   - Pull back on the syringe to remove needle from the IV bag.
7. Medication reconstitution:
   - Withdraw the required amount of diluent from a bag or vial; following steps above for piercing bags and vials.
   - Inject the required diluent into the medication vial; verifying with medication package insert for the instructions for reconstitution (into the powder cake or into the side of the vial).

- Withdraw air from the vial equal to the amount of diluent injected then withdraw needle.
- Follow medication package insert for instructions on the method for ensuring the medication goes into solution (can the medication be shaken or only swirled).

8. The following limits should be followed:
   - The maximum number of times a needle is used is five (5) times
   - The maximum needle gauge for a multiple dose vial is recommended to be 21 gauge
   - The selection of syringe size to use is based on volume being measured
9. When recapping needle, always utilize the one-handed scoop technique to avoid finger sticks:
   - With the syringe in dominant hand and needle cap laying on the DCA, scoop up the needle cap with the needle. Once cap resting over needle, press needle cap completely onto the needle.
10. All ingredients and measured volumes are checked by a pharmacist prior to being injected or mixed into the final dose.
11. Continuously inspect gloves during sterile compounding for holes, punctures, or tears. Gloves are replaced immediately upon discovery of these defects.
    - Do not don or doff gloves inside the PEC.
    - To replace gloves:
      - Step away from PEC when in a SCA
      - Remove torn, punctured, or soiled gloves
      - Reapply hand sanitizer to hands/wrists and allow to dry
      - Don new pair of sterile gloves
12. Cover critical sites of completed CSPs with a tamper evident seal, cover, or cap.
13. Compounding personnel inspect completed CSPs for cores, visible particles, discoloration, or other defects and removed from the PEC.
14. Move completed CSPs from the PEC to a cart in the buffer room, accumulate all trash in the PEC and discard, and place sharps into a hard-sided sharps container.
15. Wipe the DCA of the PEC with sIPA and allow to dry prior to beginning the next CSP.
16. Move completed CSPs from the SCA through pass-throughs or doors.

D. Conclusion of Compounding: Visual Inspection:

1. Pharmacists check completed CSPs in person and on paper logs. Items checked include:
   - Correct ingredients: medication, diluents, and fluids are used
   - Correct measured volumes are removed from vials and/or fluid bags
   - Correct measured volumes are injected into vials and/or fluid bags
   - Correct/required supplies were used (i.e., filter needle/filter straw)
   - All required steps are completed, including but not limited not, lot number/expiration date
2. Pharmacist visually checks final CSPs for inappropriate physical appearance including:
   - Particles**:** by holding CSP up to white light and black box, when available
   - Foreign matter such as vial coring pieces
   - Discoloration
   - Cloudiness
   - Other defects
3. Pharmacist visually inspects the final CSP to ensure the label matches the medication order or prescription.
4. Pharmacist ensures correct Beyond Use Date (BUD) is located on the label of the final CSP.
   - BUD is determined by Category of CSP and facility conditions during compounding. Refer to **Establishing Beyond-use Dates policy** for additional criteria**.**

5. Pharmacist signs completed CSP dose to indicate all checks have been completed
    - Signature is printed on the CSP label or hand written
6. Any CSP found to have unacceptable quality; the CSP is not signed and immediately rejected.
    - The CSP is clearly denoted by the pharmacist as rejected
    - The CSP is removed immediately and segregated, then appropriately destroyed
7. Move completed, verified, and checked CSPs to the proper storage location and storage conditions within the facility for future dispensation or dispense to the patient.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Compounded Sterile Products: End Product (Final) Examination	Policy #	PHARM2726
Responsible	Pharmacy Director	Revised/Reviewed	10/2022

I. PURPOSE

To provide guidelines to ensure all compounded sterile products (CSPs) undergo a final examination by a pharmacist.

II. POLICY

- Sterile products shall be quarantined after compounding.
- A pharmacist shall perform an end product (final) examination of all compounded sterile products prior to their release from the Pharmacy.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Examination Procedure
   1. The examination procedure must ensure:
      a. Accuracy of profiles or other records (comparison with original order).
      b. Accuracy of calculations.
      c. Use of proper solutions, additives and equipment.
      d. Labels contain at least the product name and volume, additive name and amount, patient's name and other information when applicable.
      e. Proper assignment of beyond-use-date (BUD).
      f. Integrity of the container.
      g. Qualitative integrity:
         1) Absence of particulate matter, precipitates, turbidity, discoloration, or other signs that the product should not be used.
      h. Quantitative integrity:
         1) Potency at 90 to 110% of expected

B. Disposition of Products Not Passing Final Examination
   1. The pharmacist shall reject and destroy all products that do not pass the final examination.

C. Documentation of Final Product Examination
   1. Pharmacists shall document final product examinations prior to releasing them from the pharmacy.

D. Quality Assurance:
   1. At a minimum, an annual potency test to evaluate quantitative integrity will be completed.
      a. End product test should not be performed using an antibiotic.
   2. Also, at a minimum, annual media fill and glove tip finger sampling to evaluate qualitative integrity will be completed.
   3. In the event a compounded drug product is discovered to be below standard for quality and/or quantity (potency), pharmacist shall reject and destroy all product and personnel shall be immediately re-instructed, their sterile compounding technique re-

evaluated by a pharmacist, and successfully complete written exams, competencies, and/or media-fills as required.

V. REFERENCES

Joint Commission Standards: MM.05.01.07 EP 2 – 4
California State Board of Pharmacy: CCR 1735.8

VI. STAKEHOLDERS

N/A

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Hand Hygiene and Garbing for Sterile Compounding in a Segregated Compounding Area	Policy #	PHARM2278
Responsible	Pharmacy Director	Revised/Reviewed	10/2023

I. PURPOSE

- This policy describes the requirements and procedures for hand hygiene and garbing when Compounded Sterile Preparations (CSP) are prepared in a Primary Engineering Control (PEC) within a Segregated Compounding Area (SCA) within Watsonville Community Hospital
- Personal hygiene and proper garbing are essential to minimizing microbial control of the sterile compounding environment. The human body sheds squamous cells at a rate of 10^6 or more per hour and these skin particles are covered in microorganisms. Touch contamination is the leading cause of CSP contamination. To minimize the risk of contamination into the sterile compounding environment, all persons who enter the sterile compounding environment must be properly garbed per this policy.
- This policy applies to the compounding of Category 1 CSPs only.
- This policy applies to compounding of non-hazardous CSPs only.

II. POLICY

1. It is the policy that all persons who enter the SCA of Watsonville Community Hospital comply with all aspects of this Hand Hygiene and Garbing policy to maintain microbial control of the sterile compounding environment.
2. Individuals entering the SCA are properly garbed and maintain proper personal hygiene and hand hygiene to minimize the risk of contamination to the environment and/or CSPs.
3. Gloves worn in the PEC in the SCA are always sterile.
4. Garb is replaced immediately if it becomes soiled or if the integrity is compromised.
5. All garb is stored away from the sink to avoid splashing onto clean garb and is stored in a way that minimizes contamination.
6. All personnel responsible for sterile compounding are trained in hand hygiene and garbing and have their competency evaluated. Competency in hand hygiene and garbing is assessed by the DP or an Assigned Trainer (AT)/Designee and by passing a gloved fingertip test.
7. All personnel who clean the SCA, excluding the PEC, (e.g., Environmental Services/EVS/Housekeeping) are trained in hand hygiene and garbing and have their competency evaluated. Competency in hand hygiene and garbing is assessed by the DP or AT/Designee
8. Replace all garb that has become visibly soiled (e.g., becomes moist or wet due to splashing of cleaning agents and/or perspiration) after cleaning and prior to resuming compounding duties; at a minimum, repeat hand hygiene and replace gloves before returning to compounding.

III. DEFINITIONS

- **Assigned Trainer (AT):** One or more individuals (designee) assigned by the Designated Person(s) to be responsible for directly providing the training, observation, and/or evaluation pf personnel for the preparation of CSPs
- **ISO:** International Standards Organization
- **Laminar Airflow System (LAFS):** A device or zone within a buffer area that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow. Examples of LAFS are Laminar Airflow Workbenches (LAFWs), Integrated Vertical Laminar Flow Zones (IVLFZs) and Biological Safety Cabinet, Class II (BSCs).
- **Low-lint:** Material that exhibits few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from the material in a dry condition
- **Perimeter Line:** A visible demarcation (such as a door, walls , or visible marking on the floor) that defines the SCA
- **Primary Engineering Control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding
- **Restricted-access Barrier System (RABS):** An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include Compounding Aseptic Isolators (CAIs) and Compounding Aseptic Containment Isolators (CACIs).
- **Segregated Compounding Area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only

IV. ROLES & REPONSIBILITIES

1. **The Designated Person(s) (DP)** and/or Designee**:**
   - Oversees the personnel who enter the SCA and ensures they comply with all procedures in the Hand Hygiene and Garbing policy.
   - Evaluates if compounding personnel need to be excluded from sterile compounding based on individual special conditions. Special conditions include but are not limited to: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections
   - Ensures that any non-compounding staff or visitors who enter the SCA comply with all procedures in the Hand Hygiene and Garbing policy. These include but are not limited to: Engineering, Environmental Services, inspectors, certifiers, and/or students.
2. **Compounding personnel:**
   - Maintain the sterile environment by performing hand hygiene and garbing procedures.
   - Inform the Designated Person (DP) and/or Designee if they have any conditions that could contaminate the sterile compounding environment. Examples of these conditions include but are not limited to: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.
3. **Non-compounding staff and visitors:**
   - Maintain the sterile environment by performing hand hygiene procedures.
   - Don appropriate garb according to facility SOP.

V. PROCEDURE

1. All personnel entering the SCA take appropriate steps to minimize microbial contamination of the environment and of the CSPs, including hand hygiene, garbing, and consideration of needed materials to be brought into the compounding area.
2. All individuals entering the SCA remove all items that are not easily cleanable or are not necessary for compounding. The DP may permit accommodations to the below list as long as the quality of the CSP and compounding area will not be affected, and accommodations are documented. At a minimum, individuals must:
   - Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests)
   - Remove all cosmetics
   - Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing. Cover any jewelry that cannot be removed.
   - Remove earbuds and headphones
   - Individuals will not bring in electronic devices that are not necessary for compounding or other required tasks into the compounding area
   - Nails are clean and neatly trimmed. No nail products may be worn (all nail polish, artificial nails and extenders are not allowed)
   - If eyeglasses are worn, they are cleaned with an eyeglass wipe on the lenses and with a disinfectant wipe on the frames
   - Employees entering the sterile compounding area ensure exposed skin on legs are covered (e.g., will wear socks or shoe cover " booties" long enough to cover exposed skin on legs)
   - If street clothes are worn into the compounding area, or non- pharmacy employees need to enter the sterile compounding environment, individuals will don a full non-shedding suit over street clothes prior to performing hand hygiene and garbing steps.
3. Required garb for sterile compounding Category 1 CSPs include:
   - Low-lint gown with sleeves that fit snugly around the wrist and have an enclosed neck
   - Low-lint shoe covers
   - Low-lint face mask
   - Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair
   - Sterile powder-free gloves
   - Disposable gloves may be worn inside the gloves attached to the RABS sleeves. Sterile gloves are worn over the gloves attached to the RABS sleeve.
4. Any person entering the SCA must wash hands and forearms up to the elbows with soap and water before initiating compounding activities.
   - Steps for hand hygiene:
     - Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner
     - Wash hands and forearms up to the elbows with soap and water for at least 30 seconds
     - Dry hands and forearms up to the elbows completely with low-lint disposable towels or wipers
   - Brushes and hand dryers are not used
   - A non-refillable soap dispenser is located next to the sink
5. All garb for sterile compounding is stored outside the perimeter line of the SCA.
6. Order of hand hygiene and garbing is:

(When sink is located inside the room the SCA is located):

- Outside of the SCA:
  - Tie long hair back
  - Clean eyeglasses
- Outside the perimeter line of the SCA:
  - Don mask, head, and facial hair covers
- Inside the perimeter line of the SCA:
  - Don shoe covers one foot at a time while stepping over the perimeter line
  - Perform hand hygiene (sink inside perimeter line)
  - Don gown
  - Sanitize hands/wrists with alcohol-based hand sanitizer:
    - Apply alcohol-based hand sanitizer to dry skin on one hand (volume determined by manufacturer)
    - Rub hands together, covering all surfaces of fingers, hands, and wrists until hands are dry
  - Don disposable gloves

7. Donning and doffing of garb will not occur in the perimeter line of the SCA at the same time.
8. Sterile gloves are donned and doffed inside a Restricted-Access Barrier System (RABS) ISO Class 5 PEC.
   - Sterile gloves are worn over the gauntlet gloves that are attached to the RABS sleeve per manufacture specifications.
9. Garbing for non-compounding staff or visitors:
   - When it is necessary for non-compounding staff or visitors to enter the SCA to perform maintenance, cleaning procedures, inspections; the persons entering the area performs all proper hand hygiene and garbing per this policy.
     - Before entering the SCA, either change into hospital laundered lint free scrubs or don a fully enclosed non-shedding suit prior to following all above steps for preparing to enter the sterile compounding area.
10. Doffing of gown worn while compounding CSPs occurs within the perimeter of the SCA. Order of doffing garb worn during sterile compounding:
    - Remove sterile gloves
    - Remove gown
      - For Category 1 CSPs: gowns may be stored within the perimeter of the SCA for reuse during the same shift only if the gown is not visibly soiled or torn.
    - Leave the SCA perimeter line and remove and dispose of mask, facial hair cover, head cover, and shoe covers

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding-Sterile Preparations. 2022 proposed version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Cleaning and Disinfecting Sterile Compounding Areas**
Policy Number/ Version:	797 – 2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the procedures for cleaning and disinfecting compounding areas where Compounded Preparations (CSP) are prepared within Watsonville Community Hospital.

1.2. [USP 797] Surfaces in classified areas and segregated compounding areas are potential sources of microbial contamination. In order to reduce the risk of contact contamination, surfaces within classified areas used to prepare Category 1 and Immediate Use CSP's are cleaned, disinfected, and have sporicidal disinfectants applied according to the processes and frequencies described in this procedure.

- **Cleaning** involves removing organic and inorganic materials (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces with the use of a cleaning agent and manual or mechanical action.
- **Disinfecting** involves using a chemical or physical agent on surfaces to destroy microorganisms including fungi, viruses, and bacteria.
- **Sporicidal disinfectants** are a chemical or physical agents that destroys all vegetative microorganisms including bacterial and fungal spores when applied at a sufficient concentration and for a specified "wet" contact time.

1.3. [USP 797] **Sterile 70% isopropyl alcohol (sIPA)** is a staple in day-to-day compounding activities and plays a critical role in sanitizing and reducing the bioburden on gloved hands, surfaces, and materials through both chemical application and physical wiping. sIPA, however, is not a cleaning or disinfecting agent. While it does have some disinfectant properties, it does not possess the broad-spectrum coverage of cleaning, disinfecting, or sporicidal agents and requires a lengthy (and impractical) contact time to truly convey bactericidal or fungicidal activity.

2. Policy

2.1. [USP 797] Cleaning and disinfecting of all surfaces inside compounding areas, including sinks, as well as the application of a sporicidal disinfectant occur on a regular basis and at a minimum frequency as specified in *USP <797> Pharmacecutical Compounding – Sterile Preparations 2022* and according to this policy (see Section 4.1).

2.2. [USP 797] Surfaces in compounding areas are cleaned prior to being disinfected with an EPA-registered (or equivalent outside of the US) agent. An EPA-registered (or equivalent) one-step disinfectant cleaner is an appropriate alternative that allows for both processes to occur in one step.

2.3. [USP 797] Sporicidal disinfecting agents are EPA-registered (or equivalent outside of the US) and allow for cleaning, disinfecting, and sporicidal activity concurrently in a single step.

2.4. [USP 797] Manufacturer's directions or published data for the minimum wet contact time is followed for each of the cleaning, disinfecting, and sporicidal agents used to ensure the agents have full microbial destroying action.

2.5. [USP 797] If compounding (and cleaning) is not performed each day, cleaning and disinfecting is completed before reinitiating compounding.

2.6. [USP 797] Cleaning and sanitizing is repeated when spills occur and when surfaces are visibly soiled.

2.7. [USP 797] All personnel involved in cleaning and disinfecting of classified compounding and segregated compounding areas receive training and demonstrate competency in Hand Hygiene and Garbing initially and at least annually. Refresher training is provided as needed and when changes in procedures or agents occur.

- Primary engineering controls (PECs) are cleaned by trained and qualified compounding personnel only.

2.8. [USP 797] All cleaning and disinfecting activities are performed by appropriately garbed personnel using facility-approved agents and procedures including frequency, method, and location of cleaning activity.

2.9. [USP 797] Sterile cleaning agents are used to clean the interior of, and all equipment housed inside of PECs.

2.10. [Best Practice] Cleaning agents and supplies used in PECs and SCAs are assigned an expiration (or "in-use") date once opened or prepared; expiration dates are clearly and permanently written on the bottle, container, or wrapping of the supply and do not exceed manufacturer expiration dates or recommended "in-use" dates.

Cleaning Agent or Supply ***Do not use wipes if dry***	**Location Used**	**Expiration Date*** (from initial puncture, use, or preparation)
Ready-to-Use (RTU) STERILE Cleaning, Disinfecting, and Sporicidal Agents	Inside PECs	6 months PreEmpt / Peridox
RTU Nonsterile Cleaning, Disinfecting, and Sporicidal Agents	Exterior of PECs	6 months PreEmpt / Peridox
STERILE Premoistened or Low-Lint Dry Wipes	Inside PECs	7 days Contec
Nonsterile Premoistened or Low-Lint Dry Wipes	Exterior of PECs	7 days Contec

***Consult the manufacturer for dates for specified products in use at your facility or define a more conservative expiration date.**

2.11. Safety Data Sheets (SDSs) are retained for all cleaning supplies, included in training of cleaning personnel, and are readily retrievable by all compounding staff members.

3. Roles & Responsibilities

3.1. [USP 797] The Designated Person(s) (DP) or Designee:

- Ensures cleaning staff receives appropriate training and maintains current cleaning and related competencies.
- Oversees selection of appropriate EPA-registered cleaning, disinfecting, and sporical agents and ensures staff understands and adheres to appropriate dwell times for each agent.

- Ensures the organization or facility maintains a current SDS for each cleaning agent in a readily retrievable format and location and ensures cleaning personnel understand how to access and use the SDS in case of a spill or accident.
- Ensures appropriate qualification, supervision, and quality assurance of non-pharmacy personnel performing cleaning and disinfecting activities (e.g., EVS / housekeeping).
- Determines appropriate remedial cleaning requirements for ad hoc and out-of-specification occurrences up to and including a triple clean of effected compounding areas including the following circumstances:
    - Actionable environmental findings from total particle counts, viable air sampling, or surface sampling results and/or trends.
    - Scheduled and unscheduled power and/or airflow disruptions directly impacting sterile compounding area(s).
    - Certification of sterile compounding area(s).
    - New or major construction or maintenance work performed within or adjacent to the sterile compounding area(s).

3.2. Compounding personnel:

- Undergo training and demonstrate competency initially and at least once annually in skills and competencies related to cleaning and disinfecting.
- Adhere to all cleaning procedures including cleaning agent selection, frequency, method, and sequence of cleaning activities (i.e., cleanest to dirtiest).
- Ensure appropriate use of sterile 70% IPA before, during, and after the compounding process.
- Complete timely documentation of all cleaning activities performed.

3.3. Environmental Services (EVS) or contracted cleaning personnel:

- Undergo training and demonstrate competency initially and at least once annually in skills and competencies related to cleaning and disinfecting.
- Complete all cleaning tasks as described in this policy, under the supervision of pharmacy personnel.
- Never clean the interior of any PEC and/or equipment housed within a PEC.

4. Procedures

4.1. Frequency of Cleaning, Disinfection, and Application of Sporicidal Disinfectants – Adapted from *USP <797> 2022 Table 8.*

	Cleaning and Disinfecting		Applying Sporicidal Disinfectant	
	Frequency	**Who**	**Frequency**	**Who**
Inside PECs – including all surfaces, direct compounding area and work tray, and equipment used inside the PEC	Daily on days when compounding occurs and when surface contamination is known or suspected	Pharmacy staff	Monthly	Pharmacy staff
Surfaces Underneath Removable PEC Work Tray *(if applicable)*	Monthly - surfaces under the tray	Pharmacy staff	Monthly	Pharmacy staff
Pass Through(s) – **all interior surfaces and external handles**	Daily on days when compounding occurs	Pharmacy staff	Monthly	Pharmacy staff
Work Surfaces Outside of PEC	Daily on days when compounding occurs - all "high touch" surfaces daily	Pharmacy staff and EVS	Monthly – all surfaces including high touch and underneath of tables, chairs, and carts plus wheels.	Pharmacy staff and EVS
Floors	Daily on days when compounding occurs	EVS	Monthly	EVS
Sinks	Daily on days when compounding occurs	EVS	Monthly	EVS
Walls, Door(s), and Door Frame(s)	Monthly	EVS	Monthly	EVS
Ceilings of Segregated Compounding Area (SCA)	When visibly soiled or if surface contamination is known or suspected	EVS	When visibly soiled or if surface contamination is known or suspected	EVS
Storage Shelves and Bins	Monthly	Pharmacy staff	Monthly	Pharmacy staff
Equipment Outside of the PEC(s) *(if applicable)*	Monthly	Pharmacy staff	Monthly	Pharmacy staff

- [USP 797] Cleaning activities occur from cleanest to dirtiest areas.
- [USP 797] If cleaning and disinfecting are performed as separate steps, cleaning is performed prior to disinfecting.

- [USP 797] After the application of a disinfectant, cleaning agent, or sporicidal disinfectant, the agent is allowed to dwell, or maintain a wet contact time, for the minimum duration specified by the manufacturer or published data to ensure full bactericidal, fungicidal, virucidal, and/or sporicidal action.
- [USP 797] Daily cleaning and disinfecting occurs on days when compounding occurs. If compounding does not occur for more than 24 hours (e.g., over a weekend or holiday):
    - clean and disinfect the sink(s) before initiating hand hygiene and garbing
    - complete daily cleaning and disinfecting prior to the start of compounding on the day compounding resumes
- Monthly cleaning and application of sporicidal disinfectants occurs approximately every 30 days, whenever possible, to ensure a regular and consistent cleaning schedule and is completed as one continuous process or, at a minimum, is completed with 72 hours to minimize the risk of cross-contaminating already cleaned areas.

4.2. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in the PEC

- [USP 797] If needed, remove visible particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers.
- [USP 797] **For cleaning and disinfecting**: Use a sterile low-lint wiper and apply a sterile cleaning agent followed by a sterile disinfecting agent or apply an EPA-registered (or equivalent) one-step disinfectant cleaner to equipment and all interior surfaces of the PEC.
- [USP 797] **For application of a sporicidal disinfectant**: After cleaning and disinfecting, apply a sterile sporicidal disinfectant using a sterile low-lint wiper to all equipment, interior surfaces, and the area underneath the work tray; if the sporicidal disinfectant is an EPA-registered (or equivalent) one-step disinfectant sporicidal cleaner, separate cleaning and disinfecting steps are not required.
- [USP 797] Ensure the wet contact time specified by the manufacturer is achieved.
- [USP 797] After the application of cleaning, disinfecting, and/or sporicidal agent inside PEC, apply sIPA to equipment and all interior surfaces to remove residue.
- [USP 797] Allow the surface to dry completely before beginning compounding.

4.3. Use of Sterile 70% IPA inside of a PEC

- Do not spray cleaning solutions, including sIPA, inside of a PEC to avoid deteriorating the integrity of the HEPA filter. Wet a sterile low-lint wiper with the cleaning solution or sIPA and apply directly with mechanical/manual action to the interior hood surfaces and equipment.
- [USP 797] Apply sIPA to the horizontal work surface of each PEC and allow to dry before compounding:
    - Immediately before initiating compounding or a new compounding process
    - At least every 30 minutes if the compounding process takes 30 minutes or less
    - After completing a compounding process if the process takes more than 30 minutes

4.4. Other Cleaning Considerations

- Clean high touch surfaces outside of PECs on a daily basis and all other surfaces plus the high touch surfaces on a monthly frequency, including but not limited to:

High Touch Surfaces*	Other Surfaces
○ Horizontal work surfaces, tables, counters, or carts ○ Chair seats, arms, and backs ○ Keyboards/keypads, mouse, RF scanner, touch screen monitors or tablets ○ Telephones and other communication devices ○ Light switches, door handles or hands-free activator ○ Sink surfaces, drain, and faucet ○ Gowning bench and garb storage handles ○ Pass through handles	○ Exterior of PECs ○ Legs, underside of horizontal surfaces, and feet/wheels of work surfaces, tables, counters, carts, chairs, or benches ○ Trash bins and hazardous waste disposal containers ○ Doorframes, window ledges, and other irregular surfaces

*For Segregated Compounding Areas, this includes all high touch surfaces within the perimeter line.

- [BEST PRACTICE] Cleaning, disinfecting, and the application of a sporicidal agent does not take place while active compounding is occurring.
- [USP 797] Perform cleaning from cleaner to dirtier areas.
- For all sites, clean and disinfect as needed after spills and when surface contamination (e.g., splashes) is known or suspected.
- Replace all garb that has become visibly soiled or when the integrity is compromised (e.g., becomes moist or wet due to splashing of cleaning agents and/or perspiration) after cleaning and prior to resuming compounding duties; at a minimum, repeat hand hygiene and replace sterile gloves before returning to compounding.
- Use appropriate respiratory support and eye protection when applying a sporicidal agent to surfaces within the compounding area, including the following cleaning tasks:
  - Inside PECs including under the work tray of a RABs (Restricted Access Barrier)
  - Walls, ceilings, floors, and pass throughs
  - Surfaces outside of PECs

4.5. Remedial Cleaning for Out of Specification Conditions

- As directed by the Designated Person or Designee, perform and document remedial cleaning on an as needed basis. Remedial cleaning ranges from cleaning and disinfection to application of a sporicidal disinfectant to triple cleaning effected compounding areas.
  - A **triple clean** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

- At a minimum, document purpose, date, and cleaning agent(s) used when conducting remedial cleaning. Ensure remedial cleaning documentation is retained and readily retrievable.

4.6. Selection and Use of Cleaning Agents

- [USP 797] Select and use cleaning and disinfecting agents with careful consideration of compatibilities, effectiveness, and user safety including, but not limited to, antimicrobial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected.
- [BEST PRACTICE] Use of ready-to-use and one-step disinfectant cleaner solutions is preferred over those requiring dilution or separate cleaning and disinfection steps.
- [USP 797] Clean and disinfect sterile cleaning agent containers prior to introduction into the ISO 5 environment.
- Sterile cleaning and disinfecting supplies (e.g., closed containers of sterile wipers, bottles of 70% sterile IPA) can be used for up to 6 months once opened, as per current manufacturer (e.g., PreEmpt, Peridox). Permanently and legibly write or label the expiration date on all cleaning supplies.

4.7. Selection and Use of Cleaning Supplies and Tools

- [USP 797] Use sterile cleaning supplies and tools inside a PEC whenever possible; clean and disinfect prior to use (e.g., tool handles and holders).
- [USP 797] Dedicate and do not remove reusable cleaning tools (e.g. mop frames and handles) to specific classified areas or segregated compounding areas.
    - Dispose of cleaning tools in a method that minimizes the chance of dispersing contaminants in the air.
- [USP 797] Cleaning and disinfecting supplies such as wipers, sponges, pads, and mop heads are made of low lint materials and, whenever possible are disposable.
    - Disposable cleaning supplies are discarded after use.
    - Reusable cleaning tools are made of cleanable materials that are nonporous (excluding wood) are are cleaned and disinfected before and after each use.

4.8. Documentation of Cleaning

- [USP 797] Document all cleaning, disinfecting, and application of sporicidal disinfectants electronically after completion of the task by the personnel performing the work. Detailed cleaning records are retained and readily accessible.

5. Definitions

5.1 **Classified area**: An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).

5.2 **Cleaning agent**: An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.

5.3 **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite or inside the perimeter of the SCA).

5.4 **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).

5.5 **IPA:** Isopropyl alcohol.

5.6 **Low-lint wiper**: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.

5.7 **One-step disinfectant cleaner**: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.

5.8 **Pass-through**: An enclosure with sealed doors on both sides that should be interlocked. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.

5.9 **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.

5.10 **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

5.11 **Segregated compounding area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.

5.12 **Sporicidal disinfectant**: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms

5.13 **Triple clean:** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

6. Related Policies, Documents, References

6.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2 United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval 10/2023
Next review:	Month/year

7.1 Initial version published by Wolters Kluwer 2022.

7.2 Revised MM/YYY with the following key changes…OR…with no changes.

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Cleaning and Disinfecting Sterile Compounding Areas	Policy #	PHARM2222P
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

This policy describes the procedures for cleaning and disinfecting compounding areas where Compounded Preparations (CSP) are prepared within Watsonville Community Hospital.

Surfaces in classified areas and segregated compounding areas are potential sources of microbial contamination. In order to reduce the risk of contact contamination, surfaces within classified areas used to prepare Category 1 and Immediate Use CSP's are cleaned, disinfected, and have sporicidal disinfectants applied according to the processes and frequencies described in this procedure.

- **Cleaning** involves removing organic and inorganic materials (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces with the use of a cleaning agent and manual or mechanical action.
- **Disinfecting** involves using a chemical or physical agent on surfaces to destroy microorganisms including fungi, viruses, and bacteria.
- **Sporicidal disinfectants** are a chemical or physical agents that destroys all vegetative microorganisms including bacterial and fungal spores when applied at a sufficient concentration and for a specified "wet" contact time.

Sterile 70% isopropyl alcohol (sIPA) is a staple in day-to-day compounding activities and plays a critical role in sanitizing and reducing the bioburden on gloved hands, surfaces, and materials through both chemical application and physical wiping. sIPA, however, is not a cleaning or disinfecting agent. While it does have some disinfectant properties, it does not possess the broad-spectrum coverage of cleaning, disinfecting, or sporicidal agents and requires a lengthy (and impractical) contact time to truly convey bactericidal or fungicidal activity.

II. POLICY

A. Cleaning and disinfecting of all surfaces inside compounding areas, including sinks, as well as the application of a sporicidal disinfectant occur on a regular basis and at a minimum frequency as specified in *USP <797> Pharmacecutical Compounding – Sterile Preparations 2022* and according to this policy (see Section 4.1).

B. Surfaces in compounding areas are cleaned prior to being disinfected with an EPA-registered (or equivalent outside of the US) agent. An EPA-registered (or equivalent) one-step disinfectant cleaner is an appropriate alternative that allows for both processes to occur in one step.

C. Sporicidal disinfecting agents are EPA-registered (or equivalent outside of the US) and allow for cleaning, disinfecting, and sporicidal activity concurrently in a single step.

D. Manufacturer's directions or published data for the minimum wet contact time is followed for each of the cleaning, disinfecting, and sporicidal agents used to ensure the agents have full microbial destroying action.

E. If compounding (and cleaning) is not performed each day, cleaning and disinfecting is completed before reinitiating compounding.

F. Cleaning and sanitizing is repeated when spills occur and when surfaces are visibly soiled.

G. All personnel involved in cleaning and disinfecting of classified compounding and segregated compounding areas receive training and demonstrate competency in Hand Hygiene and Garbing initially and at least annually. Refresher training is provided as needed and when changes in procedures or agents occur.

- Primary engineering controls (PECs) are cleaned by trained and qualified compounding personnel only.

H. All cleaning and disinfecting activities are performed by appropriately garbed personnel using facility-approved agents and procedures including frequency, method, and location of cleaning activity.

I. Sterile cleaning agents are used to clean the interior of, and all equipment housed inside of PECs.

J. Cleaning agents and supplies used in PECs and SCAs are assigned an expiration (or "in-use") date once opened or prepared; expiration dates are clearly and permanently written on the bottle, container, or wrapping of the supply and do not exceed manufacturer expiration dates or recommended "in-use" dates.

Cleaning Agent or Supply ***Do not use wipes if dry***	**Location Used**	**Expiration Date*** (from initial puncture, use, or preparation)
Ready-to-Use (RTU) STERILE Cleaning, Disinfecting, and Sporicidal Agents	Inside PECs	6 months PreEmpt / Peridox
RTU Nonsterile Cleaning, Disinfecting, and Sporicidal Agents	Exterior of PECs	6 months PreEmpt / Peridox
STERILE Premoistened or Low-Lint Dry Wipes	Inside PECs	7 days Contec
Nonsterile Premoistened or Low-Lint Dry Wipes	Exterior of PECs	7 days Contec

H. Safety Data Sheets (SDSs) are retained for all cleaning supplies, included in training of cleaning personnel, and are readily retrievable by all compounding staff members.

III. ROLES & RESPONSIBILITIES

1. The Designated Person(s) (DP) or Designee:
   - Ensures cleaning staff receives appropriate training and maintains current cleaning and related competencies.
   - Oversees selection of appropriate EPA-registered cleaning, disinfecting, and sporical agents and ensures staff understands and adheres to appropriate dwell times for each agent.
   - Ensures the organization or facility maintains a current SDS for each cleaning agent in a readily retrievable format and location and ensures cleaning personnel understand how to access and use the SDS in case of a spill or accident.
   - Ensures appropriate qualification, supervision, and quality assurance of non-pharmacy personnel performing cleaning and disinfecting activities (e.g., EVS / housekeeping).
   - Determines appropriate remedial cleaning requirements for ad hoc and out-of-specification occurrences up to and including a triple clean of effected compounding areas including the following circumstances:
     - Actionable environmental findings from total particle counts, viable air sampling, or surface sampling results and/or trends.
     - Scheduled and unscheduled power and/or airflow disruptions directly impacting sterile compounding area(s).

  - Certification of sterile compounding area(s).
  - New or major construction or maintenance work performed within or adjacent to the sterile compounding area(s).

2. Compounding personnel:
   - Undergo training and demonstrate competency initially and at least once annually in skills and competencies related to cleaning and disinfecting.
   - Adhere to all cleaning procedures including cleaning agent selection, frequency, method, and sequence of cleaning activities (i.e., cleanest to dirtiest).
   - Ensure appropriate use of sterile 70% IPA before, during, and after the compounding process.
   - Complete timely documentation of all cleaning activities performed.
3. Environmental Services (EVS) or contracted cleaning personnel:
   - Undergo training and demonstrate competency initially and at least once annually in skills and competencies related to cleaning and disinfecting.
   - Complete all cleaning tasks as described in this policy, under the supervision of pharmacy personnel.
   - Never clean the interior of any PEC and/or equipment housed within a PEC.

IV. DEFINITIONS

- **Classified area**: An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).
- **Cleaning agent**: An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
- **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite or inside the perimeter of the SCA).
- **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
- **IPA:** Isopropyl alcohol.
- **Low-lint wiper**: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.
- **One-step disinfectant cleaner**: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
- **Pass-through**: An enclosure with sealed doors on both sides that should be interlocked. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
- **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
- **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
- **Segregated compounding area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.
- **Sporicidal disinfectant**: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms

- **Triple clean:** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

V. PROCEDURE

A. Frequency of Cleaning, Disinfection, and Application of Sporicidal Disinfectants – Adapted from *USP <797> 2022 Table 8.*

	Cleaning and Disinfecting		Applying Sporicidal Disinfectant	
	Frequency	**Who**	**Frequency**	**Who**
Inside PECs – including all surfaces, direct compounding area and work tray, and equipment used inside the PEC	Daily on days when compounding occurs and when surface contamination is known or suspected	Pharmacy staff	Monthly	Pharmacy staff
Surfaces Underneath Removable PEC Work Tray *(if applicable)*	Monthly - surfaces under the tray	Pharmacy staff	Monthly	Pharmacy staff
Pass Through(s) – **all interior surfaces and external handles**	Daily on days when compounding occurs	Pharmacy staff	Monthly	Pharmacy staff
Work Surfaces Outside of PEC	Daily on days when compounding occurs - all "high touch" surfaces daily	Pharmacy staff and EVS	Monthly – all surfaces including high touch and underneath of tables, chairs, and carts plus wheels.	Pharmacy staff and EVS
Floors	Daily on days when compounding occurs	EVS	Monthly	EVS
Sinks	Daily on days when compounding occurs	EVS	Monthly	EVS
Walls, Door(s), and Door Frame(s)	Monthly	EVS	Monthly	EVS
Ceilings of Segregated Compounding Area (SCA)	When visibly soiled or if surface contamination is known or suspected	EVS	When visibly soiled or if surface contamination is known or suspected	EVS
Storage Shelves and Bins	Monthly	Pharmacy staff	Monthly	Pharmacy staff
Equipment Outside of the PEC(s) *(if applicable)*	Monthly	Pharmacy staff	Monthly	Pharmacy staff

- Cleaning activities occur from cleanest to dirtiest areas.
- If cleaning and disinfecting are performed as separate steps, cleaning is performed prior to disinfecting.
- After the application of a disinfectant, cleaning agent, or sporicidal disinfectant, the agent is allowed to dwell, or maintain a wet contact time, for the minimum duration specified by the manufacturer or published data to ensure full bactericidal, fungicidal, virucidal, and/or sporicidal action.
- Daily cleaning and disinfecting occurs on days when compounding occurs. If compounding does not occur for more than 24 hours (e.g., over a weekend or holiday):
  - clean and disinfect the sink(s) before initiating hand hygiene and garbing
  - complete daily cleaning and disinfecting prior to the start of compounding on the day compounding resumes
- Monthly cleaning and application of sporicidal disinfectants occurs approximately every 30 days, whenever possible, to ensure a regular and consistent cleaning schedule and is completed as one continuous process or, at a minimum, is completed with 72 hours to minimize the risk of cross-contaminating already cleaned areas.

B. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in the PEC
- If needed, remove visible particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers.
- **For cleaning and disinfecting**: Use a sterile low-lint wiper and apply a sterile cleaning agent followed by a sterile disinfecting agent or apply an EPA-registered (or equivalent) one-step disinfectant cleaner to equipment and all interior surfaces of the PEC.
- **For application of a sporicidal disinfectant**: After cleaning and disinfecting, apply a sterile sporicidal disinfectant using a sterile low-lint wiper to all equipment, interior surfaces, and the area underneath the work tray; if the sporicidal disinfectant is an EPA-registered (or equivalent) one-step disinfectant sporicidal cleaner, separate cleaning and disinfecting steps are not required.
- Ensure the wet contact time specified by the manufacturer is achieved.
- After the application of cleaning, disinfecting, and/or sporicidal agent inside PEC, apply sIPA to equipment and all interior surfaces to remove residue.
- Allow the surface to dry completely before beginning compounding.

C. Use of Sterile 70% IPA inside of a PEC
- Do not spray cleaning solutions, including sIPA, inside of a PEC to avoid deteriorating the integrity of the HEPA filter. Wet a sterile low-lint wiper with the cleaning solution or sIPA and apply directly with mechanical/manual action to the interior hood surfaces and equipment.
- Apply sIPA to the horizontal work surface of each PEC and allow to dry before compounding:
  - Immediately before initiating compounding or a new compounding process
  - At least every 30 minutes if the compounding process takes 30 minutes or less
  - After completing a compounding process if the process takes more than 30 minutes

D. Other Cleaning Considerations
- Clean high touch surfaces outside of PECs on a daily basis and all other surfaces plus the high touch surfaces on a monthly frequency, including but not limited to:

High Touch Surfaces*	Other Surfaces
○ Horizontal work surfaces, tables, counters, or carts ○ Chair seats, arms, and backs ○ Keyboards/keypads, mouse, RF scanner, touch screen monitors or tablets	○ Exterior of PECs ○ Legs, underside of horizontal surfaces, and feet/wheels of work surfaces, tables, counters, carts, chairs, or benches

○ Telephones and other communication devices ○ Light switches, door handles or hands-free activator ○ Sink surfaces, drain, and faucet ○ Gowning bench and garb storage handles ○ Pass through handles	○ Trash bins and hazardous waste disposal containers ○ Doorframes, window ledges, and other irregular surfaces

*For Segregated Compounding Areas, this includes all high touch surfaces within the perimeter line.

- Cleaning, disinfecting, and the application of a sporicidal agent does not take place while active compounding is occurring.
- Perform cleaning from cleaner to dirtier areas.
- For all sites, clean and disinfect as needed after spills and when surface contamination (e.g., splashes) is known or suspected.
- Replace all garb that has become visibly soiled or when the integrity is compromised (e.g., becomes moist or wet due to splashing of cleaning agents and/or perspiration) after cleaning and prior to resuming compounding duties; at a minimum, repeat hand hygiene and replace sterile gloves before returning to compounding.
- Use appropriate respiratory support and eye protection when applying a sporicidal agent to surfaces within the compounding area, including the following cleaning tasks:
  - Inside PECs including under the work tray of a RABs (Restricted Access Barrier)
  - Walls, ceilings, floors, and pass throughs
  - Surfaces outside of PECs

E. Remedial Cleaning for Out of Specification Conditions
- As directed by the Designated Person or Designee, perform and document remedial cleaning on an as needed basis. Remedial cleaning ranges from cleaning and disinfection to application of a sporicidal disinfectant to triple cleaning effected compounding areas.
  - A **triple clean** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.
- At a minimum, document purpose, date, and cleaning agent(s) used when conducting remedial cleaning. Ensure remedial cleaning documentation is retained and readily retrievable.

F. Selection and Use of Cleaning Agents
- Select and use cleaning and disinfecting agents with careful consideration of compatibilities, effectiveness, and user safety including, but not limited to, antimicrobial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected.
- Use of ready-to-use and one-step disinfectant cleaner solutions is preferred over those requiring dilution or separate cleaning and disinfection steps.
- Clean and disinfect sterile cleaning agent containers prior to introduction into the ISO 5 environment.
- Sterile cleaning and disinfecting supplies (e.g., closed containers of sterile wipers, bottles of 70% sterile IPA) can be used for up to 6 months once opened, as per current manufacturer (e.g., PreEmpt, Peridox). Permanently and legibly write or label the expiration date on all cleaning supplies.

G. Selection and Use of Cleaning Supplies and Tools

- Use sterile cleaning supplies and tools inside a PEC whenever possible; clean and disinfect prior to use (e.g., tool handles and holders).
- Dedicate and do not remove reusable cleaning tools (e.g. mop frames and handles) to specific classified areas or segregated compounding areas.
  - Dispose of cleaning tools in a method that minimizes the chance of dispersing contaminants in the air.
- Cleaning and disinfecting supplies such as wipers, sponges, pads, and mop heads are made of low lint materials and, whenever possible are disposable.
  - Disposable cleaning supplies are discarded after use.
  - Reusable cleaning tools are made of cleanable materials that are nonporous (excluding wood) are are cleaned and disinfected before and after each use.

H. Documentation of Cleaning
- Document all cleaning, disinfecting, and application of sporicidal disinfectants electronically after completion of the task by the personnel performing the work. Detailed cleaning records are retained and readily accessible.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Compounded Sterile Products: Cleaning and Disinfecting of the Compounding Area	Policy #	PHARM2222P
Responsible	Pharmacy Director	Revised/Reviewed	05/2021

I. PURPOSE

To describe, standardize, and define the process by which the controlled environments (ISO Class 5, 7, and 8) and the general pharmacy preparation areas are cleaned, disinfected, and maintained in a manner that ensures an environment suitable for compounding sterile preparations. Environmental contact is a major source of microbial contamination of CSPs; therefore, scrupulous attention to cleaning and disinfecting of the areas used for sterile compounding is required to reduce and minimize this potential source of CSP contamination.

II. POLICY

A. Since surfaces in ISO Class 5 work areas, including Laminar Air Flow Workbenches/Hoods (LAFWs), Compounding Aseptic Isolators (CAIs), Biological Safety Cabinets (BSCs), and Compounding Aseptic Containment Isolators (CACIs) are most intimate to the exposure of critical sites, they require disinfecting most frequently. These areas that must be cleaned on a regular basis include, but are not limited to:
   1. The beginning of each compounding shift;
   2. Immediately prior to each batch;
   3. Every 30 minutes throughout the compounding shift when ongoing compounding activities are occurring;
   4. After spills;
   5. When microbial contamination is known to have been or is suspected of having been introduced.

B. This policy is limited to cleaning and disinfection of ISO Class 7 buffer rooms, ISO Class 7/8 ante-areas, segregated compounding areas (SCAs) as well as the following PECs: LAFWs and BSCs.
   1. Refer to Policy 2779, Compounded Sterile Products: Maintenance and Use of Isolators, for specific cleaning information relative to Compounding Aseptic Isolators (CAIs) and Compounding Aseptic Containment Isolators (CACIs).

C. The Director of Pharmacy will designate an appropriate cleaning agent based upon careful consideration of compatibilities, effectiveness and inappropriate or toxic residues.
   1. Germicial example: PREempt®
   2. Sporicial example: Peridox®

D. Sterile Water for Injection or Sterile Water for Irrigation must be used to dilute disinfectant solutions if they will be used inside the ISO Class 5 areas. Though these areas are not sterile and the buckets/wipes used are not sterile, use of sterile water to dilute disinfectants reduces pyrogens and potential bioburden.

E. Though the general pharmacy preparation area is not an ISO classed environment, it must be kept clean and orderly, and is included in the cleaning schedule in this policy.

F. Ideally, cleaning of the general compounding area (buffer area/cleanroom and anteroom/area) should occur at the end of the compounding day to prevent any component residue from sitting overnight and promoting bacterial growth.
G. If cleaning occurs at the start of the compounding day, adequate time must be given to allow the cleaned surfaces to dry prior to starting any compounding activity.
H. If any compounding occurs during after-hours conditions as in an on-call situation, additional cleaning may occur at the start of the next business day.
I. Cleaning and disinfection of the controlled environments will not be performed while compounding is taking place.
J. Pharmacy compounding personnel must ensure that cleaning is being performed properly by personnel who have been adequately trained on this policy as well as on Pharmacy Policy *2778, Hand Hygiene and Garbing.*
K. Cleaning of the buffer area/cleanroom, segregated compounding area, and anteroom/ante-area may be performed by trained custodial personnel.
L. Custodial personnel may not clean ISO Class 5 PECs.
M. Cleaning Equipment and Supplies
    1. Shall be store in a designated area to ensure segregation from compounding supplies.
    2. Materials used (wipers, sponges, mops, etc.) must be non-shedding and preferably composed of synthetic micro fibers.
    3. Materials used must be dedicated to use in particular areas (buffer area/cleanroom, ante-area/room, segregated compounding area, etc.) and will not be removed from these areas except for disposal.
    4. Floor mops may be used in both the buffer area/cleanroom and the ante-area/room as long as they are used in that order.
    5. All cleaning tools should be discarded after one use.
    6. Reusable cleaning equipment must follow the guidelines as follows:
        a. Hang mops vertically to promote drying when not in use
        b. Buckets must be inverted and allowed to dry
        c. Manufacturer's instructions on the products used must ensure that the effectiveness of the device is maintained and that repeated use does not add to the bioburden of the areas cleaned.
N. Safety glasses must be worn during cleaning of ceilings and walls where there is an increased likelihood of splashing or dripping of solution since disinfectant solutions are irritants and can damage the skin and eyes.
O. Material Safety Data Sheets must be readily available for reference in the pharmacy for all disinfectants used in the cleaning and disinfecting process.
P. Any compounding equipment such as automated compounders, devices, or pumps placed into ISO Class 5 PECs is subject to the same cleaning requirements as the LAFW, BSC, CACI, or CAI itself.
Q. If any equipment or device used to compound sterile preparations is removed from the ISO Class 5 buffer area/cleanroom, it must be properly cleaned and disinfected prior to being placed back into service within the ISO Class 5 environment.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Each Materials and Equipment
   1. Plastic/stainless steel buckets with rounded edges into which mops fit or appropriate size sprayer bottles, if a bucketless system is used.
   2. Plastic/stainless steel mop handles suitable for mop heads used
   3. Low particulate shedding cellulose reusable mops or disposable micro-fiber mop heads
   4. Low particle shed wipes
   5. Appropriate disinfectant agent
   6. Sterile 70% IPA
B. Prior to the cleaning process
   1. Staff should gather all supplies needed.
   2. Adequate amounts of the designated disinfectant are prepared by carefully mixing the cleaning solutions.
   3. Follow the manufacturer's recommendations regarding appropriate dilutions as most disinfecting agents must be diluted.
   4. Fill the bucket or sprayer with the appropriate amount of water; then add the correct amount of concentrated disinfectant to the water to reduce the likelihood of splashing.
   5. Document the preparation of the cleaning solutions on the appropriate log immediately after preparing the solution.
C. Cleaning must occur from the cleanest to the dirtiest areas. The lowest class room or environment (i.e., ISO Class 5) must be cleaned before the ISO Class 7 buffer area/cleanroom followed by ISO Class 7/8 ante-area then the general pharmacy preparation area.
D. Considerations when washing floors
   1. Wash floors after the ISO Class 5 areas, counters and other easily cleanable work surfaces have been cleaned and disinfected.
   2. Begin at the location farthest from the buffer area/cleanroom entrance working toward the exit to avoid walking over cleaned areas.
   3. Move any rollable carts, shelving and chairs as cleaning is accomplished.
   4. Perform necessary restocking or other in-room activities prior to cleaning and floor washing so that buffer area/cleanroom may be exited and allowed to dry and remain at rest until the next shift.
E. No high particle shedding materials may enter the buffer area/cleanroom. This includes corrugated cardboard and paper documents, with the exception of single sheet compounding worksheets and order forms at a minimum. No worksheets or order forms may enter the ISO Class 5 environment compounding surface at any time.
F. Document the cleaning procedure on the appropriate log immediately upon completion of the task to insure proper documentation.
G. Cleaning LAFWs and BSCs
   1. Gown and glove, in accordance with Policy and Procedure 2778, Hand Hygiene and Garbing Procedure
   2. If the LAFW or BSC has been turn off, restart and allow to run for a minimum of 30 minutes prior to cleaning. Ideally, PECs should never be turned off.
   3. Inspect the inside of the hood/workbench for any spills or puddles of crystallized compounding components. Clean the spills with sterile water prior to proceeding with the routine cleaning procedure.
   4. If daily cleaning was performed the night before, at the start of the new workday, the LAFW and/or BSC must be wiped down with a wipe wetted with sterile 70% IPA.

5. Begin cleaning activity with the LAF and/or BSC environment moving outward working from inner to outer surface. Do not splash or spray the HEPA filter with disinfectant solution. Carefully clean the HEPA grills.
6. ISO Class 5 critical work areas shall be cleaned with sterile 70% IPA between batches, every 30 minutes during continuous compounding, after spills, and if contamination is suspected.
7. Document all cleaning activity on the appropriate cleaning log.

H. Cleaning Isolators (CAIs and CACIs)
1. See Policy and Procedure 2779, Maintenance and Use of Isolators

I. Daily Cleaning of Controlled Environments
1. The buffer area/cleanroom shall be cleaned before the ante-area/room.
2. Each compounding day the following must be cleaned in both the buffer area/cleanroom and in the ante-area/room:
    1. The inside of all ISO Class 5 PECs
    2. Other counters and easily cleanable work surfaces such as stool tops, stainless cart shelves, etc.
    3. Floors
3. Cleaning should be performed in the following order, when possible:
    1. Inside surfaces of ISO Class 5 PECs
    2. Counters and easily cleanable work surfaces in the buffer area/cleanroom
    3. Floors in the buffer area/cleanroom from the farthest point away from the door progressing toward the door to the ante-area while moving easily movable carts and shelving.
    4. Counters, sinks, and easily cleanable work surfaces in the ante-area as long as those areas are on clean side of the line of demarcation.
    5. Counters and easily cleanable work surfaces in the ante-area/room on the dirtier side of the line of demarcation.
    6. Floors of the ante-area/room
    7. Perform any required daily activities related to cleaning the pharmacy general preparation area as required by hospital policy.
4. Document the cleaning on the appropriate log.

J. Monthly Cleaning of Controlled Environments
1. Monthly cleaning includes all of the elements of the daily cleaning plus additional activities in the following order:
    1. The buffer area/cleanroom is cleaned before the ante-area/room.
    2. All of the daily cleaning activities defined in section 5, Daily Cleaning of Controlled Environments, listed above are required.
    3. Additionally, the following must be cleaned during a monthly cleaning
        1) Ceiling and the top of PECs
        2) Walls and all horizontal surfaces of PECs
        3) All surfaces of moveable carts, storage shelving and stools including the underside, legs, and feet/wheels
        4) All storage bins must have contents removed, bins cleaned inside and out, and allowed to dry before the contents are replaced.
        5) All surfaces in the room including doors, door handles, pass-throughs, and permanent shelving must be cleaned
2. The use of a sporicidal agent is required to be used at least monthly.
    1) Example: Peridox®

3. Document the cleaning on the appropriate log.

K. Routine Cleaning of the General Pharmacy Preparation Area
1. Though not part of the controlled environments, cleanliness and order is required in the general pharmacy preparation area.
2. The Director of Pharmacy will stipulate how and when the general pharmacy area is to be cleaned.
3. Document cleaning of the general pharmacy preparation area on the appropriate log.

L. Floor Refinishing

1. The floors of the buffer area/cleanroom and ante-area shall be stripped of their existing finish and refinished by qualified personnel on an as needed basis.
2. The Director of Pharmacy shall determine when this will occur.
3. The materials utilized will be of such composition as to not compromise the integrity of the controlled environment and should be manufactures for the expressed purpose of maintenance of the type of flooring which has been installed.

I. REFERENCES

1. Joint Commission Standards: IC.02.01.01 EP 2 IC.02.02.01 EP 1
   MM.05.01.07 EP 1
2. California Board of Pharmacy Law – CCR 1751.4(d)

II. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Handling, Storage, Packaging, & Transport of CSPs**
Policy Number/ Version:	797-2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the handling, storage, packaging, and transportation requirements and procedures for Compounded Sterile Preparations (CSPs) prepared at Watsonville Community Hospital.

1.2. CSP quality and integrity can be adversely affected by inappropriate handling, storage, packaging, and transport methods. Care and consideration are given to the determination and selection of these methods and personnel and/or vendors to carry out these duties. Proper training, processes, and quality assurance and control measures are integral to maintaining the quality of CSP during these processes.

2. Policy

2.1. [USP 797] Personnel handling, storing, packaging, and transporting CSPs are trained in the knowledge and skills needed to perform job-related responsibilities. Refer to **Sterile Compounding Personnel Training & Evaluation policy** for further information.

2.2. [USP 797] CSPs are handled in a manner that maintains CSP quality and packaging integrity and are stored in temperature controlled designated storage areas to ensure storage temperatures remain within the appropriate range.

2.3. Designated CSP storage area temperatures are monitored and logged daily on days of operation either manually or by a continuous recording device.

2.4. [USP 797] Temperature monitoring systems are verified for accuracy at least every 12 months or as required by the manufacturer.

2.5. [USP 797] Temperature excursions above or below the required limits are investigated and CSPs are discarded if available literature does not verify the affected CSP(s) are expected to retain integrity or quality.

2.6. [USP 797] CSP packaging materials protect CSPs from damage, leakage, contamination, degradation, and adsorption as well as prevent accidental exposure to transport personnel.

2.7. [USP 797] Light-resistant packaging materials are used for light-sensitive CSPs.

3. Roles & Responsibilities

3.1 The Designated Person(s) (DP) and/or Designee:

- Provide appropriate training and competency evaluations for personnel performing CSP handling, storage, packaging, and transport
- Ensure CSP storage locations are appropriately monitored, and temperature is recorded daily or readily accessible

- Research CSP stability and integrity when drug storage temperature excursions occur and determine if CSPs have retained quality and can be dispensed or must be destroyed due to a lack of uncertainty in the available stability and sterility data in the event of an excursion
- Ensure packaging procedures and materials are appropriate to help retain the quality of the CSP

3.2. Internal Personnel Handling, Storing, Packaging, & Transporting CSPs:

- Personnel successfully complete and remain current on training and competency assessments required to perform job functions. Refer to **Sterile Compounding Personnel Training & Evaluation policy** for further information.

4. Procedures

4.1. [USP 797] CSP Handling and Storage

- After CSPs have been compounded, minimize jostling, shaking, or inverting CSPs unless labeling or literature promotes these actions to maintain or reestablish homogeneity of mixture.
- Transport CSPs to drug storage locations on carts or in sanitized bins to minimize the risk of jostling, dropping, or damaging packaging and, as result, potentially impacting CSP integrity.
- Move CSPs to the designated storage areas within controlled compounding areas corresponding with the labeled storage conditions upon pharmacist final verification, when delays in final verification exceed 30 minutes from completion of compounding of CSPs requiring refrigeration.
- Move CSPs to designated storage areas within or outside of controlled areas when CSPs have been released for dispensing or administration, packaging, transport, or shipping.
- Store CSPs in the following storage locations:

Storage Condition	Within Controlled Area(s)	Outside of Controlled Area(s)
Prior to Final Verification *(including CSPs that have not undergone final verification)*		
Controlled Room Temperature: 20°C - 25°C (68°F - 77°F)	Inpatient Pharmacy	N/A
Refrigerated: 2°C - 8°C (36.8°F – 46.4°F)	Inpatient Pharmacy	N/A
After Final Verification *(CSPs released for dispensing, delivery, or shipping)*		
Controlled Room Temperature: 20°C - 25°C (68°F - 77°F)	Inpatient Pharmacy	Automated Dispensing Cabinet at Nursing Station
Refrigerated: 2°C - 8°C (36.8°F – 46.4°F)	Inpatient Pharmacy	Refrigerator associated with Automated Dispensing Cabinet at Nursing Station

4.2. [USP 797] CSP Packaging

- Select CSP packaging that does not interact physically or chemically (e.g., adsorption) with the CSP and that protect the CSP's sterility, identity, potency, purity, and similar quality criteria (e.g., light sensitivity).
  - Refer to the USP-NF drug monograph, manufacturer's packaging data, or similar literature to determine appropriate packaging.
  - Record packaging requirements and references on the Master Formulation Record (MFR), if applicable, for future reference.
- Use tamper evident CSP containers or closure systems for the following:
  - Controlled substance CSPs
  - CSPs for use via high-risk routes of administration (e.g., intrathecal, epidural)
  - CSPs delivered, transported, or shipped by a third party vendor

4.3. [USP 797] CSP Transport and Delivery

- Transport CSPs to drug storage locations within the immediate facility on well-organized carts to minimize the risk of jostling, dropping, or damaging packaging and potentially impacting CSP integrity.
  - If multiple CSP deliveries occur simultaneously, sort CSPs into sanitized and labeled bins or totes to reduce the risk of mix up or missed delivery of time-sensitive medications.
  - Transport medications in appropriate packaging and storage conditions (see table below).

Transport Scenario / Storage Conditions	**Required Packaging Materials**	
	Controlled Room Temp 20°C - 25°C (68°F - 77°F)	**Refrigerated: 2°C - 8°C** (36.8°F – 46.4°F)
Transport within immediate facility via cart	• CSP(s) placed in sanitized bins	• CSP(s) placed in clear zippered bag • CSP(s) placed in sanitized bins

- Watsonville Community Hospital does not transport or ship CSPs outside of the immediate facility.

4.4. [USP 797] Monitoring & Logging Storage Temperatures

- Monitor and log temperatures of all drug storage locations and devices daily on days of operation, either manually or via continuous monitoring device.
- Temperatures are recorded; e.g., manual temperature log or electronically via recording system [e.g., Simplifi].
- Temperature monitoring devices are maintained, and accuracy validated at least once every 12 months or per manufacturer instructions.
- Retain readily retrievable records of temperature logs and accuracy validations.

4.5. [USP 797] CSP Storage Location Temperature Excursions

- Report out of range temperatures or continuous temperature monitoring system alarms immediately to the Designated Person or Designee. Temperature deviations in drug storage

locations are considered urgent maintenance events and are remediated as quickly as possible.

- When deviations exceed ±3°C (±37.4°F) of the required storage conditions for longer than 30 minutes, quarantine CSPs located in the affected drug storage areas(s) in appropriate comparable storage conditions.
- As soon as possible, the DP or Designee conducts necessary research to determine if the affected CSP quality and integrity has been compromised.
  - If CSPs are determined to have retained quality and integrity, move CSPs back to the appropriate storage location.
  - If CSP quality or integrity cannot be determined or has been compromised, log or remove CSPs from dispensable inventory and destroy and/or dispose of per facility drug disposal policy.
- Investigate the temperature excursion to determine root cause(s) and implement corrective actions if appropriate. Consider historical trends in the investigation. Refer to the **Quality Assurance and Quality Control policy** for procedures related to conducting investigations and corrective actions.

5. Definitions

5.1. **Closure:** A material that seals an otherwise open space of a *Container* and provides protection for the contents. It also provides access to the contents of the *Container* (e.g., screw caps and stoppers).

5.2. **Container:** A receptacle that holds an intermediate compound, API, excipient, or dosage form, and is in direct contact with the article (e.g., ampules, vials, bottles, syringes, and pen injectors).

5.3. **Controlled room temperature:** The temperature maintained thermostatically that encompasses the usual and customary working environment of 20°–25° (68°–77° F).

5.4. **Freezer:** A place in which the temperature is controlled between −25° and −10° (−13° and 14° F)

5.5. **Room temperature** (also referred to as Ambient temperature)**:** The temperature prevailing in a working environment.

5.6. **Tamper-evident packaging:** A *Packaging system* that may not be accessed without obvious destruction of the seal or some portion of the *Packaging system*

6. Related Policies, Documents, References

6.1. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2. United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

6.3. United States Pharmacopeial Convention, Inc. <659> Packaging and Storage Requirements. Current version.

7. Approval and Review Summary

Approved by/date:	PTIC, Date of approval (10/2023)
Next review:	Month/year

7.1. Initial version published by Wolters Kluwer 2023.

7.2. Revised MM/YYYY with the following key changes…OR…with no changes.

Watsonville Community Hospital	**Immediate-Use Compounding**
Policy Number/ Version:	797 – 2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy provides the requirements and procedures for Immediate Use Compounded Sterile Preparations (CSPs) prepared and intended for direct and immediate administration within Watsonville Community Hospital.

1.2. [USP 797] The goal of this procedure is to minimize the risk to medications prepared under immediate use conditions from:

- Contact with nonsterile surfaces
- Introduction of particulate matter or biological fluids
- Mix-ups with other conventionally manufactured products or CSPs

1.3. [USP 797] Immediate Use CSPs are compounded in less than ISO Class 5 conditions (e.g., bedside, countertop, operating room), with 3 or fewer sterile products, and a maximum beyond use date (BUD) of 4 hours starting from the initiation of compounding.

- CSPs exceeding these parameters adhere to the requirements of Category 1 CSPs.

1.4. [USP 797] Certain drug preparation activities occurring in non-classified compounding areas fall outside the scope of USP <797> and, by definition, this SOP. Alternatively, they are governed by other USP <797> regulations or related USP Chapter requirements, including:

- **Conventionally manufactured sterile medications prepared per approved labeling** – mixing, reconstituting, or other manipulations performed according to the manufacturer's approved labeling and directions are not governed by this SOP if the following conditions are met (if not, they are subject to all of the regulations in USP <797> including this SOP):
    - Product prepared for a single dose given to a single patient only
    - Manufacturers approved labeling instructions for the diluent, resultant strength, the container closure system, and storage time are upheld.
- **Proprietary bag and vial systems** –
    - **Immediate Administration -** docking and activation per the manufacturer's labeling for immediate administration to an individual patient is not considered compounding.
    - **Future Activation & Administration -** docking of proprietary bag and vial systems for future activation and administration is considered compounding and is governed by this and related sterile practice SOPs depending on the BUD assigned (the maximum BUD for Immediate Use Compounding is $\leq$ 4 hours; if a BUD in excess of 4 hours is assigned, the docking manipulation must occur in a classified sterile compounding area and follows requirements the related Category 1 compounding).

2. Policy

2.1. [USP 797] CSPs are eligible for immediate use compounding when all of the following criteria are met:

- Personnel are trained and demonstrate competency in aseptic technique and other skills necessary to perform immediate use compounding.
- When preparing immediate use CSPs, personnel use proper aseptic technique.
- No more than 3 different sterile products are used in the compounding of an immediate use medication. An IV fluid bag, diluent used for reconstitution, or similar component count as one of the sterile products.
- BUDs are determined from the start of the compounding process and do not exceed 4 hours, independent of storage conditions (e.g., room temperature or refrigeration) and are subject to evidence-based stability considerations that require a shorter BUD.
- Single dose starting components are only used for one patient. Unused drug or components drawn from a single-dose container are properly discarded after the preparation of the CSP.
- Immediate use CSPs are labeled if the medication does not remain in the direct line of site of the preparer from the time of compounding until administration. Immediate use CSP labeling includes
  - Names and amounts of all active ingredients
  - Name or initials of the person who prepared the CSP
  - Date and time from start of CSP preparation
  - Exact 4-hour time period within which the administration of the CSP must occur

2.2. [USP 797] Administration of immediate use compounds begins within 4 hours of the start of CSP preparation or is promptly and appropriately discarded.

2.3. [Best Practice] Other considerations are made, depending on the urgency of the patient care situation, to help ensure the sterility of the immediate use CSP, including but not limited to:

- Ensure the area where immediate use compounding occurs is not located immediately adjacent to a water source, under or around a high particle generating source (e.g., directly under an air vent or next to a printer), or in a high traffic area.
- If the only area for preparation is near a sink, ensure a splash guard is installed to prevent cross-contamination.

2.4. [USP 797] A Master Formulation Record is created for immediate use CSPs prepared for more than one patient. When these preparations are compounded, the Master Formulation Record is followed, and a Compounding Record is created in a written or electronic format that is retained and readily accessible.

3. Roles & Responsibilities

3.1 [USP 797] The Designated Person(s) (DP) and/or Designee:

- Oversees training and competency assessment of personnel performing Immediate Use Compounding; determine corrective action plans for competency deficiencies.
- Ensures ongoing compliance with this SOP.

- Collects and retains training and competency documentation for Compounding Personnel in a readily retrievable format.
- [Best Practice & Conditional: … when compounding personnel are managed by other departments] Partners with other departments and health care professionals performing immediate use compounding (e.g., nursing) to ensure personnel who compound immediate use sterile preparations receive appropriate education and training necessary to safely perform related job duties.

3.2 Personnel performing immediate use compounding:

- Successfully complete all required training and competencies prior to performing immediate use compounding.
- Participate in ongoing training and competencies as determined by the DP.

4. Procedure

4.1 Training and Competency Assessments

- [USP 797] Personnel compounding immediate use CSPs are trained and demonstrate competency in the skills and foundational knowledge required to perform their job duties prior to compounding independently. Training, knowledge assessments, and observed competencies are documented, readily accessible, and include the following core skills:
    - Immediate use CSP component definition and related requirements
    - Hand hygiene, gloving, and garbing
    - Selecting, cleaning, and staging of compounding area
    - Calculations, measuring, and mixing
    - BUD assignment, stability considerations, and storage conditions
    - Aseptic technique and achieving and/or maintaining sterility
    - Labeling conditions and requirements
    - Documentation of the compounding process
- [Best Practice] Successful or "passing" results for the observed Sterile Core Competencies and Knowledge Assessment are:

Observation	**Validation**	**Initial** Prior to Compounding Independently
Competency-based checklist with 100% proficiency	USP <797> & Sterile Principles Knowledge Exam	80% cumulative score

- Observed Competency Assessments are performed and assessed initially prior to compounding independently to validate sterile practice and aseptic technique competency including:
    - Hand hygiene, gloving and garbing
    - Preparing and cleaning the compounding area
    - Aseptic technique

- [USP 797] Failure of observed competencies or knowledge assessments (requiring $\geq$ 80% passing score) results in retraining and reevaluation. Repeated failures are assessed and investigated by the Designated Person(s) or a Designee. A remediation plan is developed up to, and including, formal corrective action and suspension of immediate use compounding

duties until required knowledge and skills have been successfully performed under direct observation and by written or electronic assessments.

4.2 Immediate Use Compounding Procedure

- [Best Practice] Select and prepare a work surface that is free of clutter and is sanitized with an approved EPA-registered one-step cleaner prior to starting the compounding process.
- [Best Practice] Stage medications and supplies in such a way as to reduce the risk of introduction of particulate matter or biological fluids, or mix-up with other conventionally manufactured products or CSPs before, during, and after preparation of the CSP.
- [Best Practice] Perform hand hygiene and don medical grade gloves at a minimum, don other personal protective equipment (PPE) as available and the situation warrants. Sanitize gloves with 70% isopropyl alcohol (IPA) prior to compounding and as needed during compounding up to administration of CSP. Change gloves if they become torn or punctured.
- [USP 797] Sanitize critical sites (e.g., vial stoppers, ampule neck, injection port of an IV bag) with sterile 70% isopropyl alcohol wipes prior to puncture or entry.
- [USP 797] Prepare CSPs in accordance with evidence-based information for physical and chemical stability including, but not limited to, approved labeling mixing and storage requirements, stability and compatibility studies and data.
- [USP 797] Use proper aseptic technique during CSP compounding manipulations.
- [USP 797] Assign the most conservative BUD to the CSP possible that does not exceed 4 hours from the start of compounding. If administration does not occur within the assigned BUD (≤ 4 hours), promptly and appropriately discard the CSP.
- [USP 797] Ensure single dose starting components are only used for one patient and dispose of unused drug or components drawn from a single-dose container appropriately.
- [USP 797] When immediate use CSPs are compounded for more than one patient as a batch, refer to the Master Formulation Record for compounding instructions and ensure a Compounding Record is created, retained, and readily accessible.
- [USP 797] If the CSP(s) cannot remain in the direct line of site of the preparer from the time of compounding until administration, label the CSP (or individual dosing units if prepared for multiple patients) with the following:
    - Names and amounts of all active ingredients
    - Name or initials of the person who prepared the CSP
    - Date and time from start of CSP preparation
    - Exact 4-hour time period within which the administration of the CSP must occur.
- [USP 797] Prior to dispensing, perform a final visual verification of the CSP(s) and reject the preparation if visual contamination in found.
- [USP 797] Ensure administration of the CSP begins within 4 hours of the start of compounding. Promptly and safely discard of the CSP if administration does not occur within the 4-hour timeframe.

5. Definitions

1.1. **Administration:** The direct application of a sterile medication to a single patient by injecting, infusing, or otherwise providing a sterile medication in its final form.

1.2. **Aseptic technique:** A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.

1.3. **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.

1.4. **Classified area:** An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).

1.5. **Component:** Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

1.6. **Compounded sterile preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

1.7. **Conventionally manufactured product:** A pharmaceutical dosage form, usually the subject of an FDA approved application, and manufactured under current good manufacturing practice conditions.

1.8. **Critical site:** A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, and beakers) or openings (e.g., opened ampules and needle hubs) that are exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral, and mucosal secretions), or touch contamination.

1.9. **Designated person(s):** One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.

1.10. **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).

1.11. **Hazardous drug (HD):** Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.

1.12. **Immediate Use CSP:** CSP aseptically compounded outside of ISO classified air for direct and immediate administration to a single patient with a maximum BUD of 4 hours from the initiation of compounding.

1.13. **IPA:** Isopropyl alcohol.

1.14. **PPE:** Personal protective equipment.

6. Related Policies, Documents, References

6.1. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2. United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval 10/2023
Next review:	Month/year

7.1 Initial version published by Wolters Kluwer 2022.

Revised MM/YYY with the following key changes…OR…with no changes.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Immediate-Use Compounding	Policy #	PHARMXXX
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

This policy provides the requirements and procedures for Immediate Use Compounded Sterile Preparations (CSPs) prepared and intended for direct and immediate administration within Watsonville Community Hospital.

The goal of this procedure is to minimize the risk to medications prepared under immediate use conditions from:

- Contact with nonsterile surfaces
- Introduction of particulate matter or biological fluids
- Mix-ups with other conventionally manufactured products or CSPs

Immediate Use CSPs are compounded in less than ISO Class 5 conditions (e.g., bedside, countertop, operating room), with 3 or fewer sterile products, and a maximum beyond use date (BUD) of 4 hours starting from the initiation of compounding.

- CSPs exceeding these parameters adhere to the requirements of Category 1 CSPs.

Certain drug preparation activities occurring in non-classified compounding areas fall outside the scope of USP <797> and, by definition, this SOP. Alternatively, they are governed by other USP <797> regulations or related USP Chapter requirements, including:

- **Conventionally manufactured sterile medications prepared per approved labeling** – mixing, reconstituting, or other manipulations performed according to the manufacturer's approved labeling and directions are not governed by this SOP if the following conditions are met (if not, they are subject to all of the regulations in USP <797> including this SOP):
  - Product prepared for a single dose given to a single patient only
  - Manufacturers approved labeling instructions for the diluent, resultant strength, the container closure system, and storage time are upheld.
- **Proprietary bag and vial systems** –
  - **Immediate Administration -** docking and activation per the manufacturer's labeling for immediate administration to an individual patient is not considered compounding.
  - **Future Activation & Administration -** docking of proprietary bag and vial systems for future activation and administration is considered compounding and is governed by this and related sterile practice SOPs depending on the BUD assigned (the maximum BUD for Immediate Use Compounding is $\leq$ 4 hours; if a BUD in excess of 4 hours is assigned, the docking manipulation must occur in a classified sterile compounding area and follows requirements the related Category 1 compounding).

II. POLICY

A. CSPs are eligible for immediate use compounding when all of the following criteria are met:

- Personnel are trained and demonstrate competency in aseptic technique and other skills necessary to perform immediate use compounding.

- When preparing immediate use CSPs, personnel use proper aseptic technique.
- No more than 3 different sterile products are used in the compounding of an immediate use medication. An IV fluid bag, diluent used for reconstitution, or similar component count as one of the sterile products.
- BUDs are determined from the start of the compounding process and do not exceed 4 hours, independent of storage conditions (e.g., room temperature or refrigeration) and are subject to evidence-based stability considerations that require a shorter BUD.
- Single dose starting components are only used for one patient. Unused drug or components drawn from a single-dose container are properly discarded after the preparation of the CSP.
- Immediate use CSPs are labeled if the medication does not remain in the direct line of site of the preparer from the time of compounding until administration. Immediate use CSP labeling includes
  - Names and amounts of all active ingredients
  - Name or initials of the person who prepared the CSP
  - Date and time from start of CSP preparation
  - Exact 4-hour time period within which the administration of the CSP must occur

B. Administration of immediate use compounds begins within 4 hours of the start of CSP preparation or is promptly and appropriately discarded.

C. Other considerations are made, depending on the urgency of the patient care situation, to help ensure the sterility of the immediate use CSP, including but not limited to:

- Ensure the area where immediate use compounding occurs is not located immediately adjacent to a water source, under or around a high particle generating source (e.g., directly under an air vent or next to a printer), or in a high traffic area.
- If the only area for preparation is near a sink, ensure a splash guard is installed to prevent cross-contamination.

D. A Master Formulation Record is created for immediate use CSPs prepared for more than one patient. When these preparations are compounded, the Master Formulation Record is followed, and a Compounding Record is created in a written or electronic format that is retained and readily accessible.

III. ROLES & RESPONSIBILITIES

1. The Designated Person(s) (DP) and/or Designee:
   - Oversees training and competency assessment of personnel performing Immediate Use Compounding; determine corrective action plans for competency deficiencies.
   - Ensures ongoing compliance with this SOP.
   - Collects and retains training and competency documentation for Compounding Personnel in a readily retrievable format.
   - Partners with other departments and health care professionals performing immediate use compounding (e.g., nursing) to ensure personnel who compound immediate use sterile preparations receive appropriate education and training necessary to safely perform related job duties.
2. Personnel performing immediate use compounding:
   - Successfully complete all required training and competencies prior to performing immediate use compounding.
   - Participate in ongoing training and competencies as determined by the DP.

IV. DEFINITIONS

- **Administration:** The direct application of a sterile medication to a single patient by injecting, infusing, or otherwise providing a sterile medication in its final form.

- **Aseptic technique:** A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
- **Beyond-Use Date (BUD):** The date and time after which a CSP shall not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
- **Classified area:** An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).
- **Component:** Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
- **Compounded sterile preparation (CSP):** A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
- **Conventionally manufactured product:** A pharmaceutical dosage form, usually the subject of an FDA approved application, and manufactured under current good manufacturing practice conditions.
- **Critical site:** A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, and beakers) or openings (e.g., opened ampules and needle hubs) that are exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral, and mucosal secretions), or touch contamination.
- **Designated person(s):** One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.
- **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
- **Hazardous drug (HD):** Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.
- **Immediate Use CSP:** CSP aseptically compounded outside of ISO classified air for direct and immediate administration to a single patient with a maximum BUD of 4 hours from the initiation of compounding.
- **IPA:** Isopropyl alcohol.
- **PPE:** Personal protective equipment.

V. PROCEDURE

A. Training and Competency Assessments

- Personnel compounding immediate use CSPs are trained and demonstrate competency in the skills and foundational knowledge required to perform their job duties prior to compounding independently. Training, knowledge assessments, and observed competencies are documented, readily accessible, and include the following core skills:
  - Immediate use CSP component definition and related requirements
  - Hand hygiene, gloving, and garbing
  - Selecting, cleaning, and staging of compounding area
  - Calculations, measuring, and mixing
  - BUD assignment, stability considerations, and storage conditions
  - Aseptic technique and achieving and/or maintaining sterility
  - Labeling conditions and requirements
  - Documentation of the compounding process

- Successful or "passing" results for the observed Sterile Core Competencies and Knowledge Assessment are:

Observation	Validation	Initial Prior to Compounding Independently
Competency-based checklist with 100% proficiency	USP <797> & Sterile Principles Knowledge Exam	80% cumulative score

  - Observed Competency Assessments are performed and assessed initially prior to compounding independently to validate sterile practice and aseptic technique competency including:
    - Hand hygiene, gloving and garbing
    - Preparing and cleaning the compounding area
    - Aseptic technique
- Failure of observed competencies or knowledge assessments (requiring ≥ 80% passing score) results in retraining and reevaluation. Repeated failures are assessed and investigated by the Designated Person(s) or a Designee. A remediation plan is developed up to, and including, formal corrective action and suspension of immediate use compounding duties until required knowledge and skills have been successfully performed under direct observation and by written or electronic assessments.

B. Immediate Use Compounding Procedure

- Select and prepare a work surface that is free of clutter and is sanitized with an approved EPA-registered one-step cleaner prior to starting the compounding process.
- Stage medications and supplies in such a way as to reduce the risk of introduction of particulate matter or biological fluids, or mix-up with other conventionally manufactured products or CSPs before, during, and after preparation of the CSP.
- Perform hand hygiene and don medical grade gloves at a minimum, don other personal protective equipment (PPE) as available and the situation warrants. Sanitize gloves with 70% isopropyl alcohol (IPA) prior to compounding and as needed during compounding up to administration of CSP. Change gloves if they become torn or punctured.
- Sanitize critical sites (e.g., vial stoppers, ampule neck, injection port of an IV bag) with sterile 70% isopropyl alcohol wipes prior to puncture or entry.
- Prepare CSPs in accordance with evidence-based information for physical and chemical stability including, but not limited to, approved labeling mixing and storage requirements, stability and compatibility studies and data.
- Use proper aseptic technique during CSP compounding manipulations.
- Assign the most conservative BUD to the CSP possible that does not exceed 4 hours from the start of compounding. If administration does not occur within the assigned BUD (≤ 4 hours), promptly and appropriately discard the CSP.
- Ensure single dose starting components are only used for one patient and dispose of unused drug or components drawn from a single-dose container appropriately.
- When immediate use CSPs are compounded for more than one patient as a batch, refer to the Master Formulation Record for compounding instructions and ensure a Compounding Record is created, retained, and readily accessible.
- If the CSP(s) cannot remain in the direct line of site of the preparer from the time of compounding until administration, label the CSP (or individual dosing units if prepared for multiple patients) with the following:
  - Names and amounts of all active ingredients
  - Name or initials of the person who prepared the CSP
  - Date and time from start of CSP preparation
  - Exact 4-hour time period within which the administration of the CSP must occur.

- Prior to dispensing, perform a final visual verification of the CSP(s) and reject the preparation if visual contamination in found.
- Ensure administration of the CSP begins within 4 hours of the start of compounding. Promptly and safely discard of the CSP if administration does not occur within the 4-hour timeframe.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Facilities and Engineering Controls for Sterile Compounding Areas**
Policy Number/ Version:	797 – 2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the design standards and acceptance criteria for sterile compounding facilities and engineering controls within Watsonville Community Hospital.

- [USP 797] Sterile compounding facilities must be designed, outfitted, and maintained properly to minimize the risk of contamination of compounded sterile preparations (CSPs).

1.2. These design standards and specifications guide new construction, remodels, and maintenance of existing spaces to ensure compliance with USP <797> and other applicable standards or regulations.

1.3. [USP 797] Primary Engineering Controls (PECs) aid in achieving required air quality classifications. Proper design and controls are required to minimize the risk of exposure of CSPs to airborne contaminants.

- **Primary Engineering Controls (PECs)** are devices or zones that provide an ISO Class 5 air quality environment for sterile compounding.
- **Classified areas** in which the air quality is controlled include ante rooms, buffer rooms, and PECs.
- **Segregated Compounding Areas (SCAs)** are unclassified areas without an ante room or buffer room. PECs may be located in an SCA, but limited to Category 1 compounding.
- The ISO standards for air quality in controlled environments are provided below and referenced throughout this policy.

ISO Classification of Particulate Matter in Room Air	
ISO Class	Particle Count per Cubic Meter
3	35.2
4	352
5	3520
6	35,200
7	352,000
8	3,520,000

- Refer to the **Sterile Compounding Program Overview** for a summary of the types of PECs used at Watsonville Community Hospital.

2. Policy

2.1. [USP 797] Segregated compounding areas (SCA) are separated from areas not directly related to compounding.

2.2. [USP 797] Facility designs take into account the number of personnel and their movements, and the impact the placement of equipment, supplies, and components could have on the maintenance of air quality.

2.3. [USP 797] Compounding facilities must be designed so that air quality improves with movement through separate operational areas to the PEC.

2.4. [USP 797] **Design and Acceptance Criteria for PECs**

- The PEC provides the direct compounding area for preparation of CSPs. Unidirectional airflow must be maintained in the PEC.
- The PEC selected must meet ISO 5 classification during dynamic operating conditions and be designed to minimize the risk of contamination during compounding of CSPs.
- Placement of the PEC within the SCA must allow for cleaning around the PEC.

2.5. [USP 797] **Design and Acceptance Criteria for the SCA:**

- The SCA must contain a PEC and is suitable for compounding of Category 1 CSPs.
- The SCA and all surfaces (e.g., walls, floors, counters, and equipment) in the SCA must be clean, uncluttered and dedicated to compounding.
- Surfaces in the SCA should be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.
    - Surfaces should be resistant to damage (e.g., rust) by cleaning agents, sporicidal and other types of disinfectants, and tools used to clean.
- Dust-collecting overhangs, such as utility pipes, and ledges, such as windowsills, should be minimized.
    - If overhangs or ledges are present, they must be easily cleanable.
- The SCA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC.
- The SCA must not be located in where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA.
- The area within 1 m of the PEC should be dedicated only for sterile compounding and [Best Practice] defined with a Perimeter Line, if the SCA is not physically separated by walls.

2.6. [USP 797] **Water Sources**

- Sink placement for hand hygiene and garbing is considered based on workflow and function of the PEC.
    - Sinks should enable hands-free use.
- Segregated Compounding Area:
    - A hand-washing sink must be placed not closer than 1m to the PEC and may be either inside the SCA or in close proximity to the SCA.

2.7. [USP 797] **Other design considerations for maintaining the compounding environment:**

- Sterile compounding facilities must be designed to provide a well-lighted and comfortable working environment. Refer to *USP <1066>: Physical Environment That Promote Safe Medication Use* for additional details and considerations.
- Temperature: There are no specific requirements for temperature or humidity in an SCA. However, temperature of 20-25°C/68-77°F for controlled room temperature can minimize the risk of microbial proliferation and provide comfortable compounding conditions for personnel.

- Temperatures shall not exceed 20-25°C/68-77°F for controlled room temperature, per *USP <659> Packaging and Storage Requirements.*
- Free-standing air conditioners, humidifiers and dehumidifiers must not be used within the classified area or SCA.

- Pressure: No pressure differential is required for unclassified SCAs.

2.7. [USP 797] **Design and Acceptance Criteria for Air Quality and Air Exchange:**

- Refer to the table below for a summary of requirements for ISO classification, pressure differential and air changes.

MINIMUM REQUIREMENTS FOR ISO CLASSIFICATION, PRESSURE DIFFERENTIAL AND AIR EXCHANGES			
SEC type	ISO class	Pressure Differential (in "w.c.")	Air Changes Per Hour (ACPH)
SCA	Unclassified	N/A	N/A

- Refrigerators, freezers and other particle-generating equipment is placed near air returns whenever possible.

3. Roles & Responsibilities

3.1. The Designated Person(s):

- [USP 797] Ensure each area related to CSP preparation meets the classified air quality standards appropriate for the activities to be conducted in that area.
- [USP 797] Ensure the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have the appropriate air quality.
- Determine the definition of dynamic operating conditions for each PEC in use.
- Coordinate with building facilities and certification professionals to ensure preventive maintenance activities and/or repairs are completed with minimal impact to pharmacy operations.
- Coordinate with Infection Prevention and Construction Management regarding any planned construction to assess and mitigate impact to pharmacy operations.
- Direct corrective action and preventive action procedures to ensure facilities remain or return to as designed specifications.

3.2. Compounding Personnel:

- Know appropriate operating conditions for PECs.
- Record environmental monitoring data, as appropriate.
- Report out of specifications facility issues to the Designated Person and/or Designee for corrective action.

4. Procedures

4.1. Documentation of Environmental Monitoring Specifications

- [USP 797] Pharmacy personnel document temperature and pressure, as appropriate, in electronic log for each compounding area daily when compounding occurs.
  - If no compounding occurs, the log is clearly marked to indicate such.
- If any value is out of specifications, report to the Designated Person and follow the procedure described in the **Out of Specifications policy**.

4.2 Preventive Maintenance for PECs

- Change prefilters for all PECS every six (6) months or as indicated by the manufacturer or operating conditions. Document changes on log or electronic form (e.g., Simplifi).
- Visually assess HEPA filters for staining, rips or tears at least monthly and stop compounding immediately if any compromise is found. Visual inspection is completed by looking through the protective screen. Do not remove the diffuser screen.
- Visually assess all inside and outside surfaces PEC during the monthly clean, inspecting for signs of rust or damage.

5. Definitions

5.1 **ACPH:** Air changes per hour

5.2 **Airlock:** A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas.

5.3 **Anterooms:** and ISO 8 or cleaner room with fixed walls and doors where personnel hand hygiene and garbing are performed, as well as staging of components, and other activities that generate higher levels of particulates. The ante room is the transition room between the unclassified area of the facility and the buffer room.

5.4 **Buffer rooms**: an ISO 7 or cleaner room with fixed walls and doors where ISO Class 5 PECs are located and CSPs are prepared. The buffer room may only be access through the ante room or another buffer room.

5.5 **Classified area:** an area that maintains an air quality classification based on the ISO standards required in this chapter.

5.6 **Cleanroom suite:** the anteroom and buffer room(s).

5.7 **Dynamic operating conditions:** conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person.

5.8 **HVAC:** heating, ventilation, and air conditioning.

5.9 **Pass-through chamber:** an enclosure with sealed doors on both sides that should be interlocked; positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.

5.10 **Perimeter:** a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA.

5.11 **Primary Engineering Control (PEC):** a device or zone that provide an ISO Class 5 air quality environment for sterile compounding.

5.12 **Secondary Engineering Control (SEC):** the area where the PEC is placed e.g., a cleanroom suite or an SCA.

5.13 **Segregated Compounding Area (SCA):** a designated space, area, or room that is unclassified and defined with a visible perimeter.

5.14 **Unclassified space:** a space not required to meet any air cleanliness classification based on the ISO.

6. Related Policies, Documents, References

6.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2 United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

6.3 United States Pharmacopeial Convention, Inc. <1066> Physical Environment That Promote Safe Medication Use. Most current version.

6.4 United States Pharmacopeial Convention, Inc. <659> Packaging and Storage Requirements. Most current version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval 10/2023
Next review:	Month/year

7.1 Initial version published by Wolters Kluwer 2023.

7.2 Revised MM/YYYY with the following key changes…OR…with no changes.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Facilities and Engineering Controls for Sterile Compounding Areas	Policy #	PHARM2725
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

This policy describes the design standards and acceptance criteria for sterile compounding facilities and engineering controls within Watsonville Community Hospital.

- Sterile compounding facilities must be designed, outfitted, and maintained properly to minimize the risk of contamination of compounded sterile preparations (CSPs).

These design standards and specifications guide new construction, remodels, and maintenance of existing spaces to ensure compliance with USP <797> and other applicable standards or regulations.

Primary Engineering Controls (PECs) aid in achieving required air quality classifications. Proper design and controls are required to minimize the risk of exposure of CSPs to airborne contaminants.

- **Primary Engineering Controls (PECs)** are devices or zones that provide an ISO Class 5 air quality environment for sterile compounding.
- **Classified areas** in which the air quality is controlled include ante rooms, buffer rooms, and PECs.
- **Segregated Compounding Areas (SCAs)** are unclassified areas without an ante room or buffer room. PECs may be located in an SCA, but limited to Category 1 compounding.
- The ISO standards for air quality in controlled environments are provided below and referenced throughout this policy.

ISO Classification of Particulate Matter in Room Air	
ISO Class	Particle Count per Cubic Meter
3	35.2
4	352
5	3520
6	35,200
7	352,000
8	3,520,000

- Refer to the **Sterile Compounding Program Overview** for a summary of the types of PECs used at Watsonville Community Hospital.

II. POLICY

A. Segregated compounding areas (SCA) are separated from areas not directly related to compounding.

B. Facility designs take into account the number of personnel and their movements, and the impact the placement of equipment, supplies, and components could have on the maintenance of air quality.

C. Compounding facilities must be designed so that air quality improves with movement through separate operational areas to the PEC.

D. **Design and Acceptance Criteria for PECs**

- The PEC provides the direct compounding area for preparation of CSPs. Unidirectional airflow must be maintained in the PEC.
- The PEC selected must meet ISO 5 classification during dynamic operating conditions and be designed to minimize the risk of contamination during compounding of CSPs.
- Placement of the PEC within the SCA must allow for cleaning around the PEC.

E. **Design and Acceptance Criteria for the SCA:**

- The SCA must contain a PEC and is suitable for compounding of Category 1 CSPs.
- The SCA and all surfaces (e.g., walls, floors, counters, and equipment) in the SCA must be clean, uncluttered and dedicated to compounding.
- Surfaces in the SCA should be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.
  - Surfaces should be resistant to damage (e.g., rust) by cleaning agents, sporicidal and other types of disinfectants, and tools used to clean.
- Dust-collecting overhangs, such as utility pipes, and ledges, such as windowsills, should be minimized.
  - If overhangs or ledges are present, they must be easily cleanable.
- The SCA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC.
- The SCA must not be located in where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA.
- The area within 1 m of the PEC should be dedicated only for sterile compounding and defined with a Perimeter Line, if the SCA is not physically separated by walls.

F. **Water Sources**

- Sink placement for hand hygiene and garbing is considered based on workflow and function of the PEC.
  - Sinks should enable hands-free use.
- Segregated Compounding Area:
  - A hand-washing sink must be placed not closer than 1m to the PEC and may be either inside the SCA or in close proximity to the SCA.

G. **Other design considerations for maintaining the compounding environment:**

- Sterile compounding facilities must be designed to provide a well-lighted and comfortable working environment. Refer to *USP <1066>: Physical Environment That Promote Safe Medication Use* for additional details and considerations.
- Temperature: There are no specific requirements for temperature or humidity in an SCA. However, temperature of 20-25°C/68-77°F for controlled room temperature can minimize the risk of microbial proliferation and provide comfortable compounding conditions for personnel.
  - Temperatures shall not exceed 20-25°C/68-77°F for controlled room temperature, per *USP <659> Packaging and Storage Requirements.*
  - Free-standing air conditioners, humidifiers and dehumidifiers must not be used within the classified area or SCA.
- Pressure: No pressure differential is required for unclassified SCAs.

H. **Design and Acceptance Criteria for Air Quality and Air Exchange:**

- Refer to the table below for a summary of requirements for ISO classification, pressure differential and air changes.

MINIMUM REQUIREMENTS FOR ISO CLASSIFICATION, PRESSURE DIFFERENTIAL AND AIR EXCHANGES			
SEC type	ISO class	Pressure Differential (in "w.c.")	Air Changes Per Hour (ACPH)
SCA	Unclassified	N/A	N/A

- Refrigerators, freezers and other particle-generating equipment is placed near air returns whenever possible.

III. ROLES & RESPONSIBILITIES

1. The Designated Person(s):
   - Ensure each area related to CSP preparation meets the classified air quality standards appropriate for the activities to be conducted in that area.
   - Ensure the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have the appropriate air quality.
   - Determine the definition of dynamic operating conditions for each PEC in use.
   - Coordinate with building facilities and certification professionals to ensure preventive maintenance activities and/or repairs are completed with minimal impact to pharmacy operations.
   - Coordinate with Infection Prevention and Construction Management regarding any planned construction to assess and mitigate impact to pharmacy operations.
   - Direct corrective action and preventive action procedures to ensure facilities remain or return to designed specifications.
2. Compounding Personnel:
   - Know appropriate operating conditions for PECs.
   - Record environmental monitoring data, as appropriate.
   - Report out of specifications facility issues to the Designated Person and/or Designee for corrective action.

IV. DEFINITIONS

- **ACPH:** Air changes per hour
- **Airlock:** A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas.
- **Anterooms:** and ISO 8 or cleaner room with fixed walls and doors where personnel hand hygiene and garbing are performed, as well as staging of components, and other activities that generate higher levels of particulates. The ante room is the transition room between the unclassified area of the facility and the buffer room.
- **Buffer rooms**: an ISO 7 or cleaner room with fixed walls and doors where ISO Class 5 PECs are located and CSPs are prepared. The buffer room may only be access through the ante room or another buffer room.
- **Classified area:** an area that maintains an air quality classification based on the ISO standards required in this chapter.
- **Cleanroom suite:** the anteroom and buffer room(s).
- **Dynamic operating conditions:** conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person.
- **HVAC:** heating, ventilation, and air conditioning.
- **Pass-through chamber:** an enclosure with sealed doors on both sides that should be interlocked; positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.

- **Perimeter:** a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA.
- **Primary Engineering Control (PEC):** a device or zone that provide an ISO Class 5 air quality environment for sterile compounding.
- **Secondary Engineering Control (SEC):** the area where the PEC is placed e.g., a cleanroom suite or an SCA.
- **Segregated Compounding Area (SCA):** a designated space, area, or room that is unclassified and defined with a visible perimeter.
- **Unclassified space:** a space not required to meet any air cleanliness classification based on the ISO.

V. PROCEDURE

A. Documentation of Environmental Monitoring Specifications

- Pharmacy personnel document temperature and pressure, as appropriate, in electronic log for each compounding area daily when compounding occurs.
  - If no compounding occurs, the log is clearly marked to indicate such.
- If any value is out of specifications, report to the Designated Person and follow the procedure described in the **Out of Specifications policy**.

B. Preventive Maintenance for PECs

- Change prefilters for all PECS every six (6) months or as indicated by the manufacturer or operating conditions. Document changes on log or electronic form (e.g., Simplifi).
- Visually assess HEPA filters for staining, rips or tears at least monthly and stop compounding immediately if any compromise is found. Visual inspection is completed by looking through the protective screen. Do not remove the diffuser screen.
- Visually assess all inside and outside surfaces PEC during the monthly clean, inspecting for signs of rust or damage.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.
- United States Pharmacopeial Convention, Inc. <1066> Physical Environment That Promote Safe Medication Use. Most current version.
- United States Pharmacopeial Convention, Inc. <659> Packaging and Storage Requirements. Most current version.

VII. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Compounded Sterile Products: Sterile Compounding Facility Management	Policy #	PHARM2725
Responsible	Pharmacy Director	Revised/Reviewed	05/2022

I. PURPOSE

- To outline the general considerations involved in managing the controlled environments in the compounding area of the Pharmacy.
- The controlled environments are defined as the buffer area, cleanrooms, ante-area, anterooms, and segregated compounding areas, if applicable.

II. ABBREVIATIONS:

See Policy# 2727: Compounded Sterile Products: Sterile Compounding Procedures and Aseptic Techniques

- ACPH = air changes per hour
- BSCs = Biological Safety Cabinet
- CAIs = Compounding Aseptic Isolator
- CACIs = Compounding Aseptic Containment Isolator
- CSP = Compounded Sterile Product
- LAFWs = Laminar Air Flow Workbench
- PECs = Primary Engineering Control

III. POLICY/PROCEDURE

A. Compounding facilities must be designed and constructed in keeping with applicable federal, state, and local regulations as well as in keeping with professional standards of practice.
B. The facility is designed and maintained to minimize airborne contamination from contacting critical sites.
C. Activity related to compounded sterile preparations (CSPs) must be performed aseptically within primary engineering controls (i.e., LAFWs, BSCs, CAIs, CACIs) that are located in ISO Class 7 areas contiguous to an ISO Class 7/8 ante-area.
D. Activity within these critical environments in the facility is restricted to appropriately trained and attired personnel.
E. Compounding staff must be knowledgeable about the principles of HEPA filtered unidirectional airflow and its effect on the compounding environment.
F. Classified compounding environment and PECs must be certified by a properly credentialed vendor every 6 months according to the standards detailed in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006).
G. Primary Engineering Controls
    1. Primary engineering controls (i.e., LAFWs, BSCs, CAIs, CACIs) must be capable of maintaining ISO Class 5 conditions or better under dynamic operating conditions.
    2. Airborne contamination control is achieved through the use of HEPA filters with unidirectional flow.

3. HEPA filtered air must be supplied to the critical compounding areas at a velocity sufficient to sweep particles away from the compounding area but maintain a unidirectional flow during compounding.
4. Proper design and employee work practices ensure prevention of turbulence and stagnant air.
5. Since PECs augment the room air changes, PEC contribution to total ACPH (air changes per hour) in a given room location may be accounted for; however, the PEC may not be the only source of HEPA filtered air.
6. PECs must be located within an ISO Class 7 buffer area where personnel access is restricted to those responsible for compounding and cleaning.
7. CAIs and CACIs only shall be afforded an exception to required placement within an ISO Class 7 buffer area and only if they meet all of the following conditions:
   a. The isolator provides isolation from the room and maintains an ISO Class 5 environment during dynamic operating conditions including transfer of ingredients, components and devices into and out of the isolator during preparation of CSPs.
   b. Particle counts sampled 6 – 12 inches upstream of the critical exposure site maintain ISO Class 5 levels during compounding operations.
   c. Not more than 3520 particles (0.5 um and larger) per m^3 shall be counted during material transfer with a particle counter probe located as near to the transfer door as possible without obstructing the transfer itself.
8. Isolator manufacturers must provide documentation that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8.
9. When isolators are used for sterile compounding, the recovery time needed to achieve ISO Class 5 air quality will be documented and internal procedures are developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.
10. If a BSC and LAFW can not be located in an ISO Class 7 buffer area, then those PECs can only be used to compound low risk level non hazardous CSPs and the administration of those CSPs must commence within 12 hours of preparation or less if recommended in the manufacturer's package insert.

H. Buffer Area/Cleanrooms
1. Buffer areas, cleanrooms, must be designed to maintain at least an ISO Class 7 or better environment under dynamic operating conditions.
2. The buffer area must be segregated from unclassified spaces to reduce the risk introduction of viable and non-viable contaminants.
3. A minimum differential positive pressure of 0.02 inches water column (wc) must be maintained for buffer areas that are segregated from the ante-area by means of physical walls and doors separating the buffer area from adjacent spaces.
4. For buffer areas not physically separated from ante-areas, segregation is achieved by displacement airflow which requires an air velocity of at least 40 feet per minute from the buffer area across the line of demarcation into the ante-area.
5. Air displacement physical plants may not be used if high risk compounding is to occur at this facility.
6. Hazardous drugs will be stored and prepared in a buffer area that has not less than 0.01 inch wc negative pressure to the adjacent ISO Class 7 or better anteroom.
7. ISO 7 buffer areas and anterooms must achieve not less than 30 air changes per hour (ACPH).
8. If a given area has an ISO Class 5 re-circulating device, then air supply through the HEPA filters of 15 ACPH is adequate providing the combined room and PEC total is not less than 30 ACPH.

9. More air changes may be required and is influenced by the following: size of the room, number of compounding personnel, and types of processes.

I. Ante-area/rooms
   1. Ante-area/rooms must be designed to maintain at least an ISO Class 8 (for anterooms associated with only non-hazardous compounding) or better environment under dynamic operating conditions.
   2. Anterooms adjacent to negative pressure buffer areas used for hazardous compounding must maintain ISO Class 7 or better air under dynamic operating conditions to protect the air in the hazardous buffer area since it is negative pressure to the anteroom.

J. Construction and Design Considerations
   1. HEPA filtered air should be introduced at the ceiling
   2. Returns should be mounted low on the walls.
   3. The design should result in an overall top down dilution of area air with HEPA filtered make up air.
   4. Ceiling mounted wall returns are not recommended.
   5. All HEPA filters should be efficiency tested at the factory and then leak tested again on site to verify that HEPA was not damaged during transportation and installation.

K. Minimizing airflow disruption
   1. PECs must not be placed near doors, personnel traffic or other airstreams that may negatively affect their unidirectional airflow.
   2. PECs and other furniture shall be placed:
      a. Out of traffic flow,
      b. In a manner that avoids disruption from the HVAC system and cross drafts,
      c. Away from returns. If a PEC or other furniture must be placed in front of a return, then it must be at least 4 inches away from the front of the return grill.

L. Materials
   1. Surfaces of ceiling, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area must be smooth, impervious, free from cracks and crevices, non-shedding, and resistant to damage by disinfecting agents.
   2. The above characteristics make the surfaces easily cleanable and reduce the spaces in which microorganisms or nonviable contaminants could build up.
   3. Work surfaces must be made of smooth, impervious materials such as plastic or preferable, stainless steel, so they can withstand repeated cleanings. Furniture should be movable.
   4. Buffer and Anteroom furniture should be on casters whenever possible to facilitate cleaning. With the exception of PECs, other buffer area and ante-area furniture should be movable.
   5. Prior to bringing new furniture/equipment into the buffer area (stainless steel shelving, metro carts, ACDs, etc.), they should be triple cleaned.
   6. Equipment and furniture cleaned and placed in the buffer area should remain there.
   7. If carts are used to stage components/batches, a clean cart must be dedicated to the buffer area and not brought beyond the line of demarcation in the anteroom.
   8. Junctures of ceilings to walls and walls to floors should be coved or caulked to avoid cracks where dirt can accumulate.
   9. If ceilings consist of inlaid panels, they should be impregnated with a polymer to render them impervious and hydrophobic and they must be caulked around each perimeter to seal them to the support frame.

10. Walls may be constructed of epoxy-coated gypsum board or flexible material such as heavy gauge polymer, but panels must be locked together and sealed.
11. Floors are overlaid with wide sheet vinyl that has heat-welded seams and is coved at the sidewall.
12. Any irregularities, overhangs, sills, utility pipes and ledges that could collect dust should be avoided.
13. The exterior lens surface of ceiling light fixtures must be smooth, flush mounted and sealed. Any other penetrations in the ceilings or walls should be sealed.
14. Water sources such as sinks and drains shall not be located in the buffer area.

M. Temperature and Humidity of Controlled Environments
1. Ideally, cleanrooms/buffer rooms must be maintained at delineated temperature and humidity level that have been determined to facilitate comfortable conditions for heavily garbed and gloved compounders thereby increasing the likelihood they will perform flawlessly. These conditions also increase safety and minimize particle shed.
2. Ideal temperature of 20° Celsius (68° Fahrenheit) should be achieved during dynamic operating conditions through an acceptable range for cleanroom temperatures is 18° - 21° Celsius (64° - 70° Fahrenheit).
3. Relative humidity must be maintained within a range of 25 – 60 %.

N. Environmental and Work Practices Controls are continuously monitored.

IV. DEFINITIONS

N/A

I. REFERENCES

Joint Commission Standards: EC.02.01.01 EP 3, EC.02.05.01 EP 6, EC.02.06.01 EP 13, IC.02.02.01 EP 1, LD.03.06.01 EP 1, MM.05.01.07 EP 1

II. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Out of Specification Events Impacting Sterile Facilities, Environmental Controls, & Systems**
Policy Number/ Version:	797– 2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the procedures for managing power and airflow systems disruptions creating out of specification conditions for sterile facilities, engineering controls, and environmental controls where Compounded Sterile Preparations (CSP) are prepared within Watsonville Community Hospital.

1.2. The ability to maintain a state of control within classified and controlled sterile compounding areas is essential to maintaining CSP sterility and stability. Sterile facilities and systems are key factors in establishing and maintaining consistent airflow, pressure differentials, and storage area conditions including:

- **Facilities:** Compounding area design and construction; HEPA filter placement and function; HVAC (heating, ventilation, and air conditioning), exhaust, and supply fan systems
- **Engineering Controls**: PEC placement and contribution to airflow
- **Environmental Controls**: Pressure differential and temperature monitoring systems

1.3. Planned and unplanned maintenance, power surges/outages, system malfunction, and natural disasters impact the proper functioning the sterile facilities and systems and can have significant impact to the ability to maintain ISO Class 5 PEC function; requisite temperature in storage areas; and proper airflow and HEPA filter contribution to removing airborne contamination in PEC.

1.4. This policy addresses remedial actions for PEC out of specification (OOS) conditions are directly applicable to PECs located in Segregated Compounding Areas (SCAs).

1.5. Watsonville Community Hospital has PECs in SCA (Segregated Compounding Area).

2. Policy

2.1. [USP 797] Sterile compounding areas (e.g., SCA), engineering controls (PECs), and environmental control systems are maintained in good working order and undergo appropriate and timely certifications, calibrations, and accuracy validations per regulations and manufacturer recommendations. Refer to **Facilities and Engineering Controls policy**.

2.2. [USP 797] Required pressure differentials and air exchanges per hour within classified areas are maintained at the following levels:

MINIMUM REQUIREMENTS PER ISO CLASSIFIED AREA				
SEC type	**ISO class**	**Pressure Differential (in "w.c.")**	**Air Changes Per Hour (ACPH)**	**Temperature & Relative Humidity**
SCA	Unclassified	N/A	N/A	There are no specific requirements for temperature or humidity in an SCA

2.3. [USP 797] Controlled storage area and device temperatures are maintained at the following levels:
- Controlled Room Temperature: 20°C - 25°C (68°F - 77°F)
- Refrigerated Temperature: 2°C - 8°C (36.8°F – 46.4°F)

2.4. [USP 797] Environmental control systems are monitored via continuous monitoring systems and manually read devices and trigger alarms and alerts to key personnel including the Designated Person(s) (DP) and Designee when conditions deviate from required values.

2.5. [USP 797] When power outages or system malfunctions impact PECs or drug storage locations, immediate action is taken to protect the integrity of CSPs, components, and the state of control within the controlled compounding areas.

2.6. [USP 797] Until normal operations can be restored, and appropriate remediation occurs (as described in this policy), compounding areas and BUDs assigned to CSPs are subject to the following changes:

Area(s) Impacted by Power &/or System Disruption	Impact to Sterile Suite Classification & BUDs Until Resolved	Immediate Actions
PEC(s) Only	**CSP BUDs**: No change*	• Immediately halt compounding in affected PEC* ➔ OK to compound in functioning PECs • Record time of OOS event

* If emergency compounding performed in nonfunctiong PECs, use Immediate Use Compounding BUD of ≤ 4 hour BUD (compounding in a non-ISO Class 5 environment).

2.7. Before the resumption of normal compounding operations, the Designated Person(s) and/or Designee validates all impacted systems and equipment have been restored to normal function, appropriate remediation has occurred and validated, and a state of control has been restored to the compounding environment.

2.8. PECs are recertified before use if the outage or systems disruption exceeds 24 hours. If normal operations are restored more quickly, recertification is at the descretion of the Designated Person(s) and/or Designee.

2.9. [USP 797] Out of specification events impacting facilities, engineering controls, environmental controls, or drug storage areas are investigated, and appropriate corrective actions are taken. These efforts can occur concurrently with the immediate remediation efforts required to restore the sterile compounding area to a state of control and normal function. Corrective action efficacy is validated, and all aspects of the investigation, corrective actions, and efficacy validation is documented and retained in a readily accessible format.

3. Roles & Responsibilities

3.1. Designated Person(s) (DP) (and/or Designee):

- Oversee and coordinate personnel, supporting departments, vendors, and subject matter experts (if needed) to expiditiously and safely restore impacted systems and areas.
- In partnership with appropriate departments (e.g, Infection Prevention, Facilities), consider conducting an impact assessment to compounding operations and BUD assignments.
- Determine, coordinate, & communicate situational assessment and alternative compounding arrangements to impacted personnel, prescribers, and patients (as needed) for extended OOS events.

- After repairs, system restoration, and remediation efforts have occured, confirm impacted areas have been returned to a state of control and authorize resumption of normal compounding operations and BUD assignments.
- Lead OOS event investigation and corrective plan design, implementation, and validation; review and complete documentation and retain in a readily retrievable format.
- Provide status updates and postmortem analysis and report/presentation as needed.

3.2. Compounding Personnel:

- Immediately contact DP and/or Designee when power and/or systems disruptions occur that impact the proper functioning of PECs and/or temperature.
- Rapidly implement immediate actions as described in this policy and as directed by the DP and/or Designee in response to power or system disruptions impacting normal operations within the sterile compounding areas.
- Support all efforts to minimize actions that could contribute to the decline in the state of control within the sterile suite, such as unnecessary entry/exit of the compounding areas during OOS events
- Consult the DP and/or Designee as needed.

3.3. Supervising Pharmacist / Designee (or proxy for DP):

- When the DP is not immediately available, assume all DP responsibilities in coordinating the initial response and efforts to restore normal compounding operations as quickly and safely as possible.
- Ensure available compounding personnel understand the immediate impact to the compounding operation, ability to compound CSPs, BUDs (if appropriate), and role and responsibilities as the OOS event is addressed.
- Ensure the Facilities Department, external vendor(s), or other critical systems contacts are notified immediately; continue communication and coordination with these entities until the technical and/or mechanical issues have been restored and power and/or systems are restored to normal function.
- When power and/or systems are restored, ensure compounding staff understands the required remedial activities (e.g., cleaning, microbial sampling) that need to occur as described in this policy.
- When a hand-off to the DP or alternative Supervising Pharmacist/Designee occurs, provide a full debrief of actions taken, individuals contacted, and events that have occur to restore normal operations and ensure continuity in patient care.

4. Procedures

Managing Power Outages or Disruptions *(USP <797> does not define required remediation steps for power outages; use the following procedures and tables as a starting point to define how your organization manages these situations).*

4.1. **PEC Only**: When the power to a PEC is turned off or if a power surge or outage (e.g., cutover to generator power) disrupts power to a PEC:

- Stop compounding activities immediately in the impacted PEC(s) and restore power to the PEC(s) as soon as possible.
- Notify DP or Supervising Pharmacist/Designee.

- Determine disposition of CSPs and components inside the PEC at the time of the power disruption (see table below).
- Once the power is restored, allow the PEC to run for 30 minutes or for the timeframe stated by the manufacturer to restore the ISO Class 5 environment.
- Fully clean and disinfect all interior surfaces of PEC with an appropriate cleaning agent after the designated run time (above) and prior to resuming compounding activities as described below.

Outage Timeframe	Cleaning of PEC Interior {{*30 minutes*}} after Power Restored	Handling of Components	Handling of Affected CSPs
< 1 hour	*One-step disinfectant cleaner followed by sIPA to remove residue; observe dwell times*	*Date & store components per policy* Single use components: < 12 Hour BUD Multi-dose components: < 28 Days BUD Accessed components: Discard (spiked bags or vials with attached tubing or transfer sets)	Completed: remove from hood and label; BUD unaffected Partially compounded or "in-process" CSPs: discard or complete compounding as an Immediate Use CSP (≤ 4-hour BUD) Uncompounded batched CSPs (components): move to another PEC or sanitize and compound after power is restored to PEC and it is cleaned
1 to 24 hours	*Sporicidal disinfectant followed by sIPA; observe dwell times*		
> 24 hours	Triple clean followed by sIPA; observe dwell times		

- When an outage extends beyond 24 hours, consider recertifying the PEC(s).
- Investigate the OOS power outage event, implement corrective actions, and verify the corrective actions have been effective. Document all aspects of the investigation, corrective action plan, and data collected to verify effectiveness. Retain documentation in a readily retrievable format and location.

4.2. Drug Storage Device Power Outages & Temperature Excursions

- Record the time of power outage
- Record the temperature of each affected device when the outage occurred
- Restrict or halt device access and ***post signage on the device(s)***
- Contact Facilities Department or external device technicians immediately if the source of the outage or temperature excursion is unknown or if outage extends beyond 15 minutes. If source of excursion is known (e.g., refrigerator door left open too long while stocking), monitor device temperature for 15 minutes contact Facilities Department or external vendor.
- Continue to monitor device temperature and if/when device exceeds or is soon expected to exceed acceptable temperature deviation, relocate products to alternative storage locations meeting the required storage conditions.

Type/Purpose of Device	Expected Temp Range	Drug Relocation Trigger(s)
CSP Controlled Room Temperature Drug Storage Area	20°C - 25°C (68°F - 77°F)	*± 5°C for no more than 30 minutes (15°C = 59°F, 30°C = 86°)*

TYPE/PURPOSE OF DEVICE	EXPECTED TEMP RANGE	DRUG RELOCATION TRIGGER(S)
CSP Storage Refrigerator	2°C - 8°C (36.8°F – 46.4°F)	*± 3°C for no more than 30 minutes (-1°C = 30.2°F, 11°C = 51.8°)*

- If drug storage device (or area) excursions exceed these general guidelines, quarantine affected CSPs and components until the Designated Person(s) or Supervising Pharmacist/Designee can determine if the temperature excursion (e.g., both the maximum temp excursion documented and the duration of the OOS conditions) has degraded the quality of the individual items.

Troubleshooting Power Outages or System Disruptions

OOS EVENT IMPACTING STERILE COMPOUNDING AREA OR SYSTEM	TROUBLE SHOOTING
PEC loss of power	• Check power switch & power source to ensure device is on and receiving power • Check if PEC is plugged into an emergency backup power source • Check to see if power generator test is occurring or other facility test or emergency operation that would temporarily disrupt power to the emergency backup power supply
Pressure differential alarm (in PEC)	• If alarm has just gone off, allow ~ 1 minute with the door closed to determine if the pressure stabilizes and returns to normal range (doors open for an extended period of time will sound alarm) • Determine if door is shutting tightly (if not, pressure differential may be impacted) • Check to see if pressure gauge is powered • Check if pressure gauge requires replacement of internal board, other IT component, or battery back up
Temperature alarm – rooms or areas	• If alarm has just gone off, allow ~ 2-3 minutes to determine if the temperature stabilizes and returns to normal range • Confirm HVAC system is working properly
Temperature gauge – refrigerators *(if applicable)*	• Check power switch & power source to ensure device is on and receiving power • Confirm monitoring device is positioned correctly and is functioning properly (e.g., wires and power and/or batteries are operational • If a continuous monitoring device is also installed in the refrigerator and/or freezer, determine if it is also in alarm (if alarm is from an autonomous gauge) • Confirm monitoring device is glycol-based (more accurate reading) and has been maintained per manufacturer's specifications

OOS Event impacting Sterile Compounding Area or System	Trouble Shooting
	• If alarm has just gone off, allow ~ 2-3 minutes with the door closed to determine if the temperature stabilizes and returns to normal range (doors open for an extended period of time will sound alarm) • Determine if door is shutting tightly (if not, pressure differential may be impacted)

4.3. Refer to the **Quality Assurance and Quality Control policy** for procedures related to investigations and corrective action plans.

5. Definitions

5.1. **Classified area**: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for ISO class).

5.2. **Cleanroom suite** (aka sterile suite or IV room): A classified area that consists of both an anteroom and buffer room.

5.3. **Component**: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product. Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance Related Policies, Documents, References

5.4. **Designated person(s)**: One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs

5.5. **ISO class**: An air-quality classification from the International Organization for Standardization

5.6. **Negative-pressure room**: A room that is maintained at lower pressure than the adjacent spaces, and therefore the net airflow is into the room

5.7. **One-step disinfectant cleaner**: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step

5.8. **Oversight**: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed even if not physically present

5.9. **Primary engineering control (PEC)**: A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.

5.10. **Positive-pressure room**: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room

5.11. **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

5.12. **Segregated compounding area (SCA):** A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only

5.13. **Sporicidal disinfectant**: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms

5.14. **Unclassified space**: A space not required to meet any air cleanliness classification based on the ISO

6. References

6.1. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2. United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval (10/2023)
Next review:	Month/year

7.1. Initial version published by Wolters Kluwer 2023.

Revised MM/YYYY with the following key changes…OR…with no changes.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Out of Specification Events Impacting Sterile Facilities, Environmental Controls, & Systems	**Policy #**	PHARMXXXX
Responsible	Pharmacy Director	**Revised/Reviewed**	10/6/2023

I. PURPOSE

This policy describes the procedures for managing power and airflow systems disruptions creating out of specification conditions for sterile facilities, engineering controls, and environmental controls where Compounded Sterile Preparations (CSP) are prepared within Watsonville Community Hospital.

The ability to maintain a state of control within classified and controlled sterile compounding areas is essential to maintaining CSP sterility and stability. Sterile facilities and systems are key factors in establishing and maintaining consistent airflow, pressure differentials, and storage area conditions including:

- **Facilities:** Compounding area design and construction; HEPA filter placement and function; HVAC (heating, ventilation, and air conditioning), exhaust, and supply fan systems
- **Engineering Controls**: PEC placement and contribution to airflow
- **Environmental Controls**: Pressure differential and temperature monitoring systems

Planned and unplanned maintenance, power surges/outages, system malfunction, and natural disasters impact the proper functioning the sterile facilities and systems and can have significant impact to the ability to maintain ISO Class 5 PEC function; requisite temperature in storage areas; and proper airflow and HEPA filter contribution to removing airborne contamination in PEC.

This policy addresses remedial actions for PEC out of specification (OOS) conditions are directly applicable to PECs located in Segregated Compounding Areas (SCAs).

Watsonville Community Hospital has PECs in SCA (Segregated Compounding Area).

II. POLICY

A. Sterile compounding areas (e.g., SCA), engineering controls (PECs), and environmental control systems are maintained in good working order and undergo appropriate and timely certifications, calibrations, and accuracy validations per regulations and manufacturer recommendations. Refer to **Facilities and Engineering Controls policy**.

B. Required pressure differentials and air exchanges per hour within classified areas are maintained at the following levels:

MINIMUM REQUIREMENTS PER ISO CLASSIFIED AREA				
SEC type	**ISO class**	**Pressure Differential (in "w.c.")**	**Air Changes Per Hour (ACPH)**	**Temperature & Relative Humidity**
SCA	Unclassified	N/A	N/A	**There are no specific requirements for temperature or humidity in an SCA**

C. Controlled storage area and device temperatures are maintained at the following levels:

- Controlled Room Temperature: 20°C - 25°C (68°F - 77°F)
- Refrigerated Temperature: 2°C - 8°C (36.8°F – 46.4°F)

D. Environmental control systems are monitored via continuous monitoring systems and manually read devices and trigger alarms and alerts to key personnel including the Designated Person(s) (DP) and Designee when conditions deviate from required values.

E. When power outages or system malfunctions impact PECs or drug storage locations, immediate action is taken to protect the integrity of CSPs, components, and the state of control within the controlled compounding areas.

F. Until normal operations can be restored, and appropriate remediation occurs (as described in this policy), compounding areas and BUDs assigned to CSPs are subject to the following changes:

Area(s) Impacted by Power &/or System Disruption	Impact to Sterile Suite Classification & BUDs Until Resolved	Immediate Actions
PEC(s) Only	**CSP BUDs**: No change*	• Immediately halt compounding in affected PEC* ➔ OK to compound in functioning PECs • Record time of OOS event

*If emergency compounding performed in nonfunctiong PECs, use Immediate Use Compounding BUD of ≤ 4 hour BUD (compounding in a non-ISO Class 5 environment).

G. Before the resumption of normal compounding operations, the Designated Person(s) and/or Designee validates all impacted systems and equipment have been restored to normal function, appropriate remediation has occurred and validated, and a state of control has been restored to the compounding environment.

H. PECs are recertified before use if the outage or systems disruption exceeds 24 hours. If normal operations are restored more quickly, recertification is at the descretion of the Designated Person(s) and/or Designee.

I. Out of specification events impacting facilities, engineering controls, environmental controls, or drug storage areas are investigated, and appropriate corrective actions are taken. These efforts can occur concurrently with the immediate remediation efforts required to restore the sterile compounding area to a state of control and normal function. Corrective action efficacy is validated, and all aspects of the investigation, corrective actions, and efficacy validation is documented and retained in a readily accessible format.

III. ROLES & RESPONSIBILITIES

1. Designated Person(s) (DP) (and/or Designee):
   - Oversee and coordinate personnel, supporting departments, vendors, and subject matter experts (if needed) to expiditiously and safely restore impacted systems and areas.
   - In partnership with appropriate departments (e.g, Infection Prevention, Facilities), consider conducting an impact assessment to compounding operations and BUD assignments.
   - Determine, coordinate, & communicate situational assessment and alternative compounding arrangements to impacted personnel, prescribers, and patients (as needed) for extended OOS events.
   - After repairs, system restoration, and remediation efforts have occured, confirm impacted areas have been returned to a state of control and authorize resumption of normal compounding operations and BUD assignments.
   - Lead OOS event investigation and corrective plan design, implementation, and validation; review and complete documentation and retain in a readily retrievable format.
   - Provide status updates and postmortem analysis and report/presentation as needed.
2. Compounding Personnel:

- Immediately contact DP and/or Designee when power and/or systems disruptions occur that impact the proper functioning of PECs and/or temperature.
- Rapidly implement immediate actions as described in this policy and as directed by the DP and/or Designee in response to power or system disruptions impacting normal operations within the sterile compounding areas.
- Support all efforts to minimize actions that could contribute to the decline in the state of control within the sterile suite, such as unnecessary entry/exit of the compounding areas during OOS events
- Consult the DP and/or Designee as needed.

3. Supervising Pharmacist / Designee (or proxy for DP):
   - When the DP is not immediately available, assume all DP responsibilities in coordinating the initial response and efforts to restore normal compounding operations as quickly and safely as possible.
   - Ensure available compounding personnel understand the immediate impact to the compounding operation, ability to compound CSPs, BUDs (if appropriate), and role and responsibilities as the OOS event is addressed.
   - Ensure the Facilities Department, external vendor(s), or other critical systems contacts are notified immediately; continue communication and coordination with these entities until the technical and/or mechanical issues have been restored and power and/or systems are restored to normal function.
   - When power and/or systems are restored, ensure compounding staff understands the required remedial activities (e.g., cleaning, microbial sampling) that need to occur as described in this policy.
   - When a hand-off to the DP or alternative Supervising Pharmacist/Designee occurs, provide a full debrief of actions taken, individuals contacted, and events that have occur to restore normal operations and ensure continuity in patient care.

IV. DEFINITIONS

A. **Classified area**: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for ISO class).

B. **Cleanroom suite** (aka sterile suite or IV room): A classified area that consists of both an anteroom and buffer room.

C. **Component**: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product. Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance Related Policies, Documents, References

D. **Designated person(s)**: One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs

E. **ISO class**: An air-quality classification from the International Organization for Standardization

F. **Negative-pressure room**: A room that is maintained at lower pressure than the adjacent spaces, and therefore the net airflow is into the room

G. **One-step disinfectant cleaner**: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step

H. **Oversight**: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed even if not physically present

I. **Primary engineering control (PEC)**: A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.

J. **Positive-pressure room**: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room

K. **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

L. **Segregated compounding area (SCA):** A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only

M. **Sporicidal disinfectant**: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms

N. **Unclassified space**: A space not required to meet any air cleanliness classification based on the ISO

V. PROCEDURE

Managing Power Outages or Disruptions

A. **PEC Only**: When the power to a PEC is turned off or if a power surge or outage (e.g., cutover to generator power) disrupts power to a PEC:

- Stop compounding activities immediately in the impacted PEC(s) and restore power to the PEC(s) as soon as possible.
- Notify DP or Supervising Pharmacist/Designee.
- Determine disposition of CSPs and components inside the PEC at the time of the power disruption (see table below).
- Once the power is restored, allow the PEC to run for 30 minutes or for the timeframe stated by the manufacturer to restore the ISO Class 5 environment.
- Fully clean and disinfect all interior surfaces of PEC with an appropriate cleaning agent after the designated run time (above) and prior to resuming compounding activities as described below.

Outage Timeframe	Cleaning of PEC Interior {{*30 minutes*}} after Power Restored	Handling of Components	Handling of Affected CSPs
< 1 hour	*One-step disinfectant cleaner followed by sIPA to remove residue; observe dwell times*	*Date & store components per policy* Single use components: < 12 Hour BUD Multi-dose components: < 28 Days BUD Accessed components: Discard (spiked bags or vials with attached tubing or transfer sets)	Completed: remove from hood and label; BUD unaffected Partially compounded or "in-process" CSPs: discard or complete compounding as an Immediate Use CSP (< 4-hour BUD) Uncompounded batched CSPs (components): move to another PEC or sanitize and compound after power is restored to PEC and it is cleaned
1 to 24 hours	*Sporicidal disinfectant followed by sIPA; observe dwell times*		
> 24 hours	Triple clean followed by sIPA; observe dwell times		

- When an outage extends beyond 24 hours, consider recertifying the PEC(s).
- Investigate the OOS power outage event, implement corrective actions, and verify the corrective actions have been effective. Document all aspects of the investigation, corrective action plan, and data collected to verify effectiveness. Retain documentation in a readily retrievable format and location.

B. Drug Storage Device Power Outages & Temperature Excursions

- Record the time of power outage
- Record the temperature of each affected device when the outage occurred
- Restrict or halt device access and ***post signage on the device(s)***
- Contact Facilities Department or external device technicians immediately if the source of the outage or temperature excursion is unknown or if outage extends beyond 15 minutes. If source of excursion is known (e.g., refrigerator door left open too long while stocking), monitor device temperature for 15 minutes contact Facilities Department or external vendor.
- Continue to monitor device temperature and if/when device exceeds or is soon expected to exceed acceptable temperature deviation, relocate products to alternative storage locations meeting the required storage conditions.

TYPE/PURPOSE OF DEVICE	EXPECTED TEMP RANGE	DRUG RELOCATION TRIGGER(S)
CSP Controlled Room Temperature Drug Storage Area	20°C - 25°C (68°F - 77°F)	*± 5°C for no more than 30 minutes (15°C = 59°F, 30°C = 86°)*
CSP Storage Refrigerator	2°C - 8°C (36.8°F – 46.4°F)	*± 3°C for no more than 30 minutes (-1°C = 30.2°F, 11°C = 51.8°)*

- If drug storage device (or area) excursions exceed these general guidelines, quarantine affected CSPs and components until the Designated Person(s) or Supervising Pharmacist/Designee can determine if the temperature excursion (e.g., both the maximum temp excursion documented and the duration of the OOS conditions) has degraded the quality of the individual items.

Troubleshooting Power Outages or System Disruptions

OOS EVENT IMPACTING STERILE COMPOUNDING AREA OR SYSTEM	TROUBLE SHOOTING
PEC loss of power	• Check power switch & power source to ensure device is on and receiving power • Check if PEC is plugged into an emergency backup power source • Check to see if power generator test is occurring or other facility test or emergency operation that would temporarily disrupt power to the emergency backup power supply
Pressure differential alarm (in PEC)	• If alarm has just gone off, allow ~ 1 minute with the door closed to determine if the pressure stabilizes and returns to normal range (doors open for an extended period of time will sound alarm) • Determine if door is shutting tightly (if not, pressure differential may be impacted) • Check to see if pressure gauge is powered • Check if pressure gauge requires replacement of internal board, other IT component, or battery back up

OOS Event impacting Sterile Compounding Area or System	Trouble Shooting
Temperature alarm – rooms or areas	• If alarm has just gone off, allow ~ 2-3 minutes to determine if the temperature stabilizes and returns to normal range • Confirm HVAC system is working properly
Temperature gauge – refrigerators *(if applicable)*	• Check power switch & power source to ensure device is on and receiving power • Confirm monitoring device is positioned correctly and is functioning properly (e.g., wires and power and/or batteries are operational • If a continuous monitoring device is also installed in the refrigerator and/or freezer, determine if it is also in alarm (if alarm is from an autonomous gauge) • Confirm monitoring device is glycol-based (more accurate reading) and has been maintained per manufacturer's specifications • If alarm has just gone off, allow ~ 2-3 minutes with the door closed to determine if the temperature stabilizes and returns to normal range (doors open for an extended period of time will sound alarm) • Determine if door is shutting tightly (if not, pressure differential may be impacted)

C. Refer to the **Quality Assurance and Quality Control policy** for procedures related to investigations and corrective action plans.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Equipment, Supplies, & Components for Sterile Compounding**
Policy Number/ Version:	797-2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the requirements for, and assessment of the equipment used in controlled compounding areas and the supplies and components used in the preparation of Compounded Sterile Preparations (CSPs) by Watsonville Community Hospital.

1.2. Selection of equipment and furniture specifically designed for use in and constructed of materials appropriate for sterile compounding environments is integral in helping to maintain a state of control in classified and controlled areas. Durability, cleanability, and minimal, if any, shedding or particle generation are also important characteristics of equipment and furniture used within controlled areas.

1.3. Selection of high-quality sterile supplies and components from appropriately credentialled and inspected manufacturers is essential in maintaining the integrity of aseptic processes of final CSPs.

1.4. Diligence in vetting and selecting reputable vendors, wholesalers, and FDA-registered manufacturers; carefully reviewing quality data on purchased products used in sterile compounding (e.g., Certificate of Analysis or Conformance); and conducting in-process quality control inspections and tests all contribute to ensuring CSP veracity and patient safety.

2. Policy

2.1. [USP 797] Equipment and furniture used in sterile compounding environments is constructed of material appropriate for controlled areas, is easily cleanable, and can withstand cleaning agents used in sterile compounding environments. Equipment surfaces coming into contact with CSPs are additionally not reactive or sorptive.

2.2. [USP 797] Equipment, furniture, supplies, and components are thoroughly cleaned and disinfected per policy prior to introduction within the perimeter of a Segregated Compounding Area (SCA). Equipment, supplies, and components are sanitized again with sterile 70% isopropyl alcohol (sIPA) as they are introduced into an ISO Class 5 PEC.

2.3. [USP 797] Equipment is placed within the PEC in manner that facilitates compounding operations and does not obstruct laminar airflow during compounding manipulations.

2.4. [USP 797] Sterile compounding equipment is calibrated, maintained, cleaned, and used per manufacturer's instructions and recommendations and as described in the related SOPs (Standard Operating Procedures).

- Cleaning, maintenance, and calibration of equipment is documented and readily retrievable.

2.5. [USP 797] Equipment designed to deliver specific volumes of solution(s) automatically during the compounding process, such as automatic compounding devices (ACDs) or repeater pumps, undergo an accuracy assessment when initially installed and prior to use on days when the compounding with the equipment occurs.

- Daily accuracy measurements are recorded and evaluated over time to detect variation in the precision of the equipment.
- Corrective actions are taken if accuracy measurements are outside of manufacturer's specifications.

2.6. [USP 797] Supplies used in the compounding of CSPs (e.g., needles, syringes, tubing sets) are made of materials that are not reactive or sorptive. Supplies coming in direct contact with CSPs are sterile and depyrogenated.

2.7. [USP 797] Conventionally manufactured sterile products and components are used when available and appropriate for the intended use.

- [CONDITIONAL: Hospitals and healthcare systems compounding as 503A pharmacies]: When conventionally manufactured sterile products are not commercially available and there is a need for non-patient-specific CSPs to be prepared and held for use when a patient(s) is(are) identified, sterile drug products and components may be obtained from an FDA-registered 503B Outsourcing Pharmacy if available.

2.8. [USP 797] Temperature in drug storage areas is monitored and documented at least once daily on days the facility is open or by a continuous temperature recording device. Deviations are promptly investigated, and appropriate corrective actions are taken and documented.

2.9. [USP 797] Temperature monitoring equipment is calibrated or verified for accuracy per the manufacturer or once every 12 months if not specified by the manufacturer.

3. Roles & Responsibilities

3.1 The Designated Person(s) (DP) and/or Designee:

- Ensure sterile equipment, supply, and component suppliers, wholesalers, and manufacturers are fully vetted for USP <797> compliant quality manufacturing and documentation standards.
- Ensure sterile compounding equipment, if used, is maintained and calibrated on a timely basis and that documentation of equipment calibration, maintenance, and cleaning is stored in a readily retrievable format.
- Investigate, oversee, and document corrective actions related to equipment, supply, and/or component defects or failures.

3.2. Compounding Personnel:

- Prior to use in every CSP, evaluate and inspect components for correct identify, quality, expiration date, and storage conditions.
- Reject and quarantine components which are expired, have suspected or known defects that could impact the quality, potency, and/or sterility of the CSP. Notify the DP or Designee promptly of all defects.
- Conduct and document daily calibrations of compounding equipment, if used, automatically measuring component volumes (e.g., ACDs, repeater pumps). Notify DP or Designee of equipment that is out of specification and do not use the equipment until the equipment can be successfully calibrated.
- Clean equipment with the appropriate cleaning agent and observing required dwell times per the **Cleaning, Disinfection, & Application of Sporicidal Agents** policy and document cleaning activities appropriately.

4. Procedures

4.1. Selection of Compounding Equipment and Supplies

- Identify and vet reputable wholesalers and distributors of equipment and supplies for use in sterile compounding environments and aseptic processes.
- Select sterile compounding equipment constructed of materials suitable for compounding environments (e.g., stainless steel) including nonreactive or sorptive surfaces that come into direct contact with CSPs and designed to withstand cleaning processes and agents.
- Ensure sterile equipment and supplies are accompanied by appropriate end user documentation, instructions for use, and quality testing data including:

Equipment	Supplies
• User manual providing instructions for proper use, cleaning, and maintenance • Required calibration or recertification requirements, procedure, and frequency • Specifications and acceptance parameters for normal operation	• Lot number and expiration date • User instructions including any quality control testing procedure(s) and expected results, if applicable

4.2. [USP 797] Receipt, Evaluation, Handling, & Storage of CSP Components

- Move component shipping/delivery containers to receiving area and garb per facility policy
- Upon receipt, examine the external and internal packaging of each lot of CSP for signs of product deterioration or other quality impacting defects (e.g., temperature-sensing indicators indicate product has been exposed to excessive temperatures). Reject, quarantine, and notify DP and/or Designee of components with suspected or known defects.
- Once unpacked, examine components and container closure systems for cracks, leaks, or other indicators of product adulteration. Reject, quarantine, and notify DP and/or Designee of components with suspected or known defects.
- Confirm component expiration dating.
  - If component is expired or within 3 months of expiration, reject, quarantine, and notify DP and/or Designee.
  - When manufacturer's expiration date is not visible on label or labeling, clearly write or label container with an expiration date not to exceed one year from the date of receipt.
- Apply additional component/container labeling if appropriate.
- Handle and store components in a manner that prevents contamination, mix-ups, and deterioration.
- Store components in a designated, temperature controlled and monitored storage areas per manufacturer or official monograph instructions
  - Controlled Room Temperature: 20°C - 25°C (68°F - 77°F)
  - Refrigerated Temperature: 2°C - 8°C (36.8°F – 46.4°F)
- Monitor and record temperature in the area(s) where components are stored at least once daily on days that the facility is open or by a continuous temperature recording device.
- Record temperatures manually or electronically and ensure temperature logs are readily retrievable.

- Calibrate or verify accuracy of temperature monitoring equipment as recommended by the manufacturer or every 12 months if not specified by the manufacturer.

4.3. [USP 797] Introduction of Equipment, Supplies, & Components into Controlled Compounding Areas

- [BEST PRACTICE] Prior to introduction into a controlled compounding area, clean all visibly soiled equipment or furniture with a sporicidal disinfectant, EPA-registered disinfectant cleaner, or hospital grade cleaning agent.
- Clean all equipment, furniture, supplies, and components as they are moved across the line of demarcation (LOD) in the SCA. Wipe individual items with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (sIPA) and low-lint wipers.
- Place equipment and furniture within the SCA perimeter in a manner that facilitates compounding operations and does not impede airflow, workflow or traffic patterns.
- Refer to the **Workflow and Aseptic Technique for Sterile Compounding** policy.

5. Definitions

5.1. **ACD**: Automated compounding device.

5.2. **Active pharmaceutical ingredient (API)**: Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as Bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).

5.3. **Certificate of analysis (COA)**: A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.

5.4. **Classified area**: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for ISO class).

5.5. **Component**: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

5.6. **Compounded sterile preparation (CSP)**: A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

5.7. **Compounding area**: The area where compounding is occurring (i.e., a cleanroom suite, inside the perimeter of the SCA, or AECA).

5.8. **Compounding record (CR)**: Documents the compounding of each CSP.

5.9. **Container closure system**: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.

5.10. **Containment ventilated enclosure (CVE)**: A non-ISO classified 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.

5.11. **Conventionally manufactured product**: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.

5.12. **Master formulation record (MFR):** A detailed record of procedures that describes how the CSP is to be prepared

5.13. **Specification**: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use

6. Related Policies, Documents, References

6.1. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding - Sterile Preparations. 2022 version.

6.2. United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

6.3. United States Pharmacopeial Convention, Inc. <71> Sterility Tests. Current version.

6.4. United States Pharmacopeial Convention, Inc. <85> Bacterial Endotoxins Test. Current version

6.5. United States Pharmacopeial Convention, Inc. <1229> Sterilization of Compendial Articles. Current version.

6.6. United States Food & Drug Administration (FDA). Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry. October 2021.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval 10/2023
Next review:	Month/year

7.1. Initial version published by Wolters Kluwer 2022.

7.2. Revised MM/YYY with the following key changes…OR…with no changes.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Equipment, Supplies, & Components for Sterile Compounding	Policy #	PHARM2779
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

This policy describes the requirements for, and assessment of the equipment used in controlled compounding areas and the supplies and components used in the preparation of Compounded Sterile Preparations (CSPs) by Watsonville Community Hospital.

Selection of equipment and furniture specifically designed for use in and constructed of materials appropriate for sterile compounding environments is integral in helping to maintain a state of control in classified and controlled areas. Durability, cleanability, and minimal, if any, shedding or particle generation are also important characteristics of equipment and furniture used within controlled areas.

Selection of high-quality sterile supplies and components from appropriately credentialled and inspected manufacturers is essential in maintaining the integrity of aseptic processes of final CSPs.

Diligence in vetting and selecting reputable vendors, wholesalers, and FDA-registered manufacturers; carefully reviewing quality data on purchased products used in sterile compounding (e.g., Certificate of Analysis or Conformance); and conducting in-process quality control inspections and tests all contribute to ensuring CSP veracity and patient safety.

II. POLICY

A. Equipment and furniture used in sterile compounding environments is constructed of material appropriate for controlled areas, is easily cleanable, and can withstand cleaning agents used in sterile compounding environments. Equipment surfaces coming into contact with CSPs are additionally not reactive or sorptive.

B. Equipment, furniture, supplies, and components are thoroughly cleaned and disinfected per policy prior to introduction within the perimeter of a Segregated Compounding Area (SCA). Equipment, supplies, and components are sanitized again with sterile 70% isopropyl alcohol (sIPA) as they are introduced into an ISO Class 5 PEC.

C. Equipment is placed within the PEC in manner that facilitates compounding operations and does not obstruct laminar airflow during compounding manipulations.

D. Sterile compounding equipment is calibrated, maintained, cleaned, and used per manufacturer's instructions and recommendations and as described in the related SOPs (Standard Operating Procedures).
   - Cleaning, maintenance, and calibration of equipment is documented and readily retrievable.

E. Equipment designed to deliver specific volumes of solution(s) automatically during the compounding process, such as automatic compounding devices (ACDs) or repeater pumps, undergo an accuracy assessment when initially installed and prior to use on days when the compounding with the equipment occurs.
   - Daily accuracy measurements are recorded and evaluated over time to detect variation in the precision of the equipment.
   - Corrective actions are taken if accuracy measurements are outside of manufacturer's specifications.

F. Supplies used in the compounding of CSPs (e.g., needles, syringes, tubing sets) are made of materials that are not reactive or sorptive. Supplies coming in direct contact with CSPs are sterile and dehydrogenated.

G. Conventionally manufactured sterile products and components are used when available and appropriate for the intended use.
   - When conventionally manufactured sterile products are not commercially available and there is a need for non-patient-specific CSPs to be prepared and held for use when a patient(s) is(are) identified, sterile drug products and components may be obtained from an FDA-registered 503B Outsourcing Pharmacy if available.

H. Temperature in drug storage areas is monitored and documented at least once daily on days the facility is open or by a continuous temperature recording device. Deviations are promptly investigated, and appropriate corrective actions are taken and documented.

I. Temperature monitoring equipment is calibrated or verified for accuracy per the manufacturer or once every 12 months if not specified by the manufacturer.

III. ROLES & RESPONSIBILITIES

1. The Designated Person(s) (DP) and/or Designee:
   - Ensure sterile equipment, supply, and component suppliers, wholesalers, and manufacturers are fully vetted for USP <797> compliant quality manufacturing and documentation standards.
   - Ensure sterile compounding equipment, if used, is maintained and calibrated on a timely basis and that documentation of equipment calibration, maintenance, and cleaning is stored in a readily retrievable format.
   - Investigate, oversee, and document corrective actions related to equipment, supply, and/or component defects or failures.
2. Compounding Personnel:
   - Prior to use in every CSP, evaluate and inspect components for correct identify, quality, expiration date, and storage conditions.
   - Reject and quarantine components which are expired, have suspected or known defects that could impact the quality, potency, and/or sterility of the CSP. Notify the DP or Designee promptly of all defects.
   - Conduct and document daily calibrations of compounding equipment, if used, automatically measuring component volumes (e.g., ACDs, repeater pumps). Notify DP or Designee of equipment that is out of specification and do not use the equipment until the equipment can be successfully calibrated.
   - Clean equipment with the appropriate cleaning agent and observing required dwell times per the **Cleaning, Disinfection, & Application of Sporicidal Agents** policy and document cleaning activities appropriately.

IV. DEFINITIONS

- **ACD**: Automated compounding device.
- **Active pharmaceutical ingredient (API)**: Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as Bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
- **Certificate of analysis (COA)**: A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.

- **Classified area**: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for ISO class).
- **Component**: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
- **Compounded sterile preparation (CSP)**: A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
- **Compounding area**: The area where compounding is occurring (i.e., a cleanroom suite, inside the perimeter of the SCA, or AECA).
- **Compounding record (CR)**: Documents the compounding of each CSP.
- **Container closure system**: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.
- **Containment ventilated enclosure (CVE)**: A non-ISO classified 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.
- **Conventionally manufactured product**: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
- **Master formulation record (MFR):** A detailed record of procedures that describes how the CSP is to be prepared
- **Specification**: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use

V. PROCEDURE

A. Selection of Compounding Equipment and Supplies

- Identify and vet reputable wholesalers and distributors of equipment and supplies for use in sterile compounding environments and aseptic processes.
- Select sterile compounding equipment constructed of materials suitable for compounding environments (e.g., stainless steel) including nonreactive or sorptive surfaces that come into direct contact with CSPs and designed to withstand cleaning processes and agents.
- Ensure sterile equipment and supplies are accompanied by appropriate end user documentation, instructions for use, and quality testing data including:

Equipment	Supplies
• User manual providing instructions for proper use, cleaning, and maintenance • Required calibration or recertification requirements, procedure, and frequency • Specifications and acceptance parameters for normal operation	• Lot number and expiration date • User instructions including any quality control testing procedure(s) and expected results, if applicable

B. Receipt, Evaluation, Handling, & Storage of CSP Components

- Move component shipping/delivery containers to receiving area and garb per facility policy
- Upon receipt, examine the external and internal packaging of each lot of CSP for signs of product deterioration or other quality impacting defects (e.g., temperature-sensing indicators indicate product has been exposed to excessive temperatures). Reject, quarantine, and notify DP and/or Designee of components with suspected or known defects.

- Once unpacked, examine components and container closure systems for cracks, leaks, or other indicators of product adulteration. Reject, quarantine, and notify DP and/or Designee of components with suspected or known defects.
- Confirm component expiration dating.
  - If component is expired or within 3 months of expiration, reject, quarantine, and notify DP and/or Designee.
  - When manufacturer's expiration date is not visible on label or labeling, clearly write or label container with an expiration date not to exceed one year from the date of receipt.
- Apply additional component/container labeling if appropriate.
- Handle and store components in a manner that prevents contamination, mix-ups, and deterioration.
- Store components in a designated, temperature controlled and monitored storage areas per manufacturer or official monograph instructions
  - Controlled Room Temperature: 20°C - 25°C (68°F - 77°F)
  - Refrigerated Temperature: 2°C - 8°C (36.8°F – 46.4°F)
- Monitor and record temperature in the area(s) where components are stored at least once daily on days that the facility is open or by a continuous temperature recording device.
- Record temperatures manually or electronically and ensure temperature logs are readily retrievable.
- Calibrate or verify accuracy of temperature monitoring equipment as recommended by the manufacturer or every 12 months if not specified by the manufacturer.

C. Introduction of Equipment, Supplies, & Components into Controlled Compounding Areas

- Prior to introduction into a controlled compounding area, clean all visibly soiled equipment or furniture with a sporicidal disinfectant, EPA-registered disinfectant cleaner, or hospital grade cleaning agent.
- Clean all equipment, furniture, supplies, and components as they are moved across the line of demarcation (LOD) in the SCA. Wipe individual items with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (sIPA) and low-lint wipers.
- Place equipment and furniture within the SCA perimeter in a manner that facilitates compounding operations and does not impede airflow, workflow or traffic patterns.
- Refer to the **Workflow and Aseptic Technique for Sterile Compounding** policy.

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding - Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.
- United States Pharmacopeial Convention, Inc. <71> Sterility Tests. Current version.
- United States Pharmacopeial Convention, Inc. <85> Bacterial Endotoxins Test. Current version
- United States Pharmacopeial Convention, Inc. <1229> Sterilization of Compendial Articles. Current version.
- United States Food & Drug Administration (FDA). Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry. October 2021.

VII. STAKEHOLDERS

N/A

Watsonville Community Hospital	**Certification and Recertification of Sterile Compounding Areas**
Policy Number/ Version:	797 – 2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the procedures for certification and recertification of Primary Engineering Controls (PECs) and Segregated Compounding Areas (SCAs) within Watsonville Community Hospital. Certification indicates that the equipment and compounding area is meeting its design and air quality specifications.

Refer to the **Facility and Engineering Controls policy** for design specifications and acceptance criteria for Primary Engineering Controls (PECs), Segregated Compounding Areas (SCAs) and compounding areas.

Watsonville Community Hospital has a PEC in an SCA.

2. Policy

2.1. [USP 797] Before a compounding area is used to compound Category 1 Compounded Sterile Preparations (CSPs), it must be independently certified following the requirements in this policy and when applicable, manufacturer specifications.

2.2. [USP 797] Certification of the classified areas including the PEC must be performed initially, and recertification must be performed at least every 6 months, and must include:

- **HEPA filter integrity testing**: HEPA filters must be leak tested at the factory, after installation, and as part of recertification.
- **Total particle count testing**: performed under dynamic operating conditions using calibrated electronic equipment.
- **Dynamic airflow smoke pattern testing**: performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).

2.3. [USP 797] The Designated Person (DP) and/or Designee immediately addresses any out of specification results determined by the certification professional or vendor at the time of recertification per **Out of Specifications policy** and **QA/QC policy**.

2.4. [USP 797] Classified areas additionally must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.

- [Best Practice] Before any of the above activities, the DP(s) consults with the certification professional to confirm need for recertification and schedule availability.

2.5. [USP 797] All certification and recertification records are reviewed by the DP(s) and/or Designee to ensure the classified environments meet USP <797> requirements and documents are readily retrievable.

2.6. [BEST PRACTICE] All certification activities are completed or supervised by vendors and professionals that are credentialed by the Controlled Environment Testing Association (CETA) National Board of Testing (CNBT). Credentials are readily available from the vendor and/or Designated Person.

2.7. All equipment for testing and certification is calibrated per Intitute of Environmental Sciences and Technology (IEST) standards or manufacturer's recommendations and calibration dates are included in the certification report.

3. Roles & Responsibilities

3.1. Designated Person(s) (DP) (and/or Designee):

- [USP 797] Review all certification and recertification records) to ensure the classified environments meet USP <797> requirements and documents are readily retrievable.
- [USP 797] Initiate a corrective action for any out-of-specification results and ensures the actions taken have been effective.
- Determine dynamic operating conditions for each PEC in use.

3.2. Certification professional or vendor:

- Coordinates schedule for certification with DP and/or Designee to ensure completion within due time and for minimal disruption of pharmacy workflow.
- Follows facility hand hygiene and garbing and material handling and cleaning procedures.
- Reviews facility sampling diagram with DP and/or Designee prior to each certification activity to ensure consistent sampling plan.
- Notifies DP and/or Designee of any out-of-specification criteria and any immediate corrective actions completed before leaving the facility.

4. Procedures

4.1 Initial Certification of Compounding Areas

- Prior to certification, all construction areas are thoroughly cleaned and approved by the DP or qualified designee.
- At completion of construction, compounding areas are certified under static or as-built conditions. The goal of this certification is to ensure airflow and air exchanges are functioning as designed and that PECs meet ISO classification.

4.2 Recertification of Compounding Areas

- Routine recertification of PECs occurs at a minimum of every 6 months. Recertification is considered on time if completed by the last day of the month when certification is due.
- Recertification occurs under dynamic operating conditions.
- DP and/or Designee determines the maximum number of personnel normally working in the classified area. Recertification is performed with that determined number of personnel.
- Ensure the number of personnel in the space at the time of recertification is recorded on the recertification report.
- Recertify PECs whenever the equipment requires a signficant move such that the air quality or function may be disturbed. Consult with a certification professional if uncertain of the impact.

4.3 Review of Certification Report

- The DP and/or Designee reviews preliminary and final certification reports for every PEC under the scope of Watsonville Community Hospital's sterile compounding program within 3 business days of receipt.
- DP and/or Designee completes all applicable parts of the **Certification Report Review Form: Appendix 1.**
    - Ensure the report includes all components and a pass or fail indication for all PEC certification criteria as described in this policy.
    - Further review all pass indications for elements that may have minimally exceeded passing criteria.
- The DP and/or Designee begins a corrective action plan for all certification criteria items that are found to be out of specification on the certification report.
    - See **Out of Specifications policy** and **QA/QC policy** for procedures when review of certification report features sterile compounding areas out of compliance with USP <797> design specifications and acceptance criteria.
- Once corrective action plan remediations are complete, schedule recertification testing to determine effectiveness of remediation efforts.
- Review certification report after remediation to determine if all areas found out of specification are now within acceptable design specifications and acceptance criteria. Record successful remediation on corrective action.
- Document the review by signature and date and file for regulatory review

4.4 PEC Certification Criteria

- Airflow velocity testing, including verifying unidirectional airflow utilizing smoke pattern testing under static and dynamic conditions
- Nonviable particle counts meeting ISO class 5 or better air quality
- HEPA filter integrity test
- Induction/back streaming test
- Chamber pressure test
- Site installation assessment test
- Preparation ingress and egress test

4.5 Segregated Compounding Area (SCA) Certification Criteria:

- Non-Hazardous SCA: no minimum air requirements

5. Definitions

5.1 **Biologic safety cabinet (BSC):** A ventilated cabinet that may be used or compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).

5.1 **Dynamic operating conditions:** Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations.

5.2 **High-efficiency particulate air (HEPA) filtration (HEPA Filter):** Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.

5.3 **Primary Engineering Control (PEC):** A device or zone that provides and ISO Class 5 air quality environment for sterile compounding.

5.4 **Secondary Engineering Control (SEC):** The area where the PEC is placed (e.g. a cleanroom suite or SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

6. Related Policies, Documents, References

6.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding Sterile Preparations. 2022 version.

6.2 United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

6.3 Controlled Environment Testing Association (CETA) Application Guide CAG-003:2022. Certification of Sterile Compounding Facilities for USP Compliance.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval (10/2023)
Next review:	Month/year

8.1. Initial version published by Wolters Kluwer 2023.

7.2 Revised 9/2023.

Appendix 1: Certification Report Review Form

Watsonville Community Hospital		**Certification Report Review Form**	
Pharmacy Location			
Date of Certification		**Certification Performed By (name and vendor)**	
Date Report Received		**Reviewed By**	

All certification reports reviewed by Designated Person and/or qualified designee

	Unit(s) Tested	**Pass**	**Fail**	**N/A**	**Comments/Actions**
PECs *Add additional rows for additional PECs*	CAI model and serial # _____ • Airflow test • Smoke pattern test • Chamber pressure test • Site installation assessment test • HEPA filter integrity test • Particle containment integrity and enclosure leak test • Preparation ingress and egress test				

Action Items Reviewed With (who/date)

Action Plan for Correction of Any Deficiencies:
i.e. What/Who/By When

File copy on site with final certification reports for regulatory inspection.
Forward completed review to Designated Person or qualified Designee for review and/or escalation if needed.

Watsonville Community Hospital	**Microbiological Air and Surface Monitoring Program**
Policy Number/ Version:	797-2022 Version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1 This policy serves as the comprehensive microbiological air and surface monitoring program for all sterile compounding areas where Compounded Sterile Preparations (CSP) are prepared within Watsonville Community Hospital.

1.2 The microbiological monitoring program at Watsonville Community Hospital provides information on the environmental quality of the compounding area(s) including data that is used to:

- determine if a state of microbial control exists within Primary Engineering Controls (PECs) and the sterile compounding area collectively
- assess the effectiveness of cleaning procedures and agents
- identify environmental quality trends over time
- identify potential routes and risks of contamination
- allow for implementation of corrective actions to minimize the risk of CSP contamination
- detect trends over time

1.3 The microbiological monitoring program includes data collected via two sampling methods:

- **Viable airborne sampling** – volumetric active air sampling conducted in classified areas to detect and assess microbial air quality.
- **Surface sampling** – sampling of high touch, materials staging, and direct work surfaces to evaluate facility and work surface cleaning and disinfecting procedures, materials handling procedures, and personnel competency in related work practices.

2. Policy

2.1 [USP 797] It is the policy that Watsonville Community Hospital maintains a microbiological air and surface monitoring program in all sterile compounding areas to include 1) viable impact volumetric airborne particulate sampling and 2) surface sampling. Refer to **Sterile Compounding Program Overview** for all sterile compounding locations.

- Segregated Compounding Area in Inpatient Pharmacy with type of PEC (RABS = Restricted Access Barrier: CAI = Containment Aseptic Isolator)

2.2 [USP 797] The microbiological monitoring program includes viable impact volumetric airborne particulate sampling (air sampling) under dynamic operating conditions and surface sampling at the end of a compounding activity or shift and before the area has been cleaned and disinfected.

2.3 Viable impact volumetric airborne particulate sampling is performed by independent 3rd party, e.g., certifier (e.g., Clean Rooms Plus).

2.4 Surface sampling is performed by internal staff monthly and also by independent 3rd party, e.g., certifier (e.g., Clean Rooms Plus) for semi-annual and/or ad hoc sampling.

2.5 [USP 797] All classified ISO locations at Watsonville Community Hospital are maintained under the following action levels:

ISO Class	**Viable Air Sample** CFU/cubic meter of air per plate	**Viable Surface Sample** CFU per sampling device

ISO 5	> 1	>3
ISO 7	> 10	> 5
ISO 8	> 100	> 50

2.6 [USP 797] The frequency of microbiological sampling occurs based on the category of CSPs compounded.

Sample Type	Category 1 CSPs Frequency
Air Sample	Every 6 months
Surface Sample	Monthly
	In conjunction with media fill testing

2.7 [USP 797] All personnel who perform microbiological air and surface sampling at Watsonville Community Hospital are trained and competent in all sampling procedures and this training is documented electronically via educational modules; e.g., Critical Point.

- The DP and/or Designee determines personnel who are trained in microbiological monitoring.
- Training in microbiological monitoring is annual and includes:
  - Surface sampling procedures
  - Incubation of sample procedures
  - Analysis and documentation of microbiological sampling results and trends

2.8 [USP 797] Microbiological air and surface sampling are performed under the following circumstances:

- Upon the opening of the sterile compounding area to establish a baseline of control
- In conjunction with the certification of new facilities and new equipment
- After any servicing of facilities or equipment
- In response to identified problems
- In response to identified trends
- In response to changes that impact the sterile compounding environment

2.9 [USP 797] The locations for microbiological air and surface sampling are denoted on the sterile compounding facility diagram (see Appendix 1) and represent locations posing the highest potential for CSP contamination.

- Air sampling locations are established in all ISO Class 5 PECs in selected high traffic areas.
- Surface sample locations are established in the interiors of all the PECs and the equipment contained inside the PECs, staging or work area near the PECs, and frequently touched surfaces.
- Each sampling location on the sterile compounding facility diagram has an associated Sample ID. All Sample IDs are unique, duplicating Sample IDs is not allowed within the facility even if the sterile compounding area is in a physically different location within the facility.

2.10 [USP 797] Documentation of active air sampling devices are calibrated yearly or per manufacturer recommendation and provided by independent 3rd party in report of certification.

2.11 [USP 797] All microbial air and surface monitoring procedures, testing results, investigations into actionable results and corrective actions are documented.

3. Roles & Responsibilities

3.1 The Designated Person(s) and/or Designee:

- Compiles and evaluates results from microbial air and surface sampling. The data is reviewed to determine if contamination is present in the sterile compounding areas at unacceptable levels and detect trends. The DP or Designee also assesses: potential risks for contamination of CSPs, potential routes of contamination of CSPs, that proper personnel practices are being followed, and the adequacy of cleaning and disinfecting agents and procedures.
- Reviews results from microbiological air and surface sampling in conjunction with sterile compounding staff training records, personnel visual observations and personnel competency assessments to assess the state of microbial control in the sterile compounding area and to identify potential risks of contamination.
- Formulates corrective action plans in response to any adverse findings with microbiological air and/or surface sampling with the involvement and input of subject matter experts (e.g. microbiologist, facilities and HVAC systems engineers, etc.) as needed.
- Reviews results and data after corrective action plans are implemented to confirm that the actions taken are effective in achieving a state of microbial control in the sterile compounding area.

3.2. Microbiological sampling personnel:

- Complies with hand hygiene and garbing requirements
- When 3rd party is conducting sampling, only enters controlled areas under the supervision and guidance of the Designated Person(s) or Designee.
- Ensures all equipment and supplies introduced into a classified sterile environment are appropriately cleaned and disinfected.

4. Procedures

Viable Air Sampling: (complete by 3rd party independent certifier)

4.1 [USP 797] Volumetric active air sampling occurs in all ISO classified areas during dynamic operating conditions

- Air sampling locations are identified on the sterile compounding facility diagram (see Appendix 1).
- Air sampling occurs under static conditions upon the opening of a new sterile compounding location or after major repair and/or construction in the sterile compounding location.

4.2 [USP 797] Air sampling occurs:

- For Category 1 CSPs: initially upon opening of sterile compounding facility and every 6 months

4.3 [USP 797] The unidirectional airflow inside the Primary Engineering Control (PEC) is not disturbed when air sampling is conducted. Refer to volumetric air sampler manual for instructions of use,

including the direction of airflow after media impaction occurs. Never compromise first air inside the Direct Compounding Area (DCA) of the PEC when performing air sampling.

4.4 Complete air sampling documentation forms every time an air sampling activity occurs. Include the following information (at minimum): [3rd party independent certifier to complete]

- Date and time of air sampling
- Individual(s) sampling
- Growth media used – including manufacturer, type, lot number and expiration
- Air sampler used
- Volume of air drawn
- Sampling conditions (dynamic or static, regular scheduled testing or testing after remediation)
- Sampling locations
- Incubation temperatures and length of incubation
- Final growth media reading results

Surface Sampling:

4.5 [USP 797] Surface sampling occurs in all ISO classified areas during dynamic operating conditions

- Surface sampling locations are identified on the sterile compounding facility diagram (see Appendix 1).
- Surface sampling occurs under static conditions upon the opening of a new sterile compounding location or after major repair and/or construction in the sterile compounding location.

4.6 [USP 797] Surface sampling is performed:

- [CONDITIONAL: For facilities compounding Category 1 CSPs only] Monthly at the end of compounding activity or shift and before the area has been cleaned and disinfected.
- In conjunction with media-fill testing to assess aseptic manipulation competency
  - Surface sampling is performed on the DCA following media-fill testing

4.7 [USP 797] The microbiological growth media devises (e.g., plates) used for surface sampling support the growth of bacteria and fungi.

- Surface sampling devices contain general microbial growth media supplemented with neutralizing additives to neutralize the effects of any residual disinfecting agents.
- Surface sampling devices should have a raised convex surface
- Sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used to sample irregular surfaces and hard to reach locations such as crevices, corners, and spaces between surfaces
- Certificate of Analysis (COA) for all growth media used for sampling is obtained from the manufacturer.
  - All COA documents are verified to be sure the media meets the expected growth promotion, pH, and sterilization requirements.

4.8 [USP 797] Incubation of surface samples occurs at temperatures that promote growth of bacteria and fungi. Monitoring of incubator temperatures occurs manually. Documentation of incubator temperatures occurs electronically (e.g. in Simplifi).

- Two incubators are used:
  - One is set for 30 to 35°C

    - One is set for 20 to 25°C
- The incubator is located outside of the sterile compounding area in a dedicated area

4.9 Complete surface sampling documentation forms every time a surface sampling activity occurs. Include the following information (at minimum) on the form:

- Date and time of surface sampling
- Individual(s) sampling
- Growth media used – including manufacturer, type, lot number and expiration
- Sampling conditions (dynamic or static, regular scheduled testing or testing after remediation)
- Sampling locations
- Incubation temperatures and length of incubation
- Final growth media reading results

4.10 [USP 797] Surface sampling procedure:

- Remove sampling devices from the refrigerator and check the expiration date. Wipe the outside of the manufacture's overwrap with sIPA.
- Collect all supplies needed for surface sampling and disinfect with sIPA. Supplies needed include, but are not limited to: plate, permanent marker, tape.
- Allow sampling devices to come to room temperature prior to sampling.
- All hand hygiene and garbing procedures are completed prior to the beginning of surface sampling procedures.
- [CONDITIONAL: if using RABS] Stage surface sampling devices any other supplies needed inside the ante chamber of the compounding isolator.
- Move all components into the ISO 5 environment.
- Sanitize gloved hands with sIPA and remove the cover from the surface sampling device.
- Using a rolling motion, firmly press the growth media surface onto the surface being sampled.
- Place the cover back on the surface sampling device and apply tape to secure cover if needed.
- Sampled area is wiped with 70% sterile Isopropyl Alcohol (IPA) to remove residue
- Sampling devices are covered and stored so that condensation does not drip onto the agar

- The growth media is incubated:
  - At 30º – 35ºC (86º – 95ºF) for a minimum of 48 hours for bacterial growth
    - Examine growth media at the completion of 48 hours. Count and record the total number of discrete colonies detected as CFU per surface sample. Record all information on the surface sampling environmental sampling form indicating: type of environmental sample (surface), location of surface sample, date of sample, and number of CFUs observed.
  - The surface sample is then incubated at 20º – 25ºC (68°F - 77°F) for a minimum of 5 days for fungal growth
    - Examine growth media at the completion of 5 days. Count and record the total number of discrete colonies detected as CFU per surface sample. Record all information on the surface sampling environmental sampling form indicating: type of environmental sample (surface), location of surface sample, date of sample, and number of CFUs observed.
- At the conclusion of surface sampling all sites in the sterile compounding area, thoroughly clean all sampled locations and disinfect per policy prior to resuming sterile compounding.

Reading and Interpreting Results:

4.19 [USP 797] Compare all CFUs recovered to previous sample data to identify adverse results or trends over time.

- This comparison occurs even when the results fall below the action level for the sample taken.

4.20 [USP 797] Consult a microbiologist and/or a member of Infections Disease/Infection Prevention department to assist in determining appropriate remediation steps and assess trends in resulted alert or action levels.

ISO Class	Viable Air Sample CFU/cubic meter of air per plate		Viable Surface Sample CFU per sampling device	
	Alert Level	**Action Level**	**Alert Level**	**Action Level**
ISO 5	>0	> 1	>0	>3
ISO 7	>5	> 10	>0	> 5
ISO 8	>50	> 100	>25	> 50

Actionable Findings:

4.21 [USP 797] If levels of CFUs measured at any of the air sampling or surface sampling testing locations exceeds the action level, attempt to identify the microorganisms present down to the genus level with the assistance of a microbiologist. Take immediate action, investigate the cause of the out of limits sample and begin a corrective action plan.

- The microbiologist assists with determining the risk of compromising the sterility of CSPs based on the results; especially in the case of any concerning organisms.
- The microbiologist assists with determining the appropriate remediation steps for the ISP classified locations with actionable findings.

4.22 [USP 797] The corrective action plan is dependent on the number of CFUs resulted and the microorganism recovered.

- Examples of corrective actions include: process or facility improvements, personnel training, cleaning and disinfection, or HEPA filter repair and/or replacement
  - The corrective action investigation includes evaluation of any trends reviewed at each sampling location.
  - Immediate action is dependent on the ISO classification of the sample location.
  - Examples of immediate action based on location:

[Best Practice] **Immediate Actions based on ISO Classifications and Occurrence Frequency**

ISO Classification:	**1st Occurrence**	**2nd Occurrence**
ISO 5 PEC	- Sporicidal clean PEC - Decrease BUD to 12 hours - Schedule repeat testing	- Cease compounding in ISO 5 PEC until repeat testing passes - Triple clean (sporicidal, germicidal and sIPA) - Schedule repeat testing
ISO 7 SEC Buffer or Ante	-Sporicidal clean -Schedule repeat testing	-Decrease BUD to 12 hours until repeat testing passes -Triple clean (sporicidal, germicidal and sIPA) -Schedule repeat testing
ISO 8 SEC	-Sporicidal clean -Schedule repeat testing	-Triple clean (sporicidal, germicidal and sIPA) -Schedule repeat testing **Any subsequent occurrences, drop BUD to 12 hours until repeat testing passes

  - The corrective action investigation may include a team consisting of but not limited to:
    - Pharmacy/facility leadership
    - Infection prevention specialist
    - Engineering and/or facilities operations leadership
    - Environmental Services
    - Outside cleaning services
    - Microbiology department or microbiologist
  - All members contributing to a corrective action are documented on the corrective action plan.

- The investigation and corrective action are contingent a number of factors including, but not limited to:
    - ISO classification of area with actionable environmental findings
    - Magnitude of actionable finding (e.g., a few CFUs vs. 100s of CFUs)
    - First or repeated actionable finding upon retest
    - Environmental trends in actionable sites and controlled area(s) over time
    - ISO certifications current and in good standing
    - HEPA filter repairs and/or replacements
    - Maintenance of air flow systems current (e.g. air conditioner, exhaust and/or supply fans)
    - Maintenance and repairs of facility and compounding area current
    - Personnel training and competencies current and in good standing
    - Controlled and observed access for all non-compounding personnel and 3rd parties entering the controlled environment
    - Proper selection, use, and timing of use of cleaning, disinfecting, and application of sporicidal agents
    - Other potential factors (e.g. major facilities repair or construction projects inside or in the vicinity of the controlled area; actionable environmental findings elsewhere in the facility(ies) or community; etc.)
- Following implementation of the corrective action and abatement of the assumed contamination(s), re-test the location(s) per steps outlined previously.
- To confirm action plan effectiveness, compile and review data obtained from re-testing and update action plan with this data.
- Document the corrective action and all follow up air and surface sampling.

5. Definitions

5.1 **Certificate of analysis (COA)**: A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of material

5.2 **Designated Person (DP)**: One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.

5.3 **Dynamic operating conditions:** Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations.

5.4 **ISO Class:** An air-quality classification from the International Organization for Standardization

5.5 **Primary Engineering Control (PEC):** A device or zone that provides and ISO Class 5 air quality environment for sterile compounding.

5.6 **Restricted-access barrier system (RABS)**: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination and that generally are not to be opened during operations.

5.7 **Secondary Engineering Control (SEC)**: The area where the PEC is placed (e.g. a cleanroom suite or SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

5.8 **Triple clean:** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

6. Related Policies, Documents, References

6.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding - Sterile Preparations. 2022 proposed version.

6.2 United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

6.3 CAG-009:2020 CETA Certification Application Guide USP Viable Environmental Sampling & Gowning Evaluation.

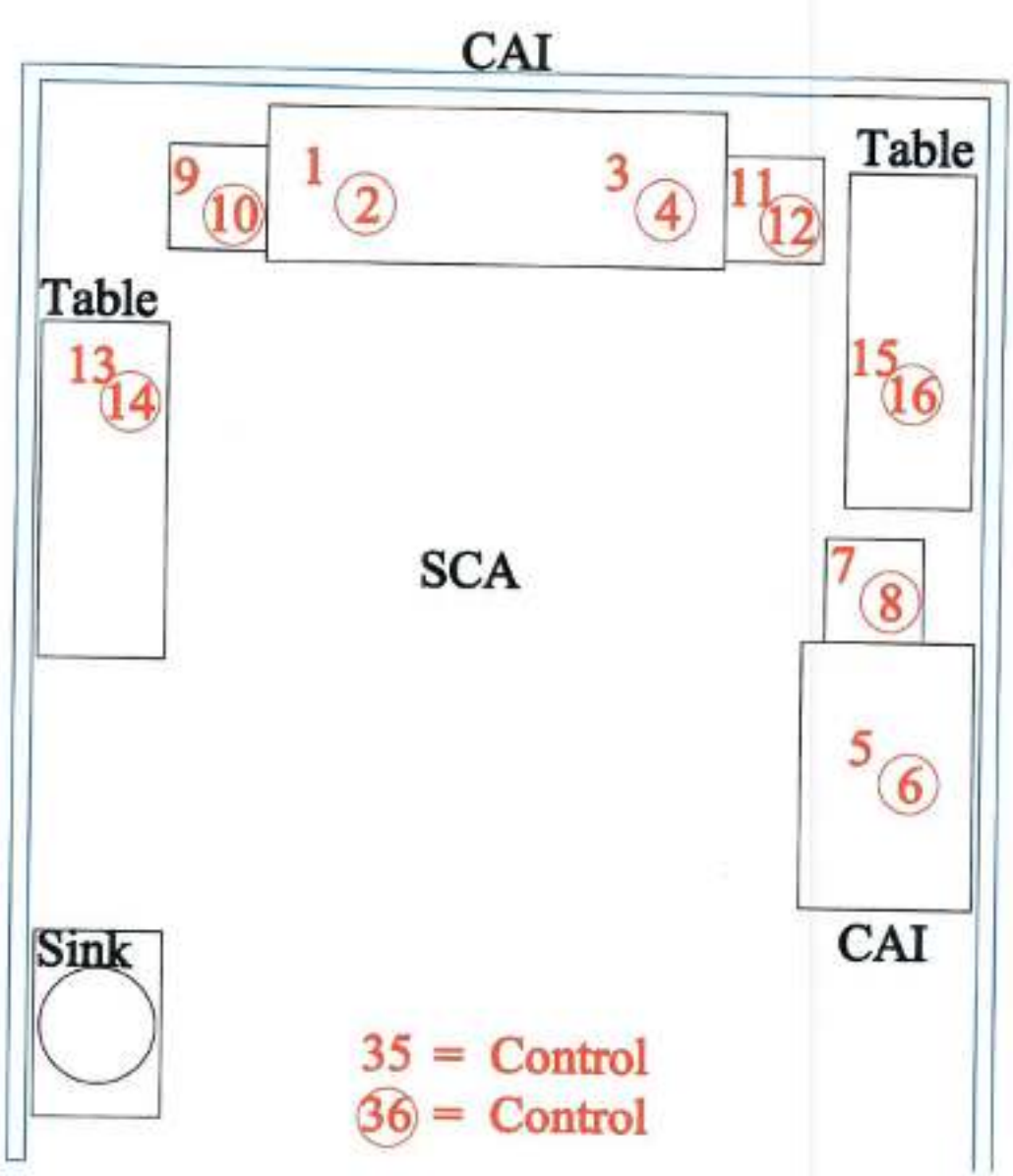
7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval (10/2023)
Next review:	Month/year

7.1 Initial version published by Wolters Kluwer 2022.

7.2 Revised MM/YYY with the following key changes…OR…with no changes.

APPENDIX ONE: Facility Sampling Diagram

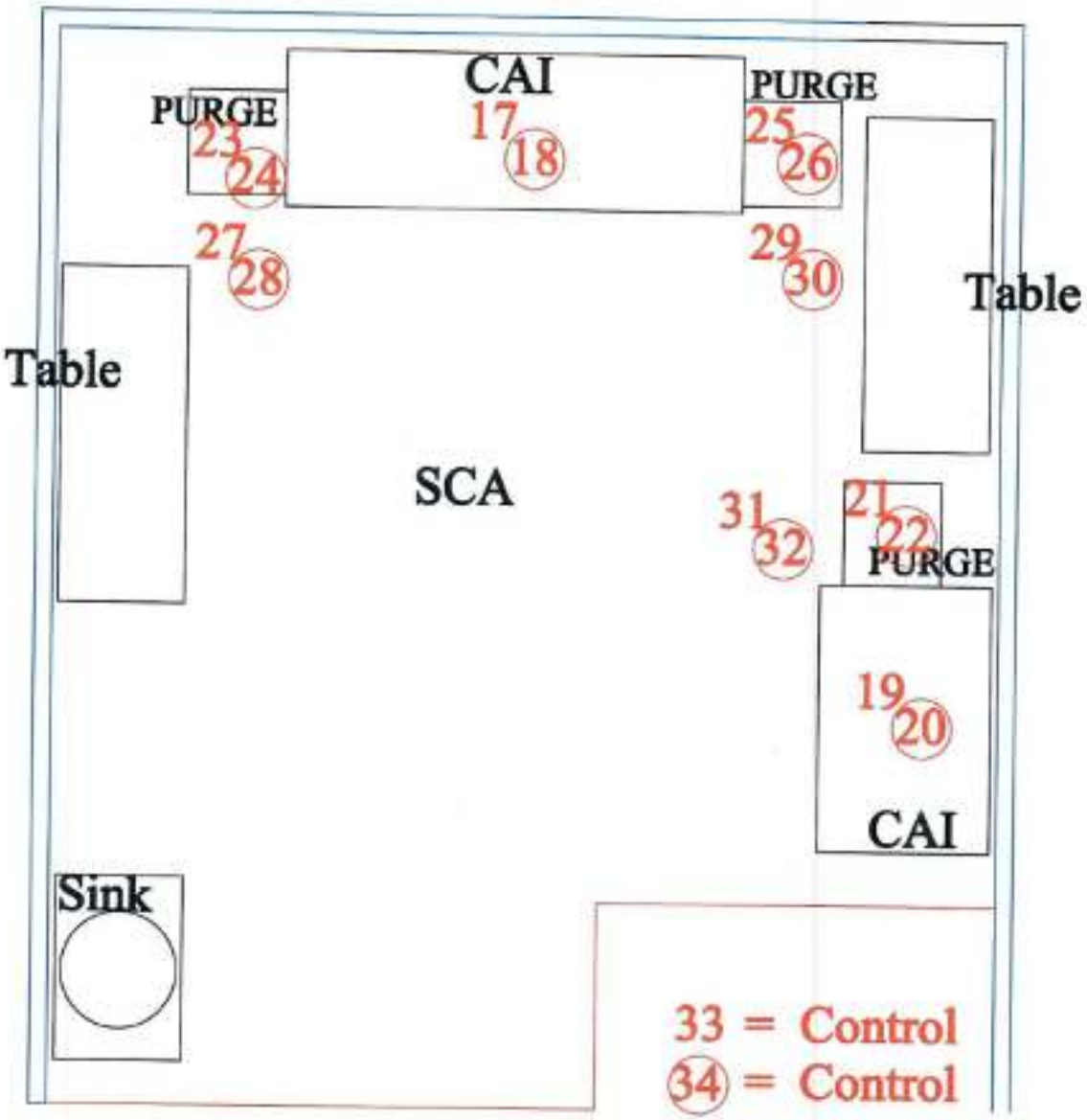


Watsonville Community Hospital

Surface Sample Locations

 # = TSA Sample

(#) = MEA Sample



Watsonville Community Hospital

Viable Air Sample Locations

\# = TSA Sample

(#) = MEA Sample

APPENDIX TWO:

Watsonville Community Hospital Environmental Monitoring Investigation & Correct Action Plan

FACILITY NAME AND LOCATION	Watsonville Community Hospital
SAMPLING DATE	
RESULT DATE	
DESIGNATED PERSON (or Designee)	
DESCRIPTION OF ACTIONABLE FINDING	Location: CFU counts: Organism(s): ISO classification: Was pre-emptive cleaning performed after samples were obtained?
DESCRIPTION OF OCCURRENCE	
DIDACTIC TRAINING RESOURCES	Critical Point

IMMEDIATE REMEDIAL ACTIONS TAKEN	
☐ Cleaning • Date: • Personnel: • Cleaning Agent: ☐ Beyond-use Date Reduced • Date/time: • Interim BUD: ☐ Retesting scheduled or completed • Date: • Qualified Sampler: ☐ Alert management and contact needed experts. List Experts: ☐ Other:	NOTES:

INVESTIGATION	
ENVIRONMENT: ☐ Environmental trends at actionable locations checked ☐ Environment free of items not necessary for compounding and/or items that shed ☐ Facilities and/or surrounding community environmental ☐ Cleaning Logs (and monthly sporicidal cleaning) current ☐ Other:	NOTES:
PERSONNEL: ☐ Compounding personnel training & competency current ☐ Comparison of environmental monitoring and personnel findings and trends to detect patterns ☐ Appropriate compounding personnel behaviors & hygiene practices upheld ☐ Non-compounding personnel and visitors escorted, observed, and compliant with hand hygiene and garbing expectations ☐ Other:	NOTES:

MICROBIOLOGY ASSESSMENT:	
{{List of actionable findings and organisms identified by classified area:}} *ISO 5 PECs:*	*{{Description of organisms cultured including vectors, pathogenicity, and other factors to be considered}}*

CORRECTIVE ACTION PLAN:		
☐ Facilities (PEC and/or SEC) repairs or improvements	DESCRIPTION:	OUTCOME:
☐ Workflow improvements		
☐ Personnel reeducation		
☐ Additional cleaning, environmental sampling, etc.		
☐ Other:		

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Microbiological Air and Surface Monitoring Program	Policy #	PHARM001
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

This policy serves as the comprehensive microbiological air and surface monitoring program for all sterile compounding areas where Compounded Sterile Preparations (CSP) are prepared within Watsonville Community Hospital.

The microbiological monitoring program at Watsonville Community Hospital provides information on the environmental quality of the compounding area(s) including data that is used to:

- determine if a state of microbial control exists within Primary Engineering Controls (PECs) and the sterile compounding area collectively
- assess the effectiveness of cleaning procedures and agents
- identify environmental quality trends over time
- identify potential routes and risks of contamination
- allow for implementation of corrective actions to minimize the risk of CSP contamination
- detect trends over time

The microbiological monitoring program includes data collected via two sampling methods:

- **Viable airborne sampling** – volumetric active air sampling conducted in classified areas to detect and assess microbial air quality.
- **Surface sampling** – sampling of high touch, materials staging, and direct work surfaces to evaluate facility and work surface cleaning and disinfecting procedures, materials handling procedures, and personnel competency in related work practices.

II. POLICY

A. It is the policy that Watsonville Community Hospital maintains a microbiological air and surface monitoring program in all sterile compounding areas to include 1) viable impact volumetric airborne particulate sampling and 2) surface sampling. Refer to **Sterile Compounding Program Overview** for all sterile compounding locations.
   - Segregated Compounding Area in Inpatient Pharmacy with type of PEC (RABS = Restricted Access Barrier: CAI = Containment Aseptic Isolator)

B. The microbiological monitoring program includes viable impact volumetric airborne particulate sampling (air sampling) under dynamic operating conditions and surface sampling at the end of a compounding activity or shift and before the area has been cleaned and disinfected.

C. Viable impact volumetric airborne particulate sampling is performed by independent 3rd party, e.g., certifier (e.g., Clean Rooms Plus).

D. Surface sampling is performed by internal staff monthly and also by independent 3rd party, e.g., certifier (e.g., Clean Rooms Plus) for semi-annual and/or ad hoc sampling.

E. All classified ISO locations at Watsonville Community Hospital are maintained under the following action levels:

ISO Class	Viable Air Sample CFU/cubic meter of air per plate	Viable Surface Sample CFU per sampling device
ISO 5	> 1	>3
ISO 7	> 10	> 5

ISO 8	> 100	> 50

F. The frequency of microbiological sampling occurs based on the category of CSPs compounded.

Sample Type	Category 1 CSPs Frequency
Air Sample	Every 6 months
Surface Sample	Monthly
	In conjunction with media fill testing

G. All personnel who perform microbiological air and surface sampling at Watsonville Community Hospital are trained and competent in all sampling procedures and this training is documented electronically via educational modules; e.g., Critical Point.
- The DP and/or Designee determines personnel who are trained in microbiological monitoring.
- Training in microbiological monitoring is annual and includes:
  - Surface sampling procedures
  - Incubation of sample procedures
  - Analysis and documentation of microbiological sampling results and trends

H. Microbiological air and surface sampling are performed under the following circumstances:
- Upon the opening of the sterile compounding area to establish a baseline of control
- In conjunction with the certification of new facilities and new equipment
- After any servicing of facilities or equipment
- In response to identified problems
- In response to identified trends
- In response to changes that impact the sterile compounding environment

I. The locations for microbiological air and surface sampling are denoted on the sterile compounding facility diagram (see Appendix 1) and represent locations posing the highest potential for CSP contamination.
- Air sampling locations are established in all ISO Class 5 PECs in selected high traffic areas.
- Surface sample locations are established in the interiors of all the PECs and the equipment contained inside the PECs, staging or work area near the PECs, and frequently touched surfaces.
- Each sampling location on the sterile compounding facility diagram has an associated Sample ID. All Sample IDs are unique, duplicating Sample IDs is not allowed within the facility even if the sterile compounding area is in a physically different location within the facility.

J. Documentation of active air sampling devices are calibrated yearly or per manufacturer recommendation and provided by independent 3rd party in report of certification.

K. All microbial air and surface monitoring procedures, testing results, investigations into actionable results and corrective actions are documented.

III. ROLES & RESPONSIBILITIES

A. The Designated Person(s) and/or Designee:

- Compiles and evaluates results from microbial air and surface sampling. The data is reviewed to determine if contamination is present in the sterile compounding areas at unacceptable levels and detect trends. The DP or Designee also assesses: potential risks for contamination of CSPs, potential routes of contamination of CSPs, that proper personnel practices are being followed, and the adequacy of cleaning and disinfecting agents and procedures.
- Reviews results from microbiological air and surface sampling in conjunction with sterile compounding staff training records, personnel visual observations and personnel competency assessments to assess the state of microbial control in the sterile compounding area and to identify potential risks of contamination.
- Formulates corrective action plans in response to any adverse findings with microbiological air and/or surface sampling with the involvement and input of subject matter experts (e.g. microbiologist, facilities and HVAC systems engineers, etc.) as needed.
- Reviews results and data after corrective action plans are implemented to confirm that the actions taken are effective in achieving a state of microbial control in the sterile compounding area.

B. Microbiological sampling personnel:

- Complies with hand hygiene and garbing requirements
- When 3rd party is conducting sampling, only enters controlled areas under the supervision and guidance of the Designated Person(s) or Designee.
- Ensures all equipment and supplies introduced into a classified sterile environment are appropriately cleaned and disinfected.

IV. DEFINITIONS

- **Certificate of analysis (COA)**: A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of material
- **Designated Person (DP)**: One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.
- **Dynamic operating conditions:** Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations.
- **ISO Class:** An air-quality classification from the International Organization for Standardization
- **Primary Engineering Control (PEC):** A device or zone that provides and ISO Class 5 air quality environment for sterile compounding.
- **Restricted-access barrier system (RABS)**: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination and that generally are not to be opened during operations.
- **Secondary Engineering Control (SEC)**: The area where the PEC is placed (e.g. a cleanroom suite or SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
- **Triple clean:** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

V. PROCEDURE

Viable Air Sampling: (complete by 3rd party independent certifier)

A. Volumetric active air sampling occurs in all ISO classified areas during dynamic operating conditions
   - Air sampling locations are identified on the sterile compounding facility diagram (see Appendix 1).
   - Air sampling occurs under static conditions upon the opening of a new sterile compounding location or after major repair and/or construction in the sterile compounding location.

B. Air sampling occurs:
   - For Category 1 CSPs: initially upon opening of sterile compounding facility and every 6 months

C. The unidirectional airflow inside the Primary Engineering Control (PEC) is not disturbed when air sampling is conducted. Refer to volumetric air sampler manual for instructions of use, including the direction of airflow after media impaction occurs. Never compromise first air inside the Direct Compounding Area (DCA) of the PEC when performing air sampling.

D. Complete air sampling documentation forms every time an air sampling activity occurs. Include the following information (at minimum): [3rd party independent certifier to complete]
   - Date and time of air sampling
   - Individual(s) sampling
   - Growth media used – including manufacturer, type, lot number and expiration
   - Air sampler used
   - Volume of air drawn
   - Sampling conditions (dynamic or static, regular scheduled testing or testing after remediation)
   - Sampling locations
   - Incubation temperatures and length of incubation
   - Final growth media reading results

Surface Sampling:

A. Surface sampling occurs in all ISO classified areas during dynamic operating conditions
   - Surface sampling locations are identified on the sterile compounding facility diagram (see Appendix 1).
   - Surface sampling occurs under static conditions upon the opening of a new sterile compounding location or after major repair and/or construction in the sterile compounding location.

B. Surface sampling is performed:
   - [CONDITIONAL: For facilities compounding Category 1 CSPs only] Monthly at the end of compounding activity or shift and before the area has been cleaned and disinfected.
   - In conjunction with media-fill testing to assess aseptic manipulation competency
     - Surface sampling is performed on the DCA following media-fill testing

C. The microbiological growth media devises (e.g., plates) used for surface sampling support the growth of bacteria and fungi.
   - Surface sampling devices contain general microbial growth media supplemented with neutralizing additives to neutralize the effects of any residual disinfecting agents.
   - Surface sampling devices should have a raised convex surface
   - Sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used to sample irregular surfaces and hard to reach locations such as crevices, corners, and spaces between surfaces
   - Certificate of Analysis (COA) for all growth media used for sampling is obtained from the manufacturer.
     - All COA documents are verified to be sure the media meets the expected growth promotion, pH, and sterilization requirements.

D. Incubation of surface samples occurs at temperatures that promote growth of bacteria and fungi. Monitoring of incubator temperatures occurs manually. Documentation of incubator temperatures occurs electronically (e.g. in Simplifi).
   - Two incubators are used:
     - One is set for 30 to 35°C
     - One is set for 20 to 25°C
   - The incubator is located outside of the sterile compounding area in a dedicated area

E. Complete surface sampling documentation forms every time a surface sampling activity occurs. Include the following information (at minimum) on the form:
   - Date and time of surface sampling
   - Individual(s) sampling
   - Growth media used – including manufacturer, type, lot number and expiration
   - Sampling conditions (dynamic or static, regular scheduled testing or testing after remediation)
   - Sampling locations
   - Incubation temperatures and length of incubation
   - Final growth media reading results

F. Surface sampling procedure:
   - Remove sampling devices from the refrigerator and check the expiration date. Wipe the outside of the manufacture's overwrap with sIPA.
   - Collect all supplies needed for surface sampling and disinfect with sIPA. Supplies needed include, but are not limited to: plate, permanent marker, tape.
   - Allow sampling devices to come to room temperature prior to sampling.
   - All hand hygiene and garbing procedures are completed prior to the beginning of surface sampling procedures.
   - Stage surface sampling devices any other supplies needed inside the ante chamber of the compounding isolator.
   - Move all components into the ISO 5 environment.
   - Sanitize gloved hands with sIPA and remove the cover from the surface sampling device.
   - Using a rolling motion, firmly press the growth media surface onto the surface being sampled.
   - Place the cover back on the surface sampling device and apply tape to secure cover if needed.
   - Sampled area is wiped with 70% sterile Isopropyl Alcohol (IPA) to remove residue
   - Sampling devices are covered and stored so that condensation does not drip onto the agar

   - The growth media is incubated:
     - At 30° – 35°C (86° – 95°F) for a minimum of 48 hours for bacterial growth
       - Examine growth media at the completion of 48 hours. Count and record the total number of discrete colonies detected as CFU per surface sample. Record all information on the surface sampling environmental sampling form indicating: type of environmental sample (surface), location of surface sample, date of sample, and number of CFUs observed.
     - The surface sample is then incubated at 20o – 25oC (68°F - 77°F) for a minimum of 5 days for fungal growth
       - Examine growth media at the completion of 5 days. Count and record the total number of discrete colonies detected as CFU per surface sample. Record all information on the surface sampling environmental sampling form indicating: type of environmental sample (surface), location of surface sample, date of sample, and number of CFUs observed.

- At the conclusion of surface sampling all sites in the sterile compounding area, thoroughly clean all sampled locations and disinfect per policy prior to resuming sterile compounding.

Reading and Interpreting Results:

A. Compare all CFUs recovered to previous sample data to identify adverse results or trends over time.
   - This comparison occurs even when the results fall below the action level for the sample taken.

B. Consult a microbiologist and/or a member of Infections Disease/Infection Prevention department to assist in determining appropriate remediation steps and assess trends in resulted alert or action levels.

ISO Class	Viable Air Sample CFU/cubic meter of air per plate		Viable Surface Sample CFU per sampling device	
	Alert Level	Action Level	Alert Level	Action Level
ISO 5	>0	> 1	>0	>3
ISO 7	>5	> 10	>0	> 5
ISO 8	>50	> 100	>25	> 50

Actionable Findings:

A. If levels of CFUs measured at any of the air sampling or surface sampling testing locations exceeds the action level, attempt to identify the microorganisms present down to the genus level with the assistance of a microbiologist. Take immediate action, investigate the cause of the out of limits sample and begin a corrective action plan.
   - The microbiologist assists with determining the risk of compromising the sterility of CSPs based on the results; especially in the case of any concerning organisms.
   - The microbiologist assists with determining the appropriate remediation steps for the ISP classified locations with actionable findings.

B. The corrective action plan is dependent on the number of CFUs resulted and the microorganism recovered.
   - Examples of corrective actions include: process or facility improvements, personnel training, cleaning and disinfection, or HEPA filter repair and/or replacement
     - The corrective action investigation includes evaluation of any trends reviewed at each sampling location.
     - Immediate action is dependent on the ISO classification of the sample location.
     - Examples of immediate action based on location:

Immediate Actions based on ISO Classifications and Occurrence Frequency

ISO Classification:	1st Occurrence	2nd Occurrence
ISO 5 PEC	- Sporicidal clean PEC - Decrease BUD to 12 hours - Schedule repeat testing	- Cease compounding in ISO 5 PEC until repeat testing passes - Triple clean (sporicidal, germicidal and sIPA) - Schedule repeat testing
ISO 7 SEC Buffer or Ante	-Sporicidal clean -Schedule repeat testing	-Decrease BUD to 12 hours until repeat testing passes -Triple clean (sporicidal, germicidal and sIPA) -Schedule repeat testing
ISO 8 SEC	-Sporicidal clean -Schedule repeat testing	-Triple clean (sporicidal, germicidal and sIPA) -Schedule repeat testing **Any subsequent occurrences, drop BUD to 12 hours until repeat testing passes

     - The corrective action investigation may include a team consisting of but not limited to:
       - Pharmacy/facility leadership
       - Infection prevention specialist
       - Engineering and/or facilities operations leadership
       - Environmental Services
       - Outside cleaning services
       - Microbiology department or microbiologist
     - All members contributing to a corrective action are documented on the corrective action plan.
     - All members contributing to a corrective action are documented on the corrective action plan.
     - The investigation and corrective action are contingent a number of factors including, but not limited to:

- ISO classification of area with actionable environmental findings
- Magnitude of actionable finding (e.g., a few CFUs vs. 100s of CFUs)
- First or repeated actionable finding upon retest
- Environmental trends in actionable sites and controlled area(s) over time
- ISO certifications current and in good standing
- HEPA filter repairs and/or replacements
- Maintenance of air flow systems current (e.g. air conditioner, exhaust and/or supply fans)
- Maintenance and repairs of facility and compounding area current
- Personnel training and competencies current and in good standing
- Controlled and observed access for all non-compounding personnel and 3rd parties entering the controlled environment
- Proper selection, use, and timing of use of cleaning, disinfecting, and application of sporicidal agents
- Other potential factors (e.g. major facilities repair or construction projects inside or in the vicinity of the controlled area; actionable environmental findings elsewhere in the facility(ies) or community; etc.)

- Following implementation of the corrective action and abatement of the assumed contamination(s), re-test the location(s) per steps outlined previously.
- To confirm action plan effectiveness, compile and review data obtained from re-testing and update action plan with this data.
- Document the corrective action and all follow up air and surface sampling.

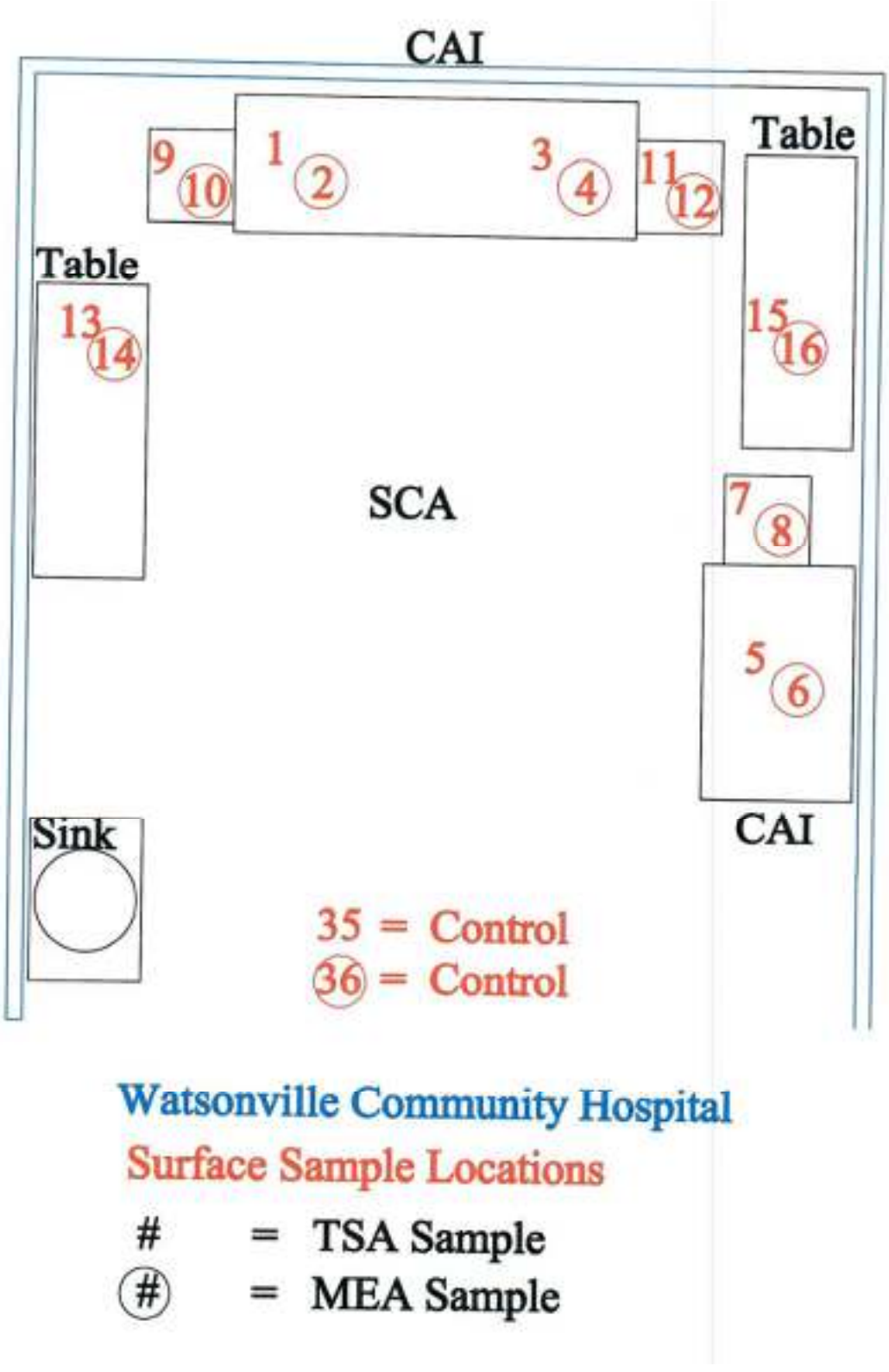
VI. REFERENCES

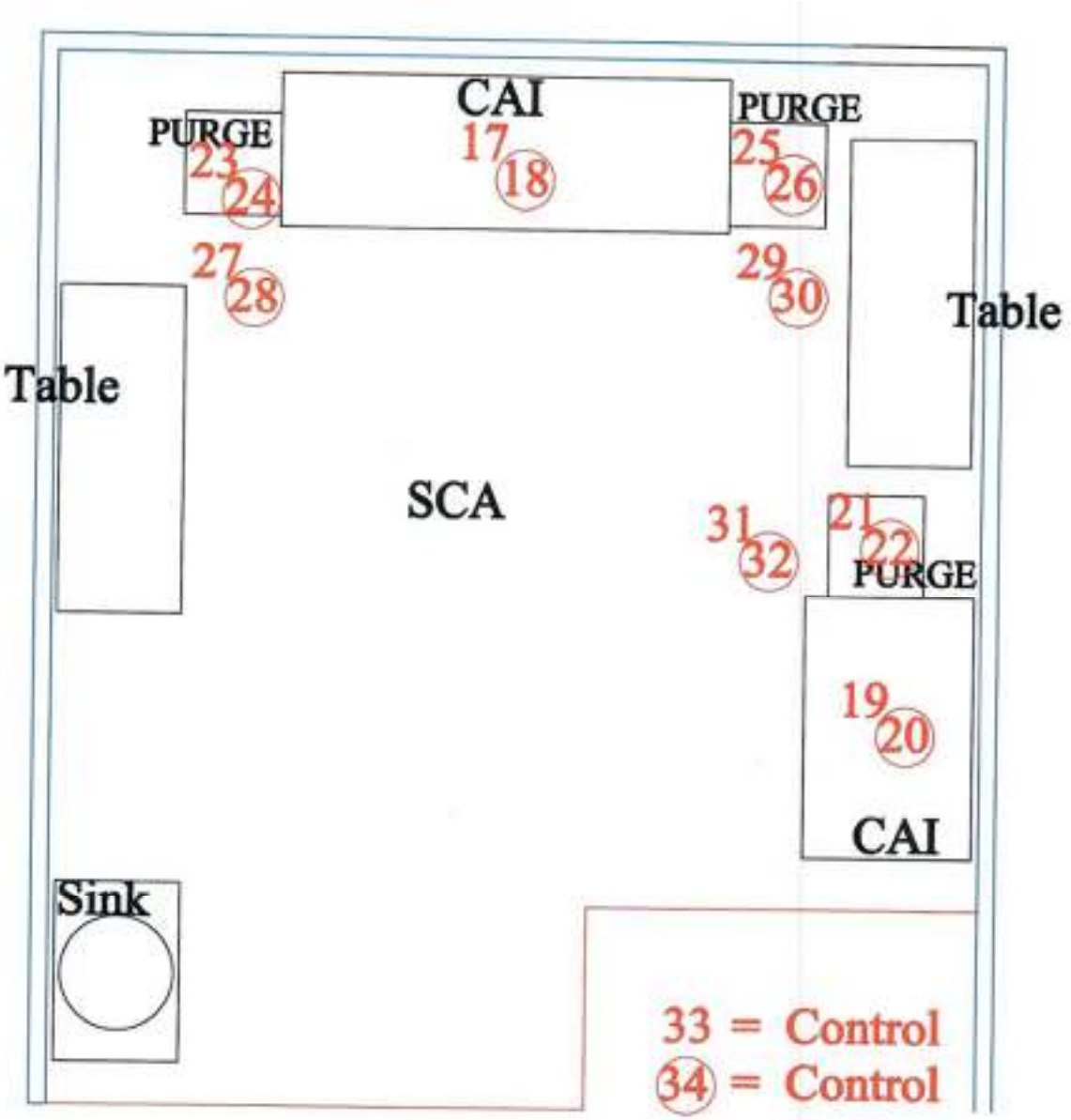
- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding - Sterile Preparations. 2022 proposed version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.
- CAG-009:2020 CETA Certification Application Guide USP Viable Environmental Sampling & Gowning Evaluation.

VII. STAKEHOLDERS

N/A

APPENDIX ONE: Facility Sampling Diagram





Watsonville Community Hospital

Viable Air Sample Locations

\# = TSA Sample

(#) = MEA Sample

APPENDIX TWO:

Watsonville Community Hospital Environmental Monitoring Investigation & Correct Action Plan

FACILITY NAME AND LOCATION	Watsonville Community Hospital
SAMPLING DATE	
RESULT DATE	
DESIGNATED PERSON (or Designee)	
DESCRIPTION OF ACTIONABLE FINDING	Location: CFU counts: Organism(s): ISO classification: Was pre-emptive cleaning performed after samples were obtained?
DESCRIPTION OF OCCURRENCE	
DIDACTIC TRAINING RESOURCES	Critical Point

IMMEDIATE REMEDIAL ACTIONS TAKEN	
☐ Cleaning • Date: • Personnel: • Cleaning Agent: ☐ Beyond-use Date Reduced • Date/time: • Interim BUD: ☐ Retesting scheduled or completed • Date: • Qualified Sampler: ☐ Alert management and contact needed experts. List Experts: ☐ Other:	NOTES:

INVESTIGATION	
ENVIRONMENT: ☐ Environmental trends at actionable locations checked ☐ Environment free of items not necessary for compounding and/or items that shed ☐ Facilities and/or surrounding community environmental ☐ Cleaning Logs (and monthly sporicidal cleaning) current ☐ Other:	NOTES:
PERSONNEL: ☐ Compounding personnel training & competency current ☐ Comparison of environmental monitoring and personnel findings and trends to detect patterns ☐ Appropriate compounding personnel behaviors & hygiene practices upheld ☐ Non-compounding personnel and visitors escorted, observed, and compliant with hand hygiene and garbing expectations ☐ Other:	NOTES:

MICROBIOLOGY ASSESSMENT:	
{{List of actionable findings and organisms identified by classified area:}} *ISO 5 PECs:*	*{{Description of organisms cultured including vectors, pathogenicity, and other factors to be considered}}*

CORRECTIVE ACTION PLAN:		
☐ Facilities (PEC and/or SEC) repairs or improvements	DESCRIPTION:	OUTCOME:
☐ Workflow improvements		
☐ Personnel reeducation		
☐ Additional cleaning, environmental sampling, etc.		
☐ Other:		

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Investigation and Remediation in the Event Sampling Exceeds Alert or Action Levels	Policy #	PHARM001
Responsible	Pharmacy Director	Revised/Reviewed	8/21/2020

I. PURPOSE

- This SOP defines what an excursion is and establishes when and how action is taken to regain a microbial state of control. It outlines a logical set of information sought during initial and ongoing investigations of microbial excursions in environmental and personnel sampling.
- No document can provide all encompassing guidance for specific investigation and remediation of new or ongoing excursions, but *Matrix of Actions for First Out of Limits Occurrence* (F-205.b) and *Matrix of Actions for Consecutive and Repeat Out of Limits Occurrence* (F-205.c) provide matrixes of actions to be considered for a first out of level (OOL) occurrence and additional OOLs respectively.
- This policy also provides general guidance followed in any investigation as well as parameters which are included and the documentation of these actions.

II. POLICY

A. It is not alarming and is, in fact, expected that small numbers of CFUs (below designated Action Levels) will be found in ISO 7 and 8 environments and even 1 CFU (colony forming unit) in ISO 5 spaces.

B. The occurrence of consistent 0 CFU returns in viable air, surface or gloved fingertip sampling prompts a high degree of suspicion that sampling procedures and activities are flawed.

C. USP 797 (2019) requires the identification of growth in viable air, surface or gloved fingertip samples to occur when growth exceeds the Action Level (as specified for each type of sampling per USP 797).

D. An OOL condition or excursion is said to exist under the following conditions:

1. Action Level: When the CFUs counted in any sample (air, surface, gloved fingertip) exceed the established Action Level for the type of sampling. Refer to policy on gloved fingertip sampling and tables attached for surface and viable air sampling for Action Levels. All sections of *Facility and Personnel Sampling Action Report* (F-205.a) must be completed.
2. Alert Level: When the CFUs counted in any sample (air, surface, gloved fingertip) exceed the established Alert Level but are below the established Action Level for the type of sampling. Refer to policy on gloved fingertip sampling and tables attached for surface and viable air sampling for Alert Levels. *Facility and Personnel Sampling Action Report* (F-205.a) is used as a tool to evaluate factors that could be contributing to elevated microbial levels. The use of Alert Levels is not required by USP 797 but is a best practice recommendation.
3. Organism of Concern: When the CFUs counted in any sample (air, surface, gloved fingertip) are *below* the established Alert and Action Level for the type of sampling, but an organism of concern is recovered. Organisms of concern are certain gram positive spore-forming rods, certain gram negative rods, coagulase positive staphylococcus and some yeasts and molds. *Facility and Personnel Sampling Action Report* (F-205.a) is used as a tool to evaluate factors that could be contributing to recovery of organisms that are not typically seen as part of the facility's microbial population or should be further investigated if they are being repeatedly recovered in the facility.

E. There are three types of OOLs.

1. First OOL: The very first time a location has an EM OOL.
2. Consecutive OOL: When a location has back to back EM OOLs, either organisms of concern or an exceeded action level.

3. Repeat OOL: When a location has an OOL again, either organisms of concern or an exceeded action level, but the OOLs have not occurred consecutively.

F. Plates are sent to the laboratory for identification of growth for the following reasons:

1. Anytime an established Action Level is exceeded the growth is identified as required by USP 797.
2. Consideration may be given to performing identifications when an established Alert Level in a specific location is exceeded more than once. Gathering additional information may be helpful in identifying the source of the microorganisms.
3. If sample counts are below the Action and Alert levels, but an organism of concern is recovered, identification of the microorganism may be sought to provide additional information about an unexpected change in work practices or facility control.

III. DEFINITIONS

N/A

IV. PROCEDURE

Specific Work Practices and Procedure Descriptions

A. When an OOL or excursion is realized, the following forms are used: *Facility and Personnel Sampling Action Report*; F-205.a and *Matrix of Actions for First Out of Limits Occurrence*, F-205.b. For a consecutive or repeat OOL use *Matrix of Actions for Consecutive and Repeat Out of Limits Occurrence* (F-205.c).

1. If the number of CFUs recovered exceed the Action Level, all sections of *Facility and Personnel Sampling Action Report* (F-205.a) are completed.
2. If the number of CFUs recovered exceed the Alert Level but fall below an Action Level, then *Facility and Personnel Sampling Action Report* (F-205.a) is used to document the evaluation that must occur.
    a. Follow up sampling is not required but may be considered during the first occasion that a sample location Alert Level is exceeded (but below an Action Level).
    b. In the event an Alert Level is exceeded during two consecutive samplings for a given location, then an investigation, remediation and resampling is required.
3. If the number of CFUs recovered is below the Alert Level (if applicable) or below the Action Level, but an organism of concern is recovered, *Facility and Personnel Sampling Action Report* (F-205.a) may be used determine the possible source of the microorganism and identify any work practice changes.

B. *Facility and Personnel Sampling Action Report* (F-205.a) is used to guide the investigation and to document actions. By completing the first section of *Facility and Personnel Sampling Action Report* (F-205.a), the appropriate information is collected, identifying the proper actions to be taken as described on *Matrix of Actions for First Out of Limits Occurrence* (F-205.b).

C. Take the actions as outlined on *Matrix of Actions for First Out of Limits Occurrence* (F-205.b), based on whether sampling is viable air, surface sampling or gloved fingertip sampling and the ISO classification of the space.

D. Additional actions may be required beyond the actions specified in *Matrix of Actions for First Out of Limits Occurrence* (F-205.b) if the first set of remedial actions do not reestablish a microbial state of control. Follow *Matrix of Actions for Consecutive and Repeat Out of Limits Occurrence* (F-205.c).

E. Continue completing *Facility and Personnel Sampling Action Report* (F-205.a) as information becomes available.

F. The investigation described on *Facility and Personnel Sampling Action Report* (F-205.a) includes identification and documentation of any or all of the following:

1. Type of sample and conditions under which sampling occurred
2. Type of excursion
3. Verification that activities related to sampling were performed correctly
4. Microbial control actions taken since sampling and before receiving results
5. Evaluation of certification reports, work logs (pressure, cleaning, humidity, etc.), competencies
6. Review of the environmental sampling results, which is to include the following questions:
    a. Was growth isolated to one location?
    b. Was growth found in adjacent sites?
    c. If so, was the organism the same in contiguous sites?
7. Evaluation of historical growth trends and determination of the frequency of the organism's recovery, which is to include the following questions:
    a. Was the location positive for this growth in last 6 months?
    b. Has the location been retested previously?
    c. Has the employee had other positive findings?
    d. If so, what were they?
8. Review of the microbiological results, which is to include the following questions:
    a. Was the typical reservoir for the microbe or microbes identified?
    b. What is the typical reservoir?
    c. Was the excursion found close to a location that would be considered a typical reservoir?

G. All excursions require remediation and the plan of remediation is documented on *Facility and Personnel Sampling Action Report* (F-205.a).
    1. It may take several follow up actions and samples to identify, remediate and bring the sample location back into a state of control.
    2. Those initial and follow up actions and their results are documented on the form.
    3. The excursion and any follow up action must be concluded and the date that the remediation plan is closed must be documented and reviewed by the designated person/s.

H. Any additional aspects related to the excursion that are included in the investigation must be thoroughly documented, including dates of action, specific action taken and the outcome of the actions.

Documentation Elements

I. When using *Facility and Personnel Sampling Action Report* (F-205.a), consider the following:
    1. Any line items that are not required or used must be checked as not applicable or an explanation given.
    2. Any Action Level requires a complete investigation which is documented by completing Section 2 of the form and a specific plan of remedial action must be developed, executed, and documented in Section 3 of the form.
    3. Serial documentation of actions and outcomes must be documented on page 4 of 4 of the form.

J. Additional pages maybe attached if needed and the added pages must be clearly numbered.

K. The date the investigation and when remediation is officially closed must be documented on the form and signed by the designated person/s.

V. REFERENCES

A. Internal Documents

1. *Facility and Personnel Sampling Action Report* (F-205.a)
2. *Matrix of Actions for First Out of Limits Occurrence* (F-205.b)
3. *Matrix of Actions for Consecutive and Repeat Out of Limits Occurrence* (F-205.c)
4. Gloved Fingertip Sampling (P#2753)
5. Personnel Aseptic Media Fill Testing and Process Verification (P#2754)
6. Training, Conduct and Competency of Compounding Personnel (P#2751)

B. External Documents (see examples below)

1. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding—Sterile Preparations. 2019.
2. United States Pharmacopeial Convention, Inc. <1116> Microbial Control and Monitoring of Aseptic Processing Environments. 2018.

VI. STAKEHOLDERS

N/A

Surface sampling microbial contamination Alert and Action Levels are summarized in the table below.

Type and Location of Surface	Alert Level	Action Level
ISO Class 5 Work Surface	>1 CFU per plate	>3 CFU per plate
ISO Class 7 Work Surface	>2 CFU per plate	> 5 CFU per plate
ISO Class 7 Non-Work Surface	>5 CFU per plate	>10 CFU per plate
ISO Class 8 Work Surface	>12 CFU per plate	> 25 CFU per plate
ISO Class 8 Non-Work Surface	>25 CFU per plate	>50 CFU per plate

Viable air sampling microbial contamination Alert and Action Levels are summarized in the table below.

Location of Air	**Alert Level** *(not required)* **Sample = 1000 liters/plate**	**Action Level*** **Sample = 1000 liters/plate**
ISO Class 5 Air	any growth is investigated	>1 CFU
ISO Class 7 Air	>5 CFU	> 10 CFU
ISO Class 8 Air	>50 CFU	> 100 CFU
* CFUs per cubic meter of air per plate (cubic meter = 1000 liters) are taken from Table 5 in USP 797		

Watsonville Community Hospital (F-205.a)

Facility and Personnel Sampling Action Report

Action began at: ☐ Interim read: _____ day or ☐ Final read

Type of Environmental Sample: ☐ **Viable Air Sampling (VAS)** ➡ ☐ Single sample or ☐ Multiple samples

Check all that apply: ☐ ISO 5 ☐ ISO 7 ☐ ISO 8 ☐ Non-ISO Classified; ☐ Negative space ☐ Positive space;

Performed under which conditions: ☐ Static ☐ Dynamic

Describe specific location/s from ESP: _____ Date sampled: _____

☐ **Surface Sampling (SS)** ➡ ☐ Single sample or ☐ Multiple samples

Check all that apply: ☐ ISO 5 ☐ ISO 7 ☐ ISO 8 ☐ Non-ISO Classified; ☐ Negative space ☐ Positive space;

Performed under which conditions: ☐ Static ☐ Dynamic

Describe unit/s location based on ESP: _____ Date sampled: _____

Type of Personnel Sample: sampled ☐ randomly or ☐ during predetermined testing occurrence

☐ ***Initial* GFS** ➡ # CFU L hand: ____ R hand: ____ Date sampled: _____

☐ ***Ongoing* GFS** (during compounding) ➡ # CFU L hand: ____ R hand: ____ Date sampled: _____

☐ ***Surface Sample*** (during compounding) ➡ # CFU L hand: ____ R hand: ____ Date sampled: _____

☐ ***Media Fill Unit (MFU)*****➡ #units made: _____** #units positive: _____ Date units prepared: _____

Type of Excursion:

☐ **Below Action Level AND organism of concern** (see SOP 205)

☐ **Alert Level Exceeded:** If Alert Level Triggered but Action Level not then perform an evaluation of appropriate facility engineering controls, personnel; work practice changes and environmental factors that could be causing this increase in personnel or environmental findings in an effort to regain microbial control. Document review, conclusions and actions taken.

☐ **Action Level Exceeded:** Complete all sections of this form.

Complete the following actions and document additional information in the space provided below:

1. Date Pharmacy Manager notified: _____
2. Was there evidence that incubated samples/MFUs were exposed/leaking during incubation? ☐ Yes☐ No

---

Send Samples for Microbial Identification:

☐ N/A (if Alert Level triggered and decision made not to send for ID)

☐ Digital image taken of each sample/MFU at end of incubation if Action Level was exceeded by: _____

☐ Name and contact info for Laboratory performing ID: _____

☐ Completed documentation and prepared units in packaging per lab instruction by: _____

☐ Transport to lab by: ☐ Hand Delivered ☐ Third Party Carrier: _____Tracking number: _____

Expected delivery: _____

Microbiological Results: ☐ N/A (if Alert Level and no ID performed) ☐ Results attached (Number pages: _____)

Date results received: _____

What is the typical reservoir for the microbe or microbes identified? ☐ Yes ☐ No

Was the location of the excursion in close proximity to the location of the typical reservoir? ☐ Yes ☐ No

Has this organism/s been found at this location previously? ☐ Yes ☐ No

Section 2: Additional Investigation Actions Taken

1. **Were there additional microbial control provisions that have occurred between when the sampling occurred and the microbial results were received?** ☐ Yes ☐ No

   If yes, describe those microbial control provisions:

   _____

2. **Was Certification documentation of SEC/PEC associated with samples reviewed?** ☐ Yes ☐ No

   Did the review identify any discrepancies or issues that were previously unidentified? ☐ Yes ☐ No

   If yes, describe the discrepancies: _____

   _____

3. **Were documentation/logs of relevant work practices associated with the finding reviewed?** ☐ Yes ☐ No

   a. Based on review of documentations and staff interviews, was correct procedure followed?

☐ GFS ☐ Yes ☐ No	☐ MFU ☐ Yes ☐ No	☐ VAS ☐ Yes ☐ No	☐ SS ☐ Yes ☐ No

   b. Check all that apply and dates checked: ☐ Cleaning Logs; Dates: _____ ☐ ES Logs; Dates: _____

   ☐ Media Fill Logs: Dates: _____ ☐ Pressure Logs; Dates: _____ ☐ Temperature Records; Dates: _____

   ☐ Humidity Records; Dates: _____ ☐ Garbing Competency; Dates: _____ ☐ Aseptic Technique Competency;

   Dates: _____ ☐ Other: _____; Dates: _____

   c. Did the review identify any discrepancies or issues that were previously unidentified? ☐ Yes ☐ No

   If yes, describe the discrepancies: _____

   _____

4. **Was the area recleaned after receiving this microbiological identification?** ☐ N/A ☐ Yes ☐ No

   If yes, what agent/s was the area treated with? _____

   If yes, when was the area recleaned (include date and time): _____

5. **Was the area taken out of service (compounding suspended)?** ☐ N/A ☐ Yes ☐ No

   If yes, explain what was done: _____

6. **Was the SEC/PEC checked or repaired by authorized personnel?** ☐ N/A ☐ Yes ☐ No

   If yes, what was the date and company and attach documentation: _____and number pages _____

   If work done inside a PEC and/or SEC, was area triple cleaned per policy? ☐ N/A ☐ Yes ☐ No

7. **Were assigned BUDs shortened for any period of time?** ☐ N/A ☐ Yes ☐ No

   If yes, explain what was done: _____

8. ***Environmental* findings only:** ☐ VAS ☐ SS (other than that taken during compounding)

a. Was historical trend of sample location reviewed? ☐ Yes ☐ No

b. Has this location/s had other positive findings within the last 6 months? ☐ Yes ☐ No

c. Are there multiple excursions found in the room? ☐ Yes ☐ No

d. Was the area/s retested? ☐ N/A ☐ Yes ☐ No

e. If yes, date of retest: _____

f. Microbiological Results of Retest: Date results received: _____ ☐ Number pages attached: _____

g. Comparison of results to initial finding: ☐ Below Alert Level on repeat ☐ Below Alert Level on repeat

(Check all that apply): ☐ Exceeds Alert Level on repeat ☐ Exceeds Action Level on repeat

Discussion of Findings: _____

_____

9. ***Personnel* findings only:** ☐ *Initial* GFS, ☐ *Ongoing* GFS ☐ MFU ☐ SS (taken during compounding)

a. Has this employee had other positive findings within the past 2 years? ☐ N/A ☐ Yes ☐ No

b. If yes, explain: _____

c. Employee removed from compounding (if ongoing GFS/SS during compounding) ☐ N/A ☐ Yes ☐ No

d. Were personnel retested after unacceptable results? ☐ N/A ☐ Yes ☐ No

e. If yes, date of retest: _____

f. Microbiological Results of Retest: Date results received: _____ ☐ Number pages attached: _____

g. Comparison of results to initial finding: ☐ Below Alert Level on repeat ☐ Below Alert Level on repeat

(Check all that apply): ☐ Exceeds Alert Level on repeat ☐ Exceeds Action Level on repeat

Discussion of Findings: _____

_____

h. Did personnel successfully complete each of the following (attach forms)?

Competency assessment for Hand Hygiene and Garbing (F-410.a) ☐ N/A ☐ Yes ☐ No

Competency assessment for Aseptic Technique (F-410.b) ☐ N/A ☐ Yes ☐ No

10. **Was any personnel retraining conducted?** ☐ N/A ☐ Yes ☐ No

If yes, explain what was done; attach training logs and other information (total # of pages attached: _____)

_____

11. **Based on the investigation, were work practices changed?** ☐ N/A ☐ Yes ☐ No

If yes, which SOPs and/or Forms were changed: _____

_____ _____

Signature of Person Completing Sections 1 and 2 Date Sections Completed in Entirety

Section 3: Plan of Remediation

Document specific plan, actions taken, outcomes and follow up. Any area checked in red in Section 2 must be explained in detail. Each entry (if multiple entries) must be dated and signed by the person making the entry if the plan was not documented during one instance.

Section 4: Resampling and Results

Type of Environmental Resample:

☐ **Viable Air Sampling (VAS) ➡** ☐ Single sample or ☐ Multiple samples

Performed under which conditions: ☐ Static ☐ Dynamic ☐ Static and Dynamic for ISO 5

Describe specific location/s from ESP: _____ Date sampled: _____

☐ **Surface Sampling (SS) ➡** ☐ Single sample or ☐ Multiple samples

Performed under which conditions: ☐ Static ☐ Dynamic ☐ Static and Dynamic for ISO 5

Describe unit/s location based on ESP: _____ Date sampled: _____

Type of Personnel Resample: sampled ☐ randomly or ☐ during predetermined testing occurrence

☐ ***Initial* GFS ➡** # CFU L hand: ____ R hand: ____ Date sampled: _____

☐ ***Ongoing* GFS** (during compounding) ➡ # CFU L hand: ____ R hand: ____ Date sampled: _____

☐ ***Surface Sample*** (during compounding) ➡ # CFU L hand: ____ R hand: ____ Date sampled: _____

☐ ***Media Fill Unit (MFU)*➡ #units made: _____** #units positive: _____ Date units prepared: _____

Results:

☐ **No Excursion. Close investigation.**

☐ **Excursion. Follow F-205.c for next steps. Document in section 3.**

_____ _____

Signature of Pharmacy Manager or Designee Date Investigation and Remediation Closed

Matrix of Actions for **First** OOL Occurrence (F-205.b)

Surface Sampling (SS)	If OOL in ISO 5 (PEC)	If OOL in ISO 7 Buffer Room	If OOL in ISO 7/8 Anteroom
	PEC is only ISO 5 Work Surface so: 1) Perform investigation (see F-205.a) and document to try to identify possible cause. 2) Investigate if something unusual happened during initial sampling thru staff interviews. 3) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 4) Follow the instructions for ISO 5 VAS OOL. ***Note:*** When SS is performed during compounding (dynamic conditions) it becomes more of a personnel metric since it is the operator's responsibility to keep the deck below the DCA disinfected. OOL for SS taken during compounding are usually related to poor operator aseptic technique. See actions and information under "ongoing GFS."	1) Perform investigation (see F-205.a) and document to try to identify possible cause. 2) Investigate if something unusual happened during initial sampling thru staff interviews. 3) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 4) Resample after daily cleaning and under static conditions (usually the next morning if cleaning done at end of day). 5) Resample toward end of first shift under dynamic conditions. 6) Note the persons who performed the last cleaning as well as those working in the area during sampling. ***Note:*** Concern is if finding same organism in multiple ISO areas, there is a possibility that cleaning agents are contaminated (e.g., bacillus spores in IPA), other components contaminated or material handling work practices need remediation.	1) Perform investigation (see F-205.a) and document to try to identify possible cause. 2) Investigate if something unusual happened during initial sampling thru staff interviews. 3) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 4) Resample after daily cleaning and under static conditions (usually the next morning if cleaning done at end of day). 5) Resample toward end of first shift under dynamic conditions. 6) Note the persons who performed the last cleaning as well as those working in the area during sampling. ***Note:*** Concern is if finding same organism in multiple ISO areas, there is a possibility that cleaning agents are contaminated (e.g., bacillus spores in IPA), other components contaminated or material handling work practices need remediation.

Matrix of Actions for **First** OOL Occurrence (F-205.b)

Viable Air Sampling (VAS) Recommend only 1000 liter samples be performed (if smaller sample, must adjust colony forming unit (CFU) findings to equivalent of 1000 liter sample)	**If OOL in ISO 5 (PEC)**	**If OOL in ISO 7 Buffer Room**	**If OOL in ISO 7/8 Anteroom**
	1) Perform investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Investigate if something unusual happened during initial sampling thru staff interviews. 3) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 4) Actions: a. Clean PEC with sporicidal followed by disinfection with sterile IPA b. Leave to rest overnight or at least 4 hours c. Perform VAS and SS during static conditions d. Assign a person to perform compounding that is different than the one compounding on the day of the OOL VAS e. Near end of shift, take VAS and SS during dynamic conditions f. If OOL again, take PEC out of service and perform investigation to determine cause g. If it is only PEC, perform 3 time clean (germicidal detergent x 2 followed by sporicidal); reduce BUD to 12 hours; schedule certifier to evaluate PEC.	1) Perform investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Investigate if something unusual happened during initial sampling thru staff interviews. 3) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 4) Resample VAS under dynamic conditions. 5) Note the persons who performed the last cleaning as well as those working in the area during sampling.	1) Perform investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Investigate if something unusual happened during initial sampling thru staff interviews. 3) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 4) Resample VAS under dynamic conditions. 5) Note persons working in the area during sampling as well as persons who performed the last cleaning. ***Note:*** The anteroom is the only space the presence of a low level of fungal hits. (e.g., ***Alert Level*** for ISO 7 room air is 5 so may have 1 fungal hit; Alert Level for ISO 8 room air is 50 so may have 5 fungal hits) are not alarming and are, in fact expected. Ungarbed people enter the dirty side of the anteroom as well as products (if no pass-through) before they are wiped off with the designated cleaner and disinfectant (preferably a sporicidal) before they are transferred to a clean cart on the clean side of the line of demarcation.

Matrix of Actions for **First** OOL Occurrence (F-205.b)

Gloved Fingertip Sampling (GFS)	***Initial GFS (always performed in ISO 7 Buffer Room or Non-ISO Classified SCA if BSC or LAFW; Performed in ISO 5 air if initial GFS performed in CACI or CACI)***
	1) Any growth is a failure. 2) Perform investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 3) Allow operator to practice putting sterile gloves on in a non-threatening environment outside of the ISO space with master performer. 4) When ready observe the practice, and assist to identify difficulties. 5) Ask the operator to talk through the hand hygiene and garbing sequence before doing it. 6) Have the operator demonstrate the ability to successfully don sterile gloves. 7) Resample the operator after they don sterile gloves. 8) Resample two more times during distinct, but consecutive occurrences of hand hygiene and garbing. ***Note:*** The ability to don sterile gloves without contaminating them is a basic essential skill and must be mastered before the operator can continue training. It is not until they demonstrate three, consecutive, but distinct instance of performing hand hygiene and garbing with sterile gloving that they can be considered to have passed Initial GFS.
	Ongoing GFS (always performed in ISO 5 air)
	Any ongoing GFS is taken during compounding (either during preparation of media fill units or randomly during compounding) and is therefore always performed during compounding (dynamic conditions). As such ongoing GFS is a personnel metric since it is the operator's responsibility to keep their gloved hands clean. OOL findings in this instance are related to a breach/s in operator aseptic technique which includes but is not limited to the following: • Touching face, adjusting garb, touching other high bioburden items (even when disinfecting hands) • Failure to redisinfect gloved hands with sterile IPA if hands are removed from PEC, after touching nonsterile items, immediately before accessing critical sites • Poor organization and disinfection of the work surface • Poor organization of supplies in designated compounding area causing turbulence Any person who fails ongoing GFS must have at least the following actions taken and documented: 1. Perform investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2. Consider having the operator repeat any didactic training and testing available at the pharmacy. 3. Meaningfully review all of the line items in the Aseptic Technique competency. 4. Ask the failed operator to explain what "first air" means, when they disinfect gloves and other elements of the aseptic technique competency so they can demonstrate (or not) their understanding. 5. Master performer to observe the operator during the next compounding instance to critique aseptic technique. 6. Resample failed operator during the next compounding instance (whether that is during media fill or during sterile compounding). 7. Randomly resample failed operator two more times toward the end of the compounding day within the next 3 work days.

Matrix of Actions for **Consecutive and Repeat** OOL Occurrence (F-205.c)

Viable Air Sampling (VAS) Consecutive OOL	If OOL in ISO 5 (PEC)	If OOL in ISO 7 Buffer Room	If OOL in ISO 7/8 Ante-room
	1) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 3) If the static resample fails with or without failure of the dynamic resample, take the PEC out of service. Schedule the certifier. Continue investigation. 4) If it is the only PEC, perform a 3-time clean (EPA registered one-step disinfectant cleaner x 2 followed by sporicidal), wipe with sterile 70% IPA. Reduce to a 12-hour BUD and schedule the certifier to evaluate the PEC. 5) If the static resample passes and the dynamic resample fails, evaluate personnel to determine if retraining in aseptic technique is necessary. Continue to apply USP <797> beyond-use-dating. Resample under dynamic conditions. If the resample fails, reduce to a 12-hour BUD. Consider repeating static testing to be sure the PEC is functioning properly.	1) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 3) Any CSP prepared must have 12-hour dating until sampling is repeated and levels are acceptable. 4) If the failure is related to non-adherence to contamination control procedures (material transfer, garbing, cleanroom behavior), staff re-training is performed. 5) If the failure is related to the performance of the buffer room, the certifier will be contacted for evaluation and repair. 6) The location is resampled after appropriate corrective actions are taken.	1) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 3) Any CSP prepared must have 12-hour dating until sampling is repeated and levels are acceptable. 4) If the failure is related to non-adherence to contamination control procedures (material transfer, garbing, cleanroom behavior), staff re-training is performed 5) If the failure is related to the performance of the ante-room, the certifier will be contacted for evaluation and repair. 6) The location is resampled after appropriate corrective actions are taken.
Repeat OOL	Depending on the time between the OOLs and the organisms recovered, the repeat OOL may be treated as a first OOL (See F-205.b) or a consecutive OOL. This determination is made by the designated person/s and is based on past data.		

Matrix of Actions for **Consecutive and Repeat** OOL Occurrence (F-205.c)

Surface Sampling (SS) Consecutive OOL	**If OOL in ISO 5 (PEC)**	**If OOL in ISO 7 Buffer Room**	**If OOL in ISO 7/8 Ante-room**
	1) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 3) Follow the instructions for ISO 5 VAS OOL.	1) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 3) Any CSP prepared must have 12-hour dating until sampling is repeated and levels are acceptable. 4) If the failure is related to non-adherence to contamination control procedures (material transfer, garbing, cleanroom behavior), staff re-training is performed. 5) If the failure is related to the performance of the buffer room, the certifier will be contacted for evaluation and repair. 6) The location is resampled after appropriate corrective actions are taken.	1) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 3) Evaluate the OOL and consider 12-hour dating until sampling is repeated and levels are acceptable. 4) If the failure is related to non-adherence to contamination control procedures (material transfer, garbing, cleanroom behavior), staff re-training is performed. 5) If the failure is related to the performance of the buffer room, the certifier will be contacted for evaluation and repair. 6) The location is resampled after appropriate corrective actions are taken.
Repeat OOL	Depending on the time between the OOLs and the organisms recovered, the repeat OOL may be treated as a first OOL (See F-205.b) or a consecutive OOL. This determination is made by the designated person/s and is based on past data.		

Matrix of Actions for **Consecutive and Repeat** OOL Occurrence (F-205.c)

Surface Sampling (SS) Consecutive OOL	**If OOL in ISO 5 (PEC)**	**If OOL in ISO 7 Buffer Room**	**If OOL in ISO 7/8 Ante-room**
	1) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 3) Follow the instructions for ISO 5 VAS OOL.	1) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 3) Any CSP prepared must have 12-hour dating until sampling is repeated and levels are acceptable. 4) If the failure is related to non-adherence to contamination control procedures (material transfer, garbing, cleanroom behavior), staff re-training is performed. 5) If the failure is related to the performance of the buffer room, the certifier will be contacted for evaluation and repair. 6) The location is resampled after appropriate corrective actions are taken.	1) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Send sample for ID to licensed lab that provides this service and has been accredited to ISO 17025. 3) Evaluate the OOL and consider 12-hour dating until sampling is repeated and levels are acceptable. 4) If the failure is related to non-adherence to contamination control procedures (material transfer, garbing, cleanroom behavior), staff re-training is performed. 5) If the failure is related to the performance of the buffer room, the certifier will be contacted for evaluation and repair. 6) The location is resampled after appropriate corrective actions are taken.
Repeat OOL	Depending on the time between the OOLs and the organisms recovered, the repeat OOL may be treated as a first OOL (See F-205.b) or a consecutive OOL. This determination is made by the designated person/s and is based on past data.		

Matrix of Actions for **Consecutive and Repeat** OOL Occurrence (F-205.c)

Gloved Fingertip Sampling (GFS)	***Initial GFS (always performed in ISO 7 Buffer Room or Non-ISO Classified SCA if BSC or LAFS; Always performed in ISO 5 air if initial GFS performed in CACI or CACI)***
	1) Any growth is a failure. 2) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 3) Allow operator to practice putting sterile gloves on in a non-threatening environment outside of the ISO space with master performer. 4) When ready observe the practice, and assist to identify difficulties. 5) Ask the operator to talk through the hand hygiene and garbing sequence before doing it. 6) Have the operator demonstrate the ability to successfully don sterile gloves. 7) Resample the operator after they don sterile gloves. 8) Resample two more times during distinct, but consecutive occurrences of hand hygiene and garbing. ***Note:*** The ability to don sterile gloves without contaminating them is a basic essential skill and must be mastered before the operator can continue training. It is not until they demonstrate three, consecutive, but distinct instance of performing hand hygiene and garbing with sterile gloving that they can be considered to have passed Initial GFS.
	Ongoing GFS (always performed in ISO 5 air regardless of PEC)
	Consecutive OOL 1) Continue investigation (see F-205.a) of relevant elements and document to try to identify possible cause. 2) Remove the operator from compounding. 3) Repeat any didactic training and testing available at the pharmacy. 4) Meaningfully review all of the line items in the Aseptic Technique competency. 5) Ask the failed operator to explain what "first air" means, when they disinfect gloves and other elements of the aseptic technique competency so they can demonstrate (or not) their understanding. 6) Master performer to observe the operator during simulated compounding activities to critique aseptic technique. 7) Once the master performer feels the operator is ready, resample failed operator during media fill or simulated sterile compounding. 8) With passing results, the operator can return to compounding. 9) Randomly resample failed operator two more times toward the end of the compounding day within the next 3 work days of returning to compounding. **Repeat OOL** 1) Depending on the time between the OOLs, the repeat OOL may be treated as a first-time OOL (See F-205.b) or a consecutive OOL. This determination is made by management and is based on past data.

Watsonville Community Hospital	**Complaint, Adverse Drug Reaction, & Recall Handling**
Policy Number/ Version:	797-2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the procedures for documenting, assessing risk of patient harm, and determining response urgency and approach for quality related complaints and adverse drug reactions (ADRs) concerning Compounded Sterile Preparations (CSPs) prepared within Watsonville Community Hospital. The policy also provides the procedures to rapidly implement a CSP recall when serious patient harm is known or suspected.

1.2. Complaints and reports of ADRs can come from a variety of sources including, but not limited to, patients, caregivers, prescribers/providers, regulatory bodies, or other healthcare related sources.

1.3. CSP recalls are initiated based on the severity of risk of serious or life-threatening patient harm associated with product quality-related issues, with special consideration given to risk assessment of high-risk patient populations and routes of administration, including:

- Reported serious or life-threatening ADR due to CSP quality
- Manufacturer recall of components or supplies used during sterile manipulations and processing of dispensed CSPs
- Facilities, sterile compounding equipment, or engineering control failures detected after CSPs are compounded and dispensed and that present a substantial risk of compromising CSP sterility, potency, or similar quality attribute

1.4. CSP complaint and ADR handling and quality related product recalls are performed according to regulatory and statutory requirements for California State Board of Pharmacy.

2. Policy

2.1. CSP related complaints and ADRs are promptly logged and documented electronically in facility event reporting system (e.g., “Verge”).

2.2. [USP 797] Adverse reactions with known or highly suspected potential to cause patient harm are reported to the Designated Person (DP) or Designee immediately upon receipt. The reported event is reviewed within 2 hours of receipt of report by the Designated Person (DP) or Designee if the DP is unavailable. CSP recall procedures, if needed, are initiated within 4 hours of review.

2.3. [USP 797] Complaints or concerns about CSPs are reviewed immediately by the Designated Person (DP) or Designee. Based on a risk assessment, an investigation and appropriate corrective actions, up to and including CSP recall, are initiated in a timely manner.

2.4. [USP 797] If a CSP recall is initiated, the following actions are required:

- Immediate notification of the prescriber regarding the CSP quality failure with the potential to cause patient harm
- Recall of unused dispensed CSPs and quarantine of stock remaining in the pharmacy
- Investigation to determine if other CSP lots are affected and recalled if necessary
- Risk severity and recall urgency assessment

- Determination of the distribution and disposition of affected CSPs
- Determination of the patients and corresponding prescribers in receipt of affected CSPs
- Documentation and disposal of recalled CSPs
- Investigation and determination of reason for quality failure
- Implementation of corrective action plan and verification of its effectiveness

2.5. [USP 797] Serious or life-threatening adverse events potentially associated with the quality of CSPs are reported per the laws and regulations of the jurisdiction in which the CSP was compounded an/or where the patient was treated (i.e., California State Board of Pharmacy).

- **[CA-BOP 4127.1,8]** A pharmacy issuing a recall notice regarding a sterile compounded drug shall contact the recipient pharmacy, prescriber, or patient of the recalled drugs, and the California State Board of Pharmacy, as soon as possible within 12 hours of the recall notice if both of the following apply:
  1. Use of or exposure to recalled drug may cause serious adverse health consequences or death.
  2. The recalled drug was dispensed, or is intended for use, in this state (i.e., California).

2.6. [USP 797] Investigations are conducted, and corrective action plans are implemented in response to ADRs or complaints regarding CSP quality. The extent of investigations and corrective action plans are consistent with the deviation and consider historical trends.

3. Roles & Responsibilities

3.1 The Designated Person(s) (DP) or Designee:

- Performs timely review and risk assessment of all reports of CSP-related complaints or adverse drug reactions.
- Leads investigations and corrective action plan development, implementation, and follow up to corrective action plans related to CSP complaints and adverse reactions.
- Partners with appropriate leadership departments and/or individuals (e.g., Quality Director and/or Compliance Officer) when serious or potentially life-threatening ADRs are reported to:
  - Finalize the risk assessment
  - Initiate CSP recalls procedures including prescriber and patient notifications, CSP retrieval and destruction, investigation and root cause analysis, and corrective actions
  - Notify appropriate regulatory bodies per policy
  - Conduct in process and post recall assessments to determine the effectiveness of corrective actions and resulting reduction in patient risk

3.2. Compounding Personnel:

- Complete initial documentation per policy of complaints and ADRs reported directly to or received by the individual from a patient, caregiver, provider, or similar source.
- Notify DP or Designee of reports of suspected or known serious ADRs immediately upon receiving a report.
- Participate in investigations and corrective actions as directed by the DP.

3.3. Appropriate leadership departments and/or individuals (e.g., Quality Director and/or Compliance Officer):

- Partner with the DP and/or Designee to conduct risk assessment and response urgency assessment for serious or potentially life-threatening ADRs associated with CSPs.

- Ensure recall process complies with all Federal, State, and Accrediting body procedural and reporting requirements.

4. Procedures

4.1. [USP 797] Adverse Drug Reaction (ADR) and Complaint Receipt & Documentation

- When a known or suspected serious or life-threatening ADR or quality-related complaint associated with a CSP is received, immediately notify the DP or Designee, if the DP is not available.
- Document all reported ADRs and CSP quality related complaints in facility's event reporting system (e.g., "Verge") immediately upon receipt of report.
- Initial document at time of report includes:

Information to Collect	ADR	Complaint
Date and time of report	✓	✓
Name of person submitting report (if other than the patient), relationship to the patient and contact information	✓	✓
Patient name or unique identifier (e.g., medical records number or similar) and contact information	✓	✓
Prescriber name, address, phone number, email, and/or other contact method, if available	✓	
Date of occurence (and occurence time, if available)	✓	
CSP name or unique identifier (e.g., prescription or order number), lot number, and expiration date (if immediately available)	✓	✓
Description of exact nature of the ADR or complaint	✓	✓
Description of known or suspected patient harm (e.g., illness, injury, death), if applicable	✓	
Description of any healthcare related intervention or follow up as a result of reported event	✓	

- During the subsequent investigation and response, document the following for ADRs and CSP quality-related complaints:
  - Results of the investigation
  - Corrective action plan or response
  - Verification of corrective action plan effectiveness, if applicable

4.2. Risk Severity Assessment & Response Urgency Determination

- Designated Person and/or Designee reviews reports and intiates a risk assessment to CSP quality related ADRs and compliants in a timely manner based on the severity of the initial ADR or compliant report ranging from:
  - Serious or life threatening patient harm: reviewed within 2 hours by DP and/or Designee
  - Low to moderate risk of patient harm: reviewed within 2 business days of report by DP and/or Designee

- Use the Risk Severity Assessment & Response Urgency Decision Matrix to determine investigation and if a CSP recall is warranted and the timeframes for prescriber and patient notification as well as physical collection of CSPs.

Risk Severity Assessment & Response Urgency Decision Matrix

Conditions	Examples	Investigation Timeframe	MD/Patient Notification Timeframe ***	Product Recall Timeframe
HIGH RISK CONDITIONS & RESPONSE URGENCY:				
CSP(s) defect/failure with HIGH RISK of Patient Harm ***AND/OR*** CSP(s) dispensed to HIGH RISK Patient Populations ***AND/OR*** CSP(s) administered via a HIGH RISK route of administration	**HIGH RISK CSP Defects or Failures**: • Known or Suspected Adverse Reaction associated with a CSP • CSP quality issue (e.g., purity, potency) • Facilities, engineering control, or equipment failure with the potential to impact CSP sterility, or other quality attribute* • Recall of CSP component* **High Risk Patient Populations**: • Pediatric • Geriatric • Critically Ill • Immunocompromised **HIGH RISK Route of Administration**: • Intrathecal • Epidural • Via Central Line*	Initiated within 2 hours of notification of CSP failure Preliminary Investigation Results within 5 business days Final Investigation Results within 2 weeks	Outbound calls & emails Initiated within 4 hours of notification of CSP failure *(continued at least daily until MD or representative reached or CSP BUD exceeded)* Certified Written Notification within 2 business days	Within 4 hours of notification & in conjunction with MD/patient notification effort
LOW TO MODERATE RISK CONDITIONS & RESPONSE URGENCY:				
CSP(s) defect/failure with LOW to MODERATE RISK of Patient Harm ***AND/OR*** Compounding Personnel, Facilities, and/or Equipment Failures	**LOW to MODERATE RISK Defects or Failures:** • Incomplete and/or nondocumented release inspections, tests, or final Pharmacist verification • CSP failure of release inspections or tests not impacting the CSP potency, sterility • Recall of CSP component* **Compounding Personnel, Facilities, and/or Equipment Failures:** • Compounding personnel evaluation and/or competency failure or delinquency • Facilities (e.g., PEC) certification failure or delinquency • Environmental controls or equipment calibration or maintenance delinquency • Facilities, environmental controls, or equipment operational failures (e.g., extended power outages or functioning out-of-specification) • Actionable microbiological air & surface sampling results** • Noncompliance with other USP <797> regulatory requirements	Initiated within 2 business days of notification Preliminary Investigation Results within 7 business days Final Investigation Results within 2 weeks	If patient harm risk deemed likely, escalate to HIGH RISK timeframes If patient harm risk deemed unlikely but possible, outbound calls & emails Initiated within 3 business days of notification Certified Written Notification within 10 business days	If patient harm risk deemed likely, escalate to HIGH RISK timeframes If patient harm risk deemed unlikely but possible, within 3 business days of notification & in conjunction with MD/patient notification effort

*Impacted CSPs are identified and assessed when information is received regarding individual CSP component recalls or serious facilities, engineering control, or equipment failures are detected.

**Risk of actionable microbiological air and/or surface sampling is based on organism, quantity, location(s), and historical trends and potential risk of CSP contamination.

*** Review with Quality Director for appropriate notification(s)

4.3. Identification of Affected CSPs

- Initial Investigation:
  - Based on the data and CSP description received from the report, identify the CSP and lot number.
  - If the CSP was part of a batch, identify the disposition of the remaining dose units.
  - If the exact CSP or CSP batch cannot be immediately determined, determine the timeframe and potentially suspect CSPs compounded during that timeframe meeting the description of the CSP in question. Include all suspected CSPs in the investigation and recall.
- Broader Investigation:
  - Once the CSP/CSP batch in question has been determined, expand the investigation to determine if additional CSPs are potentially impacted by the same quality issue.
  - Consider researching CSPs compounded within the same timeframe:
    1) By the same compounder
    2) In the same PEC
    3) With the same compounding equipment, components, or supplies
  - Consider performing analytical testing onsite or via an analytical testing lab on any undispensed doses of CSPs identified as potentially having the same/similar quality issue identified in the reported CSP/CSP batch

4.4. Identification and Notification of Affected Patients & Providers

- Once the CSPs in question have been determined, refer to workflow or compounding system to identify patients and corresponding provider(s) who have received CSPs from the lot(s) in question.
- Recall notifications are sent via phone and/or email and followed up with a certified letter.
- Recall notifications may include:

Prescriber
• Clear statement of recall • Description of recalled CSP (e.g., lot #, dosage form, packaging, intended use, BUD) • Reason for recall / potential for patient harm • Name(s) of corresponding patients receiving CSP • Information on potential side effects or patient harm to monitor for in CSPs that have been administered • Recall contact information for communication and return of recalled CSP(s) • MedWatch reporting information

4.5. Collection, Disposal, & Documentation of Recalled CSPs

- Create a Recall Log of all CSPs under recall and record the disposition of all dose units including dispensed and undispensed dose units.
- Collect and quarantine unadministered doses:

Undispensed dose units:	• Immediately quarantine during the initial investigation to prevent additional dispensing of dose
Dispensed dose units that have not been administered:	• Attempt to retrieve doses. 1) Log and quarantine retrieved doses. 2) Log disposition (e.g., disposed of by patient, unable to contact) of unretrieved doses.

Dispensed and previously administered dose units:	• Record the dose administration on the Recall Log, if possible, collect and document information pertaining to date and time of administration for future reference

- Hold collected doses in quarantine until the end of the investigation or as determined by the Designated Person and/or Designee.
- Dispose of or destroy quarantined doses per drug disposal policy.
- Log the disposal or destruction date, method, and person responsible in the Recall Log.

4.6. Investigation & Corrective Action

- Conduct a thorough and timely investigation of all potential or suspected contributing factors to the reported ADR or CSP quality-related complaint including, but not limited to:

Area of Compliance	Investigation Considerations
Facilities & Engineering Controls (PECs; HEPA Filters)	• Semi-annual certifications & detailed report • Technical or mechanical review of systems • HEPA filter efficacy review • External contributor factors (e.g., power surge) • Trends
Environmental Controls (HVAC-controlled Temperatures; Pressure Differentials)	• Current maintenance, calibration, certification reports • Technical or mechanical review of system • External contributor factors (e.g., power surge) • Trends
Personnel Competencies, Conduct, & Compounding Performance	• Personnel training and competency assessment records • Trends
Cleaning, Disinfecting, & Application of Sporicidal Agents	• Cleaning logs, agent selection, dwell times • Cleaning procedures • Personnel training and competency assessment records • Trends
Environmental Monitoring (Viable Air &/or Surface Sampling)	• All of the areas of compliance shown above • Materials movement & cleaning • Personnel and visitor behaviors • External contributing factors (e.g., particle generating activities occurring immediately outside compounding area) • Types, locations, & quantities of actionable organisms • Trends
Sterile Equipment, Components, & Supplies	• COAs demonstrating compliance with specifications • For equipment: maintenance, calibration, & certification records • Manufacturer recalls • Personnel training and competency assessment records • Trends
CSP Quality	• Compounding process, equipment, components, supplies • Personnel training and competency assessment records • Trends

- As described above, consider if CSP quality-related issue(s) potentially affects other CSPs.
- Determine immediate remediation to reduce the risk of further CSP quality issues until the investigation can be concluded including, but not limited to:
    - Halt of sterile compounding operations
    - Restriction of sterile compounding operations
    - Reclassification of compounding areas and reduction to the corresponding BUDs and compounding restrictions to a non-classified immediate use compounding area; refer to the Beyond Use Dating and Stabilities Considerations policy and Immediate Use Compounding policy for further information.
    - Remove or retrain compounding (or support) personnel involved
- After the investigation has concluded, finalize, and implement the corrective action plan. Corrective actions address known and suspected deficiencies in all aspects of the sterile compounding operation.
- Provide staff communication about the deficiencies and corrective action plan. Involve staff in the implementation of the corrective actions when appropriate.
- During and after the completion of the corrective actions, collect data and information that allows for evaluation of the effectiveness of the actions taken.
- If the corrective actions taken fully resolve the quality issue, ensure the process is fully documented, including the validations performed afterwards.
- If the corrective actions have not been fully effective, continue or renew the investigation and determine additional or enhanced corrective actions.

4.7. Serious or life-threatening ADR Reporting

- Report serious or life-threatening ADRs to FDA Consumer MedWatch and/or similar regulatory body per policy and in accordance jurisdictional laws. MedWatch contact information:
    - Toll-free line: 1-800-332-1088
    - To report online: www.fda.gove/medwatch/report.htm
    - Information: www.fda.gov/reportinghelp

5. Definitions

5.1. **Oversight:** The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed even if not physically present.

5.2. **Quality assurance (QA):** A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

5.3. **Quality control (QC):** The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.

5.4. **Release inspection and testing:** Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.

5.5. **Specification:** The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.

5.6. **Verify:** To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.

6. Related Policies, Documents, References

6.1. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2. United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval (10/2023)
Next review:	Month/year

7.1. Initial version published by Wolters Kluwer 2023.

7.2. Revised MM/YYYY with the following key changes…OR…with no changes.

ATTACHMENT ONE: Recall Log (sample)
List each lot number and dose separately.

CSP Name	Lot #	Exp Date	Dose Dispensed?	Dose Quarant'd?	Patient Name	Contact Date & Method	Prescriber Name	Contact Date & Method	Dose Admin'd?	Dose Returned?	Date Destroyed	Method	Witness

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Complaint, Adverse Drug Reaction, & Recall Handling	Policy #	PHARMXXXX
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

This policy describes the procedures for documenting, assessing risk of patient harm, and determining response urgency and approach for quality related complaints and adverse drug reactions (ADRs) concerning Compounded Sterile Preparations (CSPs) prepared within Watsonville Community Hospital. The policy also provides the procedures to rapidly implement a CSP recall when serious patient harm is known or suspected.

Complaints and reports of ADRs can come from a variety of sources including, but not limited to, patients, caregivers, prescribers/providers, regulatory bodies, or other healthcare related sources.

CSP recalls are initiated based on the severity of risk of serious or life-threatening patient harm associated with product quality-related issues, with special consideration given to risk assessment of high-risk patient populations and routes of administration, including:

- Reported serious or life-threatening ADR due to CSP quality
- Manufacturer recall of components or supplies used during sterile manipulations and processing of dispensed CSPs
- Facilities, sterile compounding equipment, or engineering control failures detected after CSPs are compounded and dispensed and that present a substantial risk of compromising CSP sterility, potency, or similar quality attribute

CSP complaint and ADR handling and quality related product recalls are performed according to regulatory and statutory requirements for California State Board of Pharmacy.

II. POLICY

A. CSP related complaints and ADRs are promptly logged and documented electronically in facility event reporting system (e.g., “Verge”).

B. Adverse reactions with known or highly suspected potential to cause patient harm are reported to the Designated Person (DP) or Designee immediately upon receipt. The reported event is reviewed within 2 hours of receipt of report by the Designated Person (DP) or Designee if the DP is unavailable. CSP recall procedures, if needed, are initiated within 4 hours of review.

C. Complaints or concerns about CSPs are reviewed immediately by the Designated Person (DP) or Designee. Based on a risk assessment, an investigation and appropriate corrective actions, up to and including CSP recall, are initiated in a timely manner.

D. If a CSP recall is initiated, the following actions are required:

- Immediate notification of the prescriber regarding the CSP quality failure with the potential to cause patient harm
- Recall of unused dispensed CSPs and quarantine of stock remaining in the pharmacy
- Investigation to determine if other CSP lots are affected and recalled if necessary
- Risk severity and recall urgency assessment
- Determination of the distribution and disposition of affected CSPs
- Determination of the patients and corresponding prescribers in receipt of affected CSPs
- Documentation and disposal of recalled CSPs
- Investigation and determination of reason for quality failure
- Implementation of corrective action plan and verification of its effectiveness

E. Serious or life-threatening adverse events potentially associated with the quality of CSPs are reported per the laws and regulations of the jurisdiction in which the CSP was compounded an/or where the patient was treated (i.e., California State Board of Pharmacy).

- **[CA-BOP 4127.1,8]** A pharmacy issuing a recall notice regarding a sterile compounded drug shall contact the recipient pharmacy, prescriber, or patient of the recalled drugs, and the California State Board of Pharmacy, as soon as possible within 12 hours of the recall notice if both of the following apply:
  1. Use of or exposure to recalled drug may cause serious adverse health consequences or death.
  2. The recalled drug was dispensed, or is intended for use, in this state (i.e., California).

F. Investigations are conducted, and corrective action plans are implemented in response to ADRs or complaints regarding CSP quality. The extent of investigations and corrective action plans are consistent with the deviation and consider historical trends.

III. ROLES & RESPONSIBILITIES

A. The Designated Person(s) (DP) or Designee:

- Performs timely review and risk assessment of all reports of CSP-related complaints or adverse drug reactions.
- Leads investigations and corrective action plan development, implementation, and follow up to corrective action plans related to CSP complaints and adverse reactions.
- Partners with appropriate leadership departments and/or individuals (e.g., Quality Director and/or Compliance Officer) when serious or potentially life-threatening ADRs are reported to:
  - Finalize the risk assessment
  - Initiate CSP recalls procedures including prescriber and patient notifications, CSP retrieval and destruction, investigation and root cause analysis, and corrective actions
  - Notify appropriate regulatory bodies per policy
  - Conduct in process and post recall assessments to determine the effectiveness of corrective actions and resulting reduction in patient risk

B. Compounding Personnel:

- Complete initial documentation per policy of complaints and ADRs reported directly to or received by the individual from a patient, caregiver, provider, or similar source.
- Notify DP or Designee of reports of suspected or known serious ADRs immediately upon receiving a report.
- Participate in investigations and corrective actions as directed by the DP.

C. Appropriate leadership departments and/or individuals (e.g., Quality Director and/or Compliance Officer):

- Partner with the DP and/or Designee to conduct risk assessment and response urgency assessment for serious or potentially life-threatening ADRs associated with CSPs.
- Ensure recall process complies with all Federal, State, and Accrediting body procedural and reporting requirements.

IV. DEFINITIONS

- **Oversight:** The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed even if not physically present.
- **Quality assurance (QA):** A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
- **Quality control (QC):** The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.

- **Release inspection and testing:** Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
- **Specification:** The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
- **Verify:** To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.

V. PROCEDURE

A. Adverse Drug Reaction (ADR) and Complaint Receipt & Documentation

- When a known or suspected serious or life-threatening ADR or quality-related complaint associated with a CSP is received, immediately notify the DP or Designee, if the DP is not available.
- Document all reported ADRs and CSP quality related complaints in facility's event reporting system (e.g., "Verge") immediately upon receipt of report.
- Initial document at time of report includes:

Information to Collect	ADR	Complaint
Date and time of report	✓	✓
Name of person submitting report (if other than the patient), relationship to the patient and contact information	✓	✓
Patient name or unique identifier (e.g., medical records number or similar) and contact information	✓	✓
Prescriber name, address, phone number, email, and/or other contact method, if available	✓	
Date of occurence (and occurence time, if available)	✓	
CSP name or unique identifier (e.g., prescription or order number), lot number, and expiration date (if immediately available)	✓	✓
Description of exact nature of the ADR or complaint	✓	✓
Description of known or suspected patient harm (e.g., illness, injury, death), if applicable	✓	
Description of any healthcare related intervention or follow up as a result of reported event	✓	

- During the subsequent investigation and response, document the following for ADRs and CSP quality-related complaints:
  - Results of the investigation
  - Corrective action plan or response
  - Verification of corrective action plan effectiveness, if applicable

B. Risk Severity Assessment & Response Urgency Determination

- Designated Person and/or Designee reviews reports and intiates a risk assessment to CSP quality related ADRs and compliants in a timely manner based on the severity of the initial ADR or compliant report ranging from:
  - Serious or life threatening patient harm: reviewed within 2 hours by DP and/or Designee
  - Low to moderate risk of patient harm: reviewed within 2 business days of report by DP and/or Designee

- Use the Risk Severity Assessment & Response Urgency Decision Matrix to determine investigation and if a CSP recall is warranted and the timeframes for prescriber and patient notification as well as physical collection of CSPs.

Risk Severity Assessment & Response Urgency Decision Matrix

Conditions	Examples	Investigation Timeframe	MD/Patient Notification Timeframe ***	Product Recall Timeframe
HIGH RISK CONDITIONS & RESPONSE URGENCY:				
CSP(s) defect/failure with HIGH RISK of Patient Harm ***AND/OR*** CSP(s) dispensed to HIGH RISK Patient Populations ***AND/OR*** CSP(s) administered via a HIGH RISK route of administration	**HIGH RISK CSP Defects or Failures**: • Known or Suspected Adverse Reaction associated with a CSP • CSP quality issue (e.g., purity, potency) • Facilities, engineering control, or equipment failure with the potential to impact CSP sterility, or other quality attribute* • Recall of CSP component* **High Risk Patient Populations**: • Pediatric • Geriatric • Critically Ill • Immunocompromised **HIGH RISK Route of Administration**: • Intrathecal • Epidural • Via Central Line*	Initiated within 2 hours of notification of CSP failure Preliminary Investigation Results within 5 business days Final Investigation Results within 2 weeks	Outbound calls & emails Initiated within 4 hours of notification of CSP failure *(continued at least daily until MD or representative reached or CSP BUD exceeded)* Certified Written Notification within 2 business days	Within 4 hours of notification & in conjunction with MD/patient notification effort
LOW TO MODERATE RISK CONDITIONS & RESPONSE URGENCY:				
CSP(s) defect/failure with LOW to MODERATE RISK of Patient Harm ***AND/OR*** Compounding Personnel, Facilities, and/or Equipment Failures	**LOW to MODERATE RISK Defects or Failures:** • Incomplete and/or nondocumented release inspections, tests, or final Pharmacist verification • CSP failure of release inspections or tests not impacting the CSP potency, sterility • Recall of CSP component* **Compounding Personnel, Facilities, and/or Equipment Failures:** • Compounding personnel evaluation and/or competency failure or delinquency • Facilities (e.g., PEC) certification failure or delinquency • Environmental controls or equipment calibration or maintenance delinquency • Facilities, environmental controls, or equipment operational failures (e.g., extended power outages or functioning out-of-specification) • Actionable microbiological air & surface sampling results** • Noncompliance with other USP <797>	Initiated within 2 business days of notification Preliminary Investigation Results within 7 business days Final Investigation Results within 2 weeks	If patient harm risk deemed likely, escalate to HIGH RISK timeframes If patient harm risk deemed unlikely but possible, outbound calls & emails Initiated within 3 business days of notification Certified Written Notification within 10 business days	If patient harm risk deemed likely, escalate to HIGH RISK timeframes If patient harm risk deemed unlikely but possible, within 3 business days of notification & in conjunction with MD/patient notification effort

Conditions	Examples	Investigation Timeframe	MD/Patient Notification Timeframe ***	Product Recall Timeframe
	regulatory requirements			

**Impacted CSPs are identified and assessed when information is received regarding individual CSP component recalls or serious facilities, engineering control, or equipment failures are detected.*

***Risk of actionable microbiological air and/or surface sampling is based on organism, quantity, location(s), and historical trends and potential risk of CSP contamination.*

**** Review with Quality Director for appropriate notification(s)*

C. Identification of Affected CSPs
- Initial Investigation:
  - Based on the data and CSP description received from the report, identify the CSP and lot number.
  - If the CSP was part of a batch, identify the disposition of the remaining dose units.
  - If the exact CSP or CSP batch cannot be immediately determined, determine the timeframe and potentially suspect CSPs compounded during that timeframe meeting the description of the CSP in question. Include all suspected CSPs in the investigation and recall.
- Broader Investigation:
  - Once the CSP/CSP batch in question has been determined, expand the investigation to determine if additional CSPs are potentially impacted by the same quality issue.
  - Consider researching CSPs compounded within the same timeframe:
    1) By the same compounder
    2) In the same PEC
    3) With the same compounding equipment, components, or supplies
  - Consider performing analytical testing onsite or via an analytical testing lab on any undispensed doses of CSPs identified as potentially having the same/similar quality issue identified in the reported CSP/CSP batch

D. Identification and Notification of Affected Patients & Providers
- Once the CSPs in question have been determined, refer to workflow or compounding system to identify patients and corresponding provider(s) who have received CSPs from the lot(s) in question.
- Recall notifications are sent via phone and/or email and followed up with a certified letter.
- Recall notifications may include:

Prescriber
• Clear statement of recall • Description of recalled CSP (e.g., lot #, dosage form, packaging, intended use, BUD) • Reason for recall / potential for patient harm • Name(s) of corresponding patients receiving CSP • Information on potential side effects or patient harm to monitor for in CSPs that have been administered • Recall contact information for communication and return of recalled CSP(s) • MedWatch reporting information

E. Collection, Disposal, & Documentation of Recalled CSPs
- Create a Recall Log of all CSPs under recall and record the disposition of all dose units including dispensed and undispensed dose units.
- Collect and quarantine unadministered doses:

Undispensed dose units:	• Immediately quarantine during the initial investigation to prevent additional dispensing of dose
Dispensed dose	• Attempt to retrieve doses.

units that have not been administered:	1) Log and quarantine retrieved doses. 2) Log disposition (e.g., disposed of by patient, unable to contact) of unretrieved doses.
Dispensed and previously administered dose units:	• Record the dose administration on the Recall Log, if possible, collect and document information pertaining to date and time of administration for future reference

- Hold collected doses in quarantine until the end of the investigation or as determined by the Designated Person and/or Designee.
- Dispose of or destroy quarantined doses per drug disposal policy.
- Log the disposal or destruction date, method, and person responsible in the Recall Log.

F. Investigation & Corrective Action

- Conduct a thorough and timely investigation of all potential or suspected contributing factors to the reported ADR or CSP quality-related complaint including, but not limited to:

Area of Compliance	Investigation Considerations
Facilities & Engineering Controls (PECs; HEPA Filters)	• Semi-annual certifications & detailed report • Technical or mechanical review of systems • HEPA filter efficacy review • External contributor factors (e.g., power surge) • Trends
Environmental Controls (HVAC-controlled Temperatures; Pressure Differentials)	• Current maintenance, calibration, certification reports • Technical or mechanical review of system • External contributor factors (e.g., power surge) • Trends
Personnel Competencies, Conduct, & Compounding Performance	• Personnel training and competency assessment records • Trends
Cleaning, Disinfecting, & Application of Sporicidal Agents	• Cleaning logs, agent selection, dwell times • Cleaning procedures • Personnel training and competency assessment records • Trends
Environmental Monitoring (Viable Air &/or Surface Sampling)	• All of the areas of compliance shown above • Materials movement & cleaning • Personnel and visitor behaviors • External contributing factors (e.g., particle generating activities occurring immediately outside compounding area) • Types, locations, & quantities of actionable organisms • Trends
Sterile Equipment, Components, & Supplies	• COAs demonstrating compliance with specifications • For equipment: maintenance, calibration, & certification records • Manufacturer recalls • Personnel training and competency assessment records

Area of Compliance	Investigation Considerations
	• Trends
CSP Quality	• Compounding process, equipment, components, supplies • Personnel training and competency assessment records • Trends

- As described above, consider if CSP quality-related issue(s) potentially affects other CSPs.
- Determine immediate remediation to reduce the risk of further CSP quality issues until the investigation can be concluded including, but not limited to:
  - Halt of sterile compounding operations
  - Restriction of sterile compounding operations
  - Reclassification of compounding areas and reduction to the corresponding BUDs and compounding restrictions to a non-classified immediate use compounding area; refer to the Beyond Use Dating and Stabilities Considerations policy and Immediate Use Compounding policy for further information.
  - Remove or retrain compounding (or support) personnel involved
- After the investigation has concluded, finalize, and implement the corrective action plan. Corrective actions address known and suspected deficiencies in all aspects of the sterile compounding operation.
- Provide staff communication about the deficiencies and corrective action plan. Involve staff in the implementation of the corrective actions when appropriate.
- During and after the completion of the corrective actions, collect data and information that allows for evaluation of the effectiveness of the actions taken.
- If the corrective actions taken fully resolve the quality issue, ensure the process is fully documented, including the validations performed afterwards.
- If the corrective actions have not been fully effective, continue or renew the investigation and determine additional or enhanced corrective actions.

G. Serious or life-threatening ADR Reporting

- Report serious or life-threatening ADRs to FDA Consumer MedWatch and/or similar regulatory body per policy and in accordance jurisdictional laws. MedWatch contact information:
  - Toll-free line: 1-800-332-1088
  - To report online: www.fda.gove/medwatch/report.htm
  - Information: www.fda.gov/reportinghelp

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

VII. STAKEHOLDERS

N/A

ATTACHMENT ONE: Recall Log (sample)
List each lot number and dose separately.

CSP Name	Lot #	Exp Date	Dose Dispensed?	Dose Quarant'd?	Patient Name	Contact Date & Method	Prescriber Name	Contact Date & Method	Dose Admin'd?	Dose Returned?	Date Destroyed	Method	Witness

Watsonville Community Hospital	**Quality Assurance & Quality Control Program – Sterile Compounding**
Policy Number/ Version:	797-2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1. This policy describes the Sterile Compounding Program quality assurance and quality control responsibilities and processes Watsonville Community Hospital where Compounded Sterile Preparations (CSPs) are compounded, verified, and stored prior to dispensing. The policy serves as Watsonville Community Hospital's written Quality Assurance and Control Program ("Quality Program") consisting of:

- **Quality Assurance (QA)**: The procedures, activities, and oversight that ensures the compounding process consistently meets quality standards
- **Quality Control (QC):** The sampling, testing, and documentation of results that, when taken together, ensure CSP specifications have been met prior to release and dispensing

1.2. The Quality Program is a comprehensive system that supports continual quality improvement within the Sterile Compounding Program and is designed to ensure:

- Regulatory and statutory compliance
- Adherence to policies and procedures
- Prevention and detection of errors or other quality deficiencies
- Evaluation and handling of complaints and adverse events
- Appropriate investigations and corrective actions

1.3. The Quality Program integrates information and data collected from patients, caregivers, and providers; compounding and support personnel; technical, mechanical, and scientific professionals; and supporting organizational and industry experts with the ultimate goal of ensuring patient safety through consistent and repeatable high quality CSPs prepared in a safe and controlled compounding environment.

2. Policy

2.1. **[USP 1163]** The Quality Director is responsible to define, implement, and oversee Watsonville Community Hospital's Quality Program and ensure it includes, at a minimum, the following integrated components:

- Compounding Personnel Training & Competency Evaluation
- Standard Operating Procedures (SOPs)
- Compliance Documentation Review & Audit
- CSP Verification
- Controlled Area(s) Cleaning, Disinfecting, & Safety
- CSP Containers, Packaging, Repackaging, Labeling, and Storage Practices
- Responsible Personnel
- **[CONDITIONAL: If outsourced vendors, suppliers, or laboratories used]:** Outsourcing Documentation Supporting BUD Assignments and Release Testing Results

2.2. [USP 797] Sterile Compounding Program compliance related activities and documentation (e.g., inspection or analytical laboratory reports, competency forms and checklists, written records, and supporting documentation) are reviewed and audited at least once annually to ensure:

- All required regulatory and statutory sterile compounding requirements are successfully completed within the appropriate timeframe, memorialized with the appropriate documentation, and reviewed by the DP (if appropriate)
- Out of specification findings, occurrences, and events are investigated and remediated
- Corrective actions are fully documented, and data collected in response to corrective actions is reviewed to confirm action taken have been effective
- Opportunities of continual process improvement are identified and initiated

3. Roles & Responsibilities

3.1 The Designated Person(s) (DP):

- Partner with Quality Director to develop, implement, and manage the Sterile Compounding Quality Program
- Educate Compounding Personnel on the Quality Program including individual and team quality related responsibilities, processes, documentation, and tools
- Alert and engage the Quality Director of issues impacting quality or regulatory and/or statutory changes impacting the Quality Program
- Ensure quality assurance audits of the Sterile Compounding Practice compliance and related documentation are conducted on a timely basis
- Oversee remediation and documentation of any deficiencies found in QA audit process

3.2. Compounding Personnel:

- Understand individual and compounding team role and responsibilities in supporting sterile practice quality assurance and control through compliance with all the Sterile Compounding Program policies and procedures (i.e., Standard Operating Procedures or SOPs)
- Alert DP or compounding supervisor/Designee of any known or suspected deficiencies, failures, or out of specification results related to any aspect of sterile compounding operations and assist with remediation efforts if appropriate, including, but not limited to issues with:
  - Facilities operations or certification
  - Engineering controls (e.g., PECs)
  - Environmental controls for compounding and drug storage locations (e.g., pressure differentials, temperatures)
  - Equipment, supplies, components
  - Cleaning, disinfecting, or application of sporicidal disinfectants
  - Materials movement and personnel conduct with controlled areas
  - Sterile compounding
  - Personnel training and competency evaluations
  - Documentation of compliance activities

3.3. Quality Director, or similar:

- Partner with DP to understand sterile practice regulatory and statutory requirements, how to locate and interpret compliance documentation, QA/QC audit parameters, and specifics of Watsonville Community Hospital's sterile compounding Quality Program
- Partner with DP and/or designee to resolve audit deficiencies; conduct follow up verification of corrective actions taken to resolve deficiencies

4. Procedures

[USP 797] **Sterile Program Quality Assurance Compliance Review & Audit**

4.1. [USP 797] Review Sterile Compounding Program compliance activities and audit at least once annually to ensure all regulatory and statutory requirements and supporting documentation are effectively and fully completed within the appropriate timeframe(s) and per policy. This audit also confirms DP and compounding personnel compliance with policies and procedures and allows for the detection and potential prevention of other quality deficiencies.

4.2. Confirm compliance documentation is retained in a readily retrievable electronic and/or written format and can be easily located with minimal instruction.

4.3. **Facilities and environmental controls QA audit parameters** follow criteria in the table below. Refer to the **Facilities & Environmental Controls policy** and **Certification & Recertification policy** for additional information regarding these regulatory requirements.

REQUIREMENT	COMPLIANCE ACTIVITY FREQUENCY	QUALITY ASSURANCE PARAMETER
FACILITIES & ENGINEERING CONTROLS		
Sterile facilities certification / recertification	Initially & every 6 months* *Performed by a qualified certification vendor*	• Formal SCA certification report & ISO classification certificate for SCA; includes: ○ HEPA filter integrity testing (PECs) ○ Dynamic airflow smoke pattern test (PECs only) • Certificate of compliance posted on each PEC
Total particle counts / ISO classifications		• Sampling plan diagram • ISO Class 5 (PEC): < 3520
PEC HEPA filter integrity testing		• 99.99% efficacy documented for each HEPA filter • Description of patch size applied to HEPA filter *(PEC HEPA filters should not exceed 2% of filter surface area)*
PEC dynamic airflow smoke pattern test & video		• Documented and video evidence of successful completion of airflow smoke pattern test performed *"under dynamic operating conductions demonstrating unidirectional airflow and sweeping action over and away from the preparation"*
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of facilities or engineering controls OOS or failures, investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken have been effective
ENVIRONMENTAL CONTOLS		
Drug storage location temperatures	Measured by continuous monitoring device or recorded manually	• Daily review and documentation of compounding room and drug storage location temperatures every day compounding occurs ○ Compounding areas: ≤ 20°C (≤ 68°F) *(recommended for compounder comfort; not a firm requirement)*

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
		○ Ambient Drug Storage Areas (Controlled Room Temp): 20 - 25°C (68 - 77°F) ○ Refrigerated Drug Storage Areas: 2 - 8°C (36.8 – 46.4°F)
Calibration, maintenance, and certification records	Every 12 months	For each continuous monitoring system, device, or gauge monitoring pressure differentials, temperatures (room and drug storage locations): • Documentation of annual calibration and certification by a qualified technician • Documentation of maintenance as needed
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of daily pressure differential and temperature monitoring OOS or failures results, investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken have been effective

*Facilities are also recertified after events impacting the quality of the environment including, but not limited to redesign, construction/major repairs, relocation or replacement of PEC, or room configuration/traffic pattern changes that could affect airflow or air quality.

4.3. **Microbial air and surface sampling QA audit parameters** follow criteria in the table below. Refer to the **Microbial Air & Surface Sampling policy** and **Out of Specification policy** for additional information regarding these regulatory requirements.

<table>
<tr><th>Requirement</th><th>Compliance Activity Frequency</th><th>Quality Assurance Parameter</th></tr>
<tr><td colspan="3">MICROBIAL AIR & SURFACE SAMPLING</td></tr>
<tr><td>Viable Air Sampling Results</td><td>Every 6 months</td><td rowspan="2">• Viable sampling diagram (including sites within PECs sufficient to adequately characterize the state of microbial control within area)
• Sampling results reports:
○ Date, time, & person performing sampling
○ Identification of sampling locations and person/entity who performed sampling
○ Media incubation dates and temperatures
○ Media used: manufacturer, lot number, expiration date, and validation of growth promotion (e.g., control plate results)
○ Sampling equipment used: manufacturer, model, certification
○ CFU enumeration per site (reported as a single number per site if only TSA media plates used; reported as 2 separate numbers if two types of media plates are used per site)
○ Microbial identification of CFUs to the genus level (not required unless action levels are exceeded)
<table>
<tr><th>ISO Class</th><th>Viable Air Sample
CFU/m³ of air per plate (1000L sample)</th><th>Viable Surface Sample
CFU per sampling plate</th></tr>
<tr><td>ISO 5</td><td>> 1</td><td>> 3</td></tr>
<tr><td>ISO 7</td><td>> 10</td><td>> 5</td></tr>
<tr><td>ISO 8</td><td>> 100</td><td>> 50</td></tr>
</table>
</td></tr>
<tr><td>[Best Practice] Sampling results after OOS events</td><td>As needed and for major air</td><td>• OOS event written description including:
○ Date, time, and location (e.g., area(s) impacted)</td></tr>
</table>

REQUIREMENT	COMPLIANCE ACTIVITY FREQUENCY	QUALITY ASSURANCE PARAMETER
	handling system maintenance	○ Impact to environmental controls (e.g., pressure differentials, temperatures) ○ Impact to operations of PECs, if applicable ○ Impact to compounding operations and immediate remediation steps taken (e.g., restricting compounding operations, temporarily reclassifying BUDs to immediate use.) ○ Remedial cleaning after event, if applicable ○ Validation of restored state of microbial control (e.g., sampling results report)
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of OOS results (e.g., CFUs exceeding action levels at any site, pathogenicity of microorganisms identified, or trends of actionable results, etc.), investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective • Resampling report results confirming successful remediation
COAs for media used onsite	Media ordered for environmental sampling	For each lot of media used: • Manufacturer (or internal) lot number and expiration date • Manufacturer COA verifying media has been tested and meets expected microbial growth promotion, media pH within acceptable limits, and sterilization requirements

4.4. **Personnel training and competency QA audit parameters** follow criteria in the table below. Refer to the **Personnel Training & Evaluation policy** for additional information regarding these regulatory requirements.

REQUIREMENT	COMPLIANCE ACTIVITY FREQUENCY	QUALITY ASSURANCE PARAMETER
PERSONNEL TRAINING & COMPETENCY EVALUATIONS		
Compounding Personnel	Initially & every 6 or 12 months depending on evaluation	For each employee: • Competency documentation showing successful completion initially (prior to compounding) and <u>every 12 months</u> of: 1. **Foundational and job-related knowledge exam** – ▪ Initially & Ongoing: minimum 80% passing score 2. **Observed validation of core skills** in maintaining the quality of the sterile compounding environment (e.g., cleaning, materials movement, etc.) ▪ Initially & Ongoing: 100% observed skills assessment • Competency documentation showing successful completion initially (prior to compounding) and <u>every 6 months</u> of: 3. **Observed Hand Hygiene & Garbing Competency** including gloved fingertip (GFT) results – ▪ Initially: performed three (3) times with zero (0) CFUs detected ▪ Ongoing: performed once with zero (0) CFUs detected & 100% observed skills assessment

REQUIREMENT	COMPLIANCE ACTIVITY FREQUENCY	QUALITY ASSURANCE PARAMETER
		4. **Observed Aseptic Technique Competency** including media fill (MF) and post media fill GFT and surface sample (SS) results ▪ Initial & Ongoing: no turbidity in MF, ≤ 3 CFU on GFT, & ≤ 3 CFU on SS & 100% observed skills assessment • Documentation of media manufacturer, lot number, & expiration date plus incubation dates and temperatures for competencies using media (i.e., #3 & #4) • Evaluation date, time, and evaluator name for all observed competencies (i.e., #2, #3, & #4)
Personnel directly overseeing compounding	Initially & every 12 months	See above Exception: #3 & #4 competencies are performed initially and once every 12 months
Personnel performing Immediate Use Compounding	Initially & PRN	See above Exception: personnel who exclusively perform immediate use compounding are only perform job-related knowledge exam (#1) & observed core skills assessment (#2)
Personnel providing supporting roles	Initially and annually	• Personnel who may perform supporting roles inside of controlled compounding areas (e.g., cleaning personnel) perform observed core skills assessment (#2), Hand Hygiene & Garbing Competency (not GFT or media fill)
Competency Failure & Corrective Action Plans	As needed	• Documentation and description of failed results, investigation, prescribed remedial training and/or corrective action plan, and review of remediation to confirm actions taken were effective • Results of repeated competencies (required for failures, refer to policy for more information)
COAs for media used onsite	Media/media fill components ordered for personnel sampling	For each lot of media used: • Manufacturer (or internal) lot number and expiration date • Manufacturer COA verifying media has been tested and meets expected microbial growth promotion, media pH within acceptable limits, and sterilization requirements

4.5. **Cleaning of controlled compounding area QA audit parameters** follow criteria in the table below. Refer to the **Cleaning, Disinfecting, & Application of Sporicidal Agent policy** for additional information regarding these regulatory requirements.

<table>
<tr><th>REQUIREMENT</th><th>COMPLIANCE ACTIVITY FREQUENCY</th><th>QUALITY ASSURANCE PARAMETER</th></tr>
<tr><td colspan="3">CLEANING & DISINFECTING</td></tr>
<tr><td>Cleaning, Disinfecting, & Application of Sporicidal Agents</td><td>Per Policy</td><td>Refer to the policy for a detailed description of the cleaning tasks, frequency, and agents to be used; in general, the following occurs:
<table>
<tr><th>Minimum Frequency</th><th>Task/Area</th><th>Cleaning Agent</th></tr>
<tr><td>Daily</td><td>Cleaning & disinfecting:
• Interior of each PEC (including work tray)
• Equipment resident in PEC
• Pass Through(s)</td><td>EPA registered one step disinfectant cleaner or separate agents</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Requirement</th><th>Compliance Activity Frequency</th><th colspan="3">Quality Assurance Parameter</th></tr>
<tr><td></td><td></td><td></td><td>• Work surfaces outside of PEC and SCA
• Floors
• Sinks</td><td></td></tr>
<tr><td></td><td></td><td>Monthly</td><td>• All daily tasks (above)
• Underneath PEC work tray
• Walls & Ceilings
• All surfaces outside of PEC (not only high touch)
• Storage bins & shelves
• Equipment outside of PECs</td><td>Sporicidal Agent (with cleaning & disinfecting activity)</td></tr>
<tr><td></td><td></td><td>Ad Hoc</td><td colspan="2">As determined by the DP and/or Designee or per policy for
Out of Specification (OOS) occurrences</td></tr>
<tr><td></td><td></td><td colspan="3">• Timely and complete documentation of regularly scheduled and ad hoc cleaning tasks that occur including identification of person completing task</td></tr>
<tr><td>OOS or Failure Investigation & Corrective Action Plans</td><td>As needed</td><td colspan="3">• Documentation of OOS results (e.g., incomplete or undocumented cleaning tasks, cleaning agent defects, etc.), investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective</td></tr>
</table>

4.6. **Sterile supplies, components, and compounding equipment QA audit parameters** follow criteria in the table below. Refer to the **Equipment, Supplies, & Components for Sterile Compounding policy** for additional information regarding these regulatory requirements.

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
STERILE COMPOUNDING EQUIPMENT		
Sterile Equipment Calibration, Maintenance, & Certification	Per Manufacturer's Instructions or at least once per year	Per each piece of sterile compounding equipment (e.g., ACDs, analytical balances, incubators, autoclave, dry heat oven, etc.): • Documentation of calibration and certification by a qualified technician • Documentation of maintenance as needed
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of OOS results (e.g., substandard APIs, components, or supplies), investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective

4.7. **Compounding records and CSP release inspection QA evaluation parameters** follow criteria in the table below. Refer to the **Master Formulation Record & Compounding Record policy** for additional information regarding these regulatory requirements.

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
Compounding Records		
Master Formula Record (MFR) & Compounding Record (CR) Creation; BUD/storage/stability reference	MFR: For batched CSPs CR: For every CSP or CSP batch	For each each batched CSP formulation: • MFR: refer to policy for the required data and instructions included in each MFR; confirm each MFR has validated BUD, storage condition, and/or stability references (in addition to USP <797> Chapter including USP-NF monograph or other published and validated study or data) For each Category 1 CSP: • CR: refer to policy for the required data included in each CR ○ *For CSPs not requiring a MFR*, the CR can be prescription or medication order or representation of the same stored in a workflow management system, ACD, or similar ○ *For CSPs requiring a MFR*, the CR must include a reference to a MFR, component manufacturing information, measured quantities used
Release Inspections & Tests		
Visual Inspections, Measurements, & Calculations	Every CSP or CSP Batch	Results documented on CR or implied by RPh final verification: • Visual inspections: components & final CSP, label (including BUD assignment & storage conditions) • Measurements: component and/or final CSP weights, volumes, etc. • Calculations/Conversions: per formulation
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of OOS results, investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective

4.8. **Standard operating procedure, complaints and adverse drug reaction (ADR) handling, and CSP recalls QA evaluation parameters** follow criteria in the table below. Refer to the **Complaints, Adverse Reactions** and **CSP Recall Handling policy** for additional information regarding these regulatory requirements.

REQUIREMENT	COMPLIANCE ACTIVITY FREQUENCY	QUALITY ASSURANCE PARAMETER
SOPs, Complaint and ADR Handling, & Recalls		
Sterile Practice SOPs & Annual Review	Every 12 months	• SOPs meeting USP <797> documentation requirements • Annual review, revisions, updates by Designated Person • Staff communication regarding SOP updates
Complaints & Adverse Drug Reaction (ADR) Handling	As needed per reports by patients, providers, staff, public	For each compliant or ADR: • Reported, documented, and tracked per policy • Patient/public harm risk assessment including severity and response urgency determination • Root cause analysis and investigation description • Corrective action(s) description, timeline, and evaluation criteria if appropriate • Evaluation of data collected in response to corrective action; determination if corrective action was successful

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
Recalls	As needed	• Description of specific failures and impacted CSPs and/or CSP compounding processes (e.g., CSP sterility, strength, endotoxin burden, or other quality attribute) • List of patients and prescribers effected (or potentially effected) • Description of recall process and timeline for unused dispensed CSPs • Communication to prescribers (and patients/caregivers) • Assessment of undispensed CSPs for inclusion in recall • Disposal documentation for recalled CSPs • Investigation, corrective action, and follow up to ensure failure has been remedied and recall process has been concluded • Reporting of ADR to appropriate regulatory bodies and required follow up • Provide to the California State Board of Pharmacy within 12 hours any recall notice issued by the pharmacy for sterile drug product it has compounded (BPC 4127.1(e)(3))

[USP 797] **Evaluation and Handling of Complaints and Adverse Events**

4.9. Refer to the **Complaint, Adverse Drug Reaction, & CSP Recall Handling** policy.

[USP 797] **Investigations and Corrective Actions**

4.10. When OOS, failures, complaints, or adverse drug reactions occur in any facet of the Sterile Compounding Program, perform an investigation that is consistent with the extent of the deviation and include an evaluation of historical trends for areas of concern.

4.11. Document the OOS, failure, complaint, or ADR per policy and ensure investigation findings, corrective action plans, and data collected to validate effectiveness of corrective actions is documented and retained in a readily accessible electronic or written format.

4.12. Investigations and immediate and longer-term corrective action plans include but are not limited to the following: *(USP does not specify investigation and corrective actions; the following table is intended to be a starting point. Revise as appropriate.)*

Area of Compliance	potential Investigation reviews	Potential Corrective Actions	
		Immediate	Longer Term
Facilities & Engineering Controls (PECs; HEPA Filters)	• Verification of current certifications • Certification report review for deficiencies or discrepancies • Evaluation of engineering & technical systems, equipment, HEPA filters for needed repairs or replacement • Evaluation of external factors that could impact function (e.g., power surges) • Trends	• Risk assessment to current compounding operations & CSPs • Halt or limit compounding in effected • Staff communication	• Repair or replacement of equipment or systems • Assessment of certification vendor, certification report, and OOS or potential OOS communication • Assessment of and revisions to certification report review and sign off process

Area of Compliance	potential Investigation reviews	Potential Corrective Actions	
		Immediate	Longer Term
Environmental Controls (Temperatures; Pressure Differentials)	• Verification that maintenance, calibration, and certification of monitoring of airflow and monitoring systems and gauges are current • Evaluation of systems and gauges for needed repairs or replacements • Assessment of proper staff reading and documenting data • Trends	• Risk assessment to current compounding operations, CSPs, & compounding staff • Halt or limit compounding or drug storage in effected area • Staff communication	• Repair or replacement of equipment or systems • Placement of additional monitoring devices • Staff education about daily monitoring and maintenance of gauges • SOP changes & revised work instructions for vendors/personnel performing sampling
Personnel Competencies, Conduct, & Compounding Performance	• Review of training process and progress • Review of performance records and previous competency results (if applicable) • Interview of trainer and compounding supervisors • Interview with trainee • Live or video QA audits • CSP QC testing • Trends	• Risk assessment of previously compounded CSPs • Determine compounding status of individual (e.g., removal or limited work duties) • Immediate training & competency eval • Ad hoc QA audits • Staff communication	• Additional training, observed skill, and competency evaluations • QA live or video audits • Coaching or Performance improvement Plan • SOP changes & staff communication/training
Cleaning, Disinfecting, & Application of Sporicidal Agents	• Review of personnel training & competency records • Review of cleaning logs, agents, & dwell times used • Review of cleaning procedures • Live or video QA audits	• Risk assessment of previously compounded CSPs • Remedial cleaning with appropriate agent(s) • Coaching or training • Staff Communication	• Additional training, observed skill, and competency evaluations • QA live or video audits • Coaching or training • SOP changes & staff communication/training
Environmental Monitoring (Viable Air &/or Surface Sampling)	• Review operating conditions when samples taken (e.g., trainees or visitors present • Review of types of organisms, locations, CFU counts, & trends • Review personnel data (e.g., training records, visual observations, competencies) • Review of cleaning practices & documentation • Review of HEPA filter efficacy & ACPH as reported in cert. report • Review of materials movement • Review of media COAs, expiration, & proper storage • Confirmation of air sampler maintenance & certification • Review of sampler's training, competency, and technique	• Risk assessment to current compounding operations & CSPs • Remedial cleaning with appropriate agent(s) • Perform and/or reschedule retesting ASAP • Individual coaching or retraining if appropriate • Staff communication	• Staff education and retraining, if needed • Assessment of appropriateness of engineering & environmental controls for current conditions (e.g., volume, number of personnel, etc.) • Smoke studies to find airflow eddies, turbulence, and/or staled airflow • Consider redesigning workflows, traffic patterns, & personnel congestion points • SOP changes & staff communication/training
Sterile Equipment,	• Review of COAs and sign off upon receipt and/or before use	• Risk assessment to current compounding operations & CSPs	• Repair or replacement of equipment

Area of Compliance	potential Investigation reviews	Potential Corrective Actions	
		Immediate	Longer Term
Components, & Supplies	• For equipment, confirmation of current maintenance, calibration, & certification • For ACDs, review of daily accuracy measurement records • Review of manufacturer information or recalls • Review of proper use or operation by compounding staff • Trends	• Removal of equipment, components, supplies until issue resolved • Individual or team coaching or training • Staff communication	• Source components or supplies for alternative vendors • SOP changes & staff communication • Additional training, competency, and/or quality audits
CSP Quality	• Review facilities, engineering and environmental controls certifications • Review compounding process including supplies, components, & equipment used • Review personnel records of compounder(s) & QA audits of compliance • Review of analytical laboratory credentials & protocols • Trends	• Patient risk assessment & recall determination if CSPs dispensed prior to final verification • Investigation for other CSPs potentially impacted by quality issue; CSP recall consideration • Individual or team coaching or training • Staff communication	• SOP changes & staff communication • Additional training, competency, and/or quality audits
Complaints & Adverse Drug Reaction Reports	Review of all areas of sterile practice for possible contributory or causative factors; prioritize investigation by the most likely causes; ***see above***	• Risk assessment to current compounding operations & CSPs up to and including halting or restricting compounding operations, limiting BUDs to immediate use until issue resolved • Reassigning personnel involved pending investigation • Staff communication	Corrective actions appropriate to address the suspected or known root cause(s); ***see above*** • Enhanced QA/QC monitoring to ensure corrective actions have been effective • Staff communication

5. Definitions

5.1. **Cycle parameters**: A description of the unique sterilization or depyrogenation parameters used for a defined purpose or process including temperature, duration, and pressure (if appropriate).

5.2. **Cycle validation indicators**: including biological indicators and endotoxin challenge vials (ECVs) used to validate the respective sterilization or depyrogenation cycles achieved the conditions necessary to achieve the desired result in the CSPs or items included in the cycle; is not absolute proof of sterility (or depyrogenation).

5.3. **Load characteristics**: A description and visual representation/diagram of each sterilization or depyrogenation process such as maximum number of items loaded, configuration and placement of items inside the load, and wrapping, if any, of the loaded items

5.4. **Oversight:** The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed even if not physically present.

5.5. **Quality assurance (QA):** A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

5.6. **Quality control (QC):** The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.

5.7. **Release inspection and testing:** Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.

5.8. **Specification:** The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.

5.9. **Verify:** To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.

6. Related Policies, Documents, References

6.1. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

6.2. United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

6.3. United States Pharmacopeial Convention, Inc. <1163> Quality Assurance in Pharmaceutical Compounding. Current version.

7. Approval and Review Summary

Approved by/date:	Role or committee, Date of approval (10/2023)
Next review:	Month/year

7.1. Initial version published by Wolters Kluwer 2023.

7.2. Revised MM/YYYY with the following key changes…OR…with no changes.

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Quality Assurance & Quality Control Program – Sterile Compounding	Policy #	PHARMXXXX
Responsible	Pharmacy Director	Revised/Reviewed	10/06/2023

I. PURPOSE

This policy describes the Sterile Compounding Program quality assurance and quality control responsibilities and processes Watsonville Community Hospital where Compounded Sterile Preparations (CSPs) are compounded, verified, and stored prior to dispensing. The policy serves as Watsonville Community Hospital's written Quality Assurance and Control Program ("Quality Program") consisting of:

- **Quality Assurance (QA)**: The procedures, activities, and oversight that ensures the compounding process consistently meets quality standards
- **Quality Control (QC):** The sampling, testing, and documentation of results that, when taken together, ensure CSP specifications have been met prior to release and dispensing

The Quality Program is a comprehensive system that supports continual quality improvement within the Sterile Compounding Program and is designed to ensure:

- Regulatory and statutory compliance
- Adherence to policies and procedures
- Prevention and detection of errors or other quality deficiencies
- Evaluation and handling of complaints and adverse events
- Appropriate investigations and corrective actions

The Quality Program integrates information and data collected from patients, caregivers, and providers; compounding and support personnel; technical, mechanical, and scientific professionals; and supporting organizational and industry experts with the ultimate goal of ensuring patient safety through consistent and repeatable high quality CSPs prepared in a safe and controlled compounding environment.

II. POLICY

A. The Quality Director is responsible to define, implement, and oversee Watsonville Community Hospital's Quality Program and ensure it includes, at a minimum, the following integrated components:
   - Compounding Personnel Training & Competency Evaluation
   - Standard Operating Procedures (SOPs)
   - Compliance Documentation Review & Audit
   - CSP Verification
   - Controlled Area(s) Cleaning, Disinfecting, & Safety
   - CSP Containers, Packaging, Repackaging, Labeling, and Storage Practices
   - Responsible Personnel
   - Outsourcing Documentation Supporting BUD Assignments and Release Testing Results

B. Sterile Compounding Program compliance related activities and documentation (e.g., inspection or analytical laboratory reports, competency forms and checklists, written records, and supporting documentation) are reviewed and audited at least once annually to ensure:
   - All required regulatory and statutory sterile compounding requirements are successfully completed within the appropriate timeframe, memorialized with the appropriate documentation, and reviewed by the DP (if appropriate)
   - Out of specification findings, occurrences, and events are investigated and remediated

- Corrective actions are fully documented, and data collected in response to corrective actions is reviewed to confirm action taken have been effective
- Opportunities of continual process improvement are identified and initiated

III. ROLES & RESPONSIBILITIES

1. The Designated Person(s) (DP):
   - Partner with Quality Director to develop, implement, and manage the Sterile Compounding Quality Program
   - Educate Compounding Personnel on the Quality Program including individual and team quality related responsibilities, processes, documentation, and tools
   - Alert and engage the Quality Director of issues impacting quality or regulatory and/or statutory changes impacting the Quality Program
   - Ensure quality assurance audits of the Sterile Compounding Practice compliance and related documentation are conducted on a timely basis
   - Oversee remediation and documentation of any deficiencies found in QA audit process
2. Compounding Personnel:
   - Understand individual and compounding team role and responsibilities in supporting sterile practice quality assurance and control through compliance with all the Sterile Compounding Program policies and procedures (i.e., Standard Operating Procedures or SOPs)
   - Alert DP or compounding supervisor/Designee of any known or suspected deficiencies, failures, or out of specification results related to any aspect of sterile compounding operations and assist with remediation efforts if appropriate, including, but not limited to issues with:
     - Facilities operations or certification
     - Engineering controls (e.g., PECs)
     - Environmental controls for compounding and drug storage locations (e.g., pressure differentials, temperatures)
     - Equipment, supplies, components
     - Cleaning, disinfecting, or application of sporicidal disinfectants
     - Materials movement and personnel conduct with controlled areas
     - Sterile compounding
     - Personnel training and competency evaluations
     - Documentation of compliance activities
3. Quality Director, or similar:
   - Partner with DP to understand sterile practice regulatory and statutory requirements, how to locate and interpret compliance documentation, QA/QC audit parameters, and specifics of Watsonville Community Hospital's sterile compounding Quality Program
   - Partner with DP and/or designee to resolve audit deficiencies; conduct follow up verification of corrective actions taken to resolve deficiencies

IV. DEFINITIONS

A. **Cycle parameters**: A description of the unique sterilization or depyrogenation parameters used for a defined purpose or process including temperature, duration, and pressure (if appropriate).

B. **Cycle validation indicators**: including biological indicators and endotoxin challenge vials (ECVs) used to validate the respective sterilization or depyrogenation cycles achieved the conditions necessary to achieve the desired result in the CSPs or items included in the cycle; is not absolute proof of sterility (or depyrogenation).

C. **Load characteristics**: A description and visual representation/diagram of each sterilization or depyrogenation process such as maximum number of items loaded, configuration and placement of items inside the load, and wrapping, if any, of the loaded items

D. **Oversight:** The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed even if not physically present.

E. **Quality assurance (QA):** A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

F. **Quality control (QC):** The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.

G. **Release inspection and testing:** Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.

H. **Specification:** The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.

I. **Verify:** To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.

V. PROCEDURE

- **Sterile Program Quality Assurance Compliance Review & Audit**

A. Review Sterile Compounding Program compliance activities and audit at least once annually to ensure all regulatory and statutory requirements and supporting documentation are effectively and fully completed within the appropriate timeframe(s) and per policy. This audit also confirms DP and compounding personnel compliance with policies and procedures and allows for the detection and potential prevention of other quality deficiencies.

B. Confirm compliance documentation is retained in a readily retrievable electronic and/or written format and can be easily located with minimal instruction.

C. **Facilities and environmental controls QA audit parameters** follow criteria in the table below. Refer to the **Facilities & Environmental Controls policy** and **Certification & Recertification policy** for additional information regarding these regulatory requirements.

REQUIREMENT	COMPLIANCE ACTIVITY FREQUENCY	QUALITY ASSURANCE PARAMETER
FACILITIES & ENGINEERING CONTROLS		
Sterile facilities certification / recertification	Initially & every 6 months* *Performed by a qualified certification vendor*	• Formal SCA certification report & ISO classification certificate for SCA; includes: ○ HEPA filter integrity testing (PECs) ○ Dynamic airflow smoke pattern test (PECs only) • Certificate of compliance posted on each PEC
Total particle counts / ISO classifications		• Sampling plan diagram • ISO Class 5 (PEC): < 3520
PEC HEPA filter integrity testing		• 99.99% efficacy documented for each HEPA filter • Description of patch size applied to HEPA filter *(PEC HEPA filters should not exceed 2% of filter surface area)*
PEC dynamic airflow smoke pattern test & video		• Documented and video evidence of successful completion of airflow smoke pattern test performed *"under dynamic operating conductions demonstrating unidirectional airflow and sweeping action over and away from the preparation"*
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of facilities or engineering controls OOS or failures, investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken have been effective

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
ENVIRONMENTAL CONTOLS		
Drug storage location temperatures	Measured by continuous monitoring device or recorded manually	• Daily review and documentation of compounding room and drug storage location temperatures every day compounding occurs o Compounding areas: ≤ 20°C (≤ 68°F) *(recommended for compounder comfort; not a firm requirement)* o Ambient Drug Storage Areas (Controlled Room Temp): 20 - 25°C (68 - 77°F) o Refrigerated Drug Storage Areas: 2 - 8°C (36.8 – 46.4°F)
Calibration, maintenance, and certification records	Every 12 months	For each continuous monitoring system, device, or gauge monitoring pressure differentials, temperatures (room and drug storage locations): • Documentation of annual calibration and certification by a qualified technician • Documentation of maintenance as needed
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of daily pressure differential and temperature monitoring OOS or failures results, investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken have been effective

*Facilities are also recertified after events impacting the quality of the environment including, but not limited to redesign, construction/major repairs, relocation or replacement of PEC, or room configuration/traffic pattern changes that could affect airflow or air quality.

D. **Microbial air and surface sampling QA audit parameters** follow criteria in the table below. Refer to the **Microbial Air & Surface Sampling policy** and **Out of Specification policy** for additional information regarding these regulatory requirements.

<table>
<tr><th>Requirement</th><th>Compliance Activity Frequency</th><th>Quality Assurance Parameter</th></tr>
<tr><td colspan="3">MICROBIAL AIR & SURFACE SAMPLING</td></tr>
<tr><td>Viable Air Sampling Results</td><td>Every 6 months</td><td rowspan="2">• Viable sampling diagram (including sites within PECs sufficient to adequately characterize the state of microbial control within area)
• Sampling results reports:
o Date, time, & person performing sampling
o Identification of sampling locations and person/entity who performed sampling
o Media incubation dates and temperatures
o Media used: manufacturer, lot number, expiration date, and validation of growth promotion (e.g., control plate results)
o Sampling equipment used: manufacturer, model, certification
o CFU enumeration per site (reported as a single number per site if only TSA media plates used; reported as 2 separate numbers if two types of media plates are used per site)
o Microbial identification of CFUs to the genus level (not required unless action levels are exceeded)
<table>
<tr><th>ISO Class</th><th>Viable Air Sample
CFU/m³ of air per plate (1000L sample)</th><th>Viable Surface Sample
CFU per sampling plate</th></tr>
<tr><td>ISO 5</td><td>> 1</td><td>> 3</td></tr>
<tr><td>ISO 7</td><td>> 10</td><td>> 5</td></tr>
</table>
</td></tr>
<tr><td>Surface Sampling Results</td><td>Every Month</td></tr>
</table>

REQUIREMENT	COMPLIANCE ACTIVITY FREQUENCY	QUALITY ASSURANCE PARAMETER
		ISO 8 | > 100 | > 50
Sampling results after OOS events	As needed and for major air handling system maintenance	• OOS event written description including: ○ Date, time, and location (e.g., area(s) impacted) ○ Impact to environmental controls (e.g., pressure differentials, temperatures) ○ Impact to operations of PECs, if applicable ○ Impact to compounding operations and immediate remediation steps taken (e.g., restricting compounding operations, temporarily reclassifying BUDs to immediate use.) ○ Remedial cleaning after event, if applicable ○ Validation of restored state of microbial control (e.g., sampling results report)
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of OOS results (e.g., CFUs exceeding action levels at any site, pathogenicity of microorganisms identified, or trends of actionable results, etc.), investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective • Resampling report results confirming successful remediation
COAs for media used onsite	Media ordered for environmental sampling	For each lot of media used: • Manufacturer (or internal) lot number and expiration date • Manufacturer COA verifying media has been tested and meets expected microbial growth promotion, media pH within acceptable limits, and sterilization requirements

E. **Personnel training and competency QA audit parameters** follow criteria in the table below. Refer to the **Personnel Training & Evaluation policy** for additional information regarding these regulatory requirements.

REQUIREMENT	COMPLIANCE ACTIVITY FREQUENCY	QUALITY ASSURANCE PARAMETER
PERSONNEL TRAINING & COMPETENCY EVALUATIONS		
Compounding Personnel	Initially & every 6 or 12 months depending on evaluation	For each employee: • Competency documentation showing successful completion initially (prior to compounding) and <u>every 12 months</u> of: 1. **Foundational and job-related knowledge exam** – ▪ Initially & Ongoing: minimum 80% passing score 2. **Observed validation of core skills** in maintaining the quality of the sterile compounding environment (e.g., cleaning, materials movement, etc.) ▪ Initially & Ongoing: 100% observed skills assessment • Competency documentation showing successful completion initially (prior to compounding) and <u>every 6 months</u> of: 3. **Observed Hand Hygiene & Garbing Competency** including gloved fingertip (GFT) results – ▪ Initially: performed three (3) times with zero (0) CFUs detected ▪ Ongoing: performed once with zero (0) CFUs detected & 100%

REQUIREMENT	COMPLIANCE ACTIVITY FREQUENCY	QUALITY ASSURANCE PARAMETER
		observed skills assessment 4. **Observed Aseptic Technique Competency** including media fill (MF) and post media fill GFT and surface sample (SS) results ▪ Initial & Ongoing: no turbidity in MF, ≤ 3 CFU on GFT, & ≤ 3 CFU on SS & 100% observed skills assessment • Documentation of media manufacturer, lot number, & expiration date plus incubation dates and temperatures for competencies using media (i.e., #3 & #4) • Evaluation date, time, and evaluator name for all observed competencies (i.e., #2, #3, & #4)
Personnel directly overseeing compounding	Initially & every 12 months	See above Exception: #3 & #4 competencies are performed initially and once every 12 months
Personnel performing Immediate Use Compounding	Initially & PRN	See above Exception: personnel who exclusively perform immediate use compounding are only perform job-related knowledge exam (#1) & observed core skills assessment (#2)
Personnel providing supporting roles	Initially and annually	• Personnel who may perform supporting roles inside of controlled compounding areas (e.g., cleaning personnel) perform observed core skills assessment (#2), Hand Hygiene & Garbing Competency (not GFT or media fill)
Competency Failure & Corrective Action Plans	As needed	• Documentation and description of failed results, investigation, prescribed remedial training and/or corrective action plan, and review of remediation to confirm actions taken were effective • Results of repeated competencies (required for failures, refer to policy for more information)
COAs for media used onsite	Media/media fill components ordered for personnel sampling	For each lot of media used: • Manufacturer (or internal) lot number and expiration date • Manufacturer COA verifying media has been tested and meets expected microbial growth promotion, media pH within acceptable limits, and sterilization requirements

F. **Cleaning of controlled compounding area QA audit parameters** follow criteria in the table below. Refer to the **Cleaning, Disinfecting, & Application of Sporicidal Agent policy** for additional information regarding these regulatory requirements.

<table>
<tr><th>REQUIREMENT</th><th>COMPLIANCE ACTIVITY FREQUENCY</th><th>QUALITY ASSURANCE PARAMETER</th></tr>
<tr><td colspan="3">CLEANING & DISINFECTING</td></tr>
<tr><td>Cleaning, Disinfecting, & Application of Sporicidal Agents</td><td>Per Policy</td><td>Refer to the policy for a detailed description of the cleaning tasks, frequency, and agents to be used; in general, the following occurs:
<table>
<tr><th>Minimum Frequency</th><th>Task/Area</th><th>Cleaning Agent</th></tr>
<tr><td>Daily</td><td>Cleaning & disinfecting:
• Interior of each PEC (including work tray)
• Equipment resident in PEC
• Pass Through(s)</td><td>EPA registered one step disinfectant cleaner or separate agents</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Requirement</th><th>Compliance Activity Frequency</th><th>Quality Assurance Parameter</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td></td><td>• Work surfaces outside of PEC and SCA
• Floors
• Sinks</td><td></td></tr>
<tr><td>Monthly</td><td>• All daily tasks (above)
• Underneath PEC work tray
• Walls & Ceilings
• All surfaces outside of PEC (not only high touch)
• Storage bins & shelves
• Equipment outside of PECs</td><td>Sporicidal Agent (with cleaning & disinfecting activity)</td></tr>
<tr><td>Ad Hoc</td><td colspan="2">As determined by the DP and/or Designee or per policy for
Out of Specification (OOS) occurrences</td></tr>
</table>
• Timely and complete documentation of regularly scheduled and ad hoc cleaning tasks that occur including identification of person completing task
</td></tr>
<tr><td>OOS or Failure Investigation & Corrective Action Plans</td><td>As needed</td><td>• Documentation of OOS results (e.g., incomplete or undocumented cleaning tasks, cleaning agent defects, etc.), investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective</td></tr>
</table>

G. **Sterile supplies, components, and compounding equipment QA audit parameters** follow criteria in the table below. Refer to the **Equipment, Supplies, & Components for Sterile Compounding policy** for additional information regarding these regulatory requirements.

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
STERILE COMPOUNDING EQUIPMENT		
Sterile Equipment Calibration, Maintenance, & Certification	Per Manufacturer's Instructions or at least once per year	Per each piece of sterile compounding equipment (e.g., ACDs, analytical balances, incubators, autoclave, dry heat oven, etc.): • Documentation of calibration and certification by a qualified technician • Documentation of maintenance as needed
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of OOS results (e.g., substandard APIs, components, or supplies), investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective

H. **Compounding records and CSP release inspection QA evaluation parameters** follow criteria in the table below. Refer to the **Master Formulation Record & Compounding Record policy** for additional information regarding these regulatory requirements.

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
Compounding Records		
Master Formula Record (MFR) & Compounding Record (CR) Creation; BUD/storage/stability reference	MFR: For batched CSPs CR: For every CSP or CSP batch	For each batched CSP formulation: • MFR: refer to policy for the required data and instructions included in each MFR; confirm each MFR has validated BUD, storage condition, and/or stability references (in addition to USP <797> Chapter including USP-NF monograph or other published and validated study or data) For each Category 1 CSP: • CR: refer to policy for the required data included in each CR ○ *For CSPs not requiring a MFR*, the CR can be prescription or medication order or representation of the same stored in a workflow management system, ACD, or similar ○ *For CSPs requiring a MFR*, the CR must include a reference to a MFR, component manufacturing information, measured quantities used
Release Inspections & Tests		
Visual Inspections, Measurements, & Calculations	Every CSP or CSP Batch	Results documented on CR or implied by RPh final verification: • Visual inspections: components & final CSP, label (including BUD assignment & storage conditions) • Measurements: component and/or final CSP weights, volumes, etc. • Calculations/Conversions: per formulation
OOS or Failure Investigation & Corrective Action Plans	As needed	• Documentation of OOS results, investigation to determine root cause(s), corrective action plan, and review of remediation to confirm actions taken were effective

I. **Standard operating procedure, complaints and adverse drug reaction (ADR) handling, and CSP recalls QA evaluation parameters** follow criteria in the table below. Refer to the **Complaints, Adverse Reactions** and **CSP Recall Handling policy** for additional information regarding these regulatory requirements.

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
SOPs, Complaint and ADR Handling, & Recalls		
Sterile Practice SOPs & Annual Review	Every 12 months	• SOPs meeting USP <797> documentation requirements • Annual review, revisions, updates by Designated Person • Staff communication regarding SOP updates
Complaints & Adverse Drug Reaction (ADR) Handling	As needed per reports by patients, providers, staff, public	For each compliant or ADR: • Reported, documented, and tracked per policy • Patient/public harm risk assessment including severity and response urgency determination • Root cause analysis and investigation description • Corrective action(s) description, timeline, and evaluation criteria if appropriate • Evaluation of data collected in response to corrective action; determination if corrective action was successful
Recalls	As needed	• Description of specific failures and impacted CSPs and/or CSP

Requirement	Compliance Activity Frequency	Quality Assurance Parameter
		compounding processes (e.g., CSP sterility, strength, endotoxin burden, or other quality attribute) • List of patients and prescribers effected (or potentially effected) • Description of recall process and timeline for unused dispensed CSPs • Communication to prescribers (and patients/caregivers) • Assessment of undispensed CSPs for inclusion in recall • Disposal documentation for recalled CSPs • Investigation, corrective action, and follow up to ensure failure has been remedied and recall process has been concluded • Reporting of ADR to appropriate regulatory bodies and required follow up • Provide to the California State Board of Pharmacy within 12 hours any recall notice issued by the pharmacy for sterile drug product it has compounded (BPC 4127.1(e)(3))

- **Evaluation and Handling of Complaints and Adverse Events**

A. Refer to the **Complaint, Adverse Drug Reaction, & CSP Recall Handling** policy.

- **Investigations and Corrective Actions**

A. When OOS, failures, complaints, or adverse drug reactions occur in any facet of the Sterile Compounding Program, perform an investigation that is consistent with the extent of the deviation and include an evaluation of historical trends for areas of concern.

B. Document the OOS, failure, complaint, or ADR per policy and ensure investigation findings, corrective action plans, and data collected to validate effectiveness of corrective actions is documented and retained in a readily accessible electronic or written format.

C. Investigations and immediate and longer-term corrective action plans include but are not limited to the following: *(USP does not specify investigation and corrective actions; the following table is intended to be a starting point. Revise as appropriate.)*

Area of Compliance	potential Investigation reviews	Potential Corrective Actions	
		Immediate	Longer Term
Facilities & Engineering Controls (PECs; HEPA Filters)	• Verification of current certifications • Certification report review for deficiencies or discrepancies • Evaluation of engineering & technical systems, equipment, HEPA filters for needed repairs or replacement • Evaluation of external factors that could impact function (e.g., power surges) • Trends	• Risk assessment to current compounding operations & CSPs • Halt or limit compounding in effected • Staff communication	• Repair or replacement of equipment or systems • Assessment of certification vendor, certification report, and OOS or potential OOS communication • Assessment of and revisions to certification report review and sign off process
Environmental Controls (Temperatures; Pressure Differentials)	• Verification that maintenance, calibration, and certification of monitoring of airflow and monitoring systems and gauges are current • Evaluation of systems and	• Risk assessment to current compounding operations, CSPs, & compounding staff • Halt or limit compounding or drug	• Repair or replacement of equipment or systems • Placement of additional monitoring devices • Staff education about daily monitoring and

AREA OF COMPLIANCE	POTENTIAL INVESTIGATION REVIEWS	POTENTIAL CORRECTIVE ACTIONS IMMEDIATE	POTENTIAL CORRECTIVE ACTIONS LONGER TERM
	gauges for needed repairs or replacements • Assessment of proper staff reading and documenting data • Trends	storage in effected area • Staff communication	maintenance of gauges • SOP changes & revised work instructions for vendors/personnel performing sampling
Personnel Competencies, Conduct, & Compounding Performance	• Review of training process and progress • Review of performance records and previous competency results (if applicable) • Interview of trainer and compounding supervisors • Interview with trainee • Live or video QA audits • CSP QC testing • Trends	• Risk assessment of previously compounded CSPs • Determine compounding status of individual (e.g., removal or limited work duties) • Immediate training & competency eval • Ad hoc QA audits • Staff communication	• Additional training, observed skill, and competency evaluations • QA live or video audits • Coaching or Performance improvement Plan • SOP changes & staff communication/training
Cleaning, Disinfecting, & Application of Sporicidal Agents	• Review of personnel training & competency records • Review of cleaning logs, agents, & dwell times used • Review of cleaning procedures • Live or video QA audits	• Risk assessment of previously compounded CSPs • Remedial cleaning with appropriate agent(s) • Coaching or training • Staff Communication	• Additional training, observed skill, and competency evaluations • QA live or video audits • Coaching or training • SOP changes & staff communication/training
Environmental Monitoring (Viable Air &/or Surface Sampling)	• Review operating conditions when samples taken (e.g., trainees or visitors present • Review of types of organisms, locations, CFU counts, & trends • Review personnel data (e.g., training records, visual observations, competencies) • Review of cleaning practices & documentation • Review of HEPA filter efficacy & ACPH as reported in cert. report • Review of materials movement • Review of media COAs, expiration, & proper storage • Confirmation of air sampler maintenance & certification • Review of sampler's training, competency, and technique	• Risk assessment to current compounding operations & CSPs • Remedial cleaning with appropriate agent(s) • Perform and/or reschedule retesting ASAP • Individual coaching or retraining if appropriate • Staff communication	• Staff education and retraining, if needed • Assessment of appropriateness of engineering & environmental controls for current conditions (e.g., volume, number of personnel, etc.) • Smoke studies to find airflow eddies, turbulence, and/or staled airflow • Consider redesigning workflows, traffic patterns, & personnel congestion points • SOP changes & staff communication/training
Sterile Equipment, Components, & Supplies	• Review of COAs and sign off upon receipt and/or before use • For equipment, confirmation of current maintenance, calibration, & certification • For ACDs, review of daily accuracy measurement records • Review of manufacturer information or recalls	• Risk assessment to current compounding operations & CSPs • Removal of equipment, components, supplies until issue resolved • Individual or team coaching or training	• Repair or replacement of equipment • Source components or supplies for alternative vendors • SOP changes & staff communication • Additional training, competency, and/or

AREA OF COMPLIANCE	POTENTIAL INVESTIGATION REVIEWS	POTENTIAL CORRECTIVE ACTIONS IMMEDIATE	POTENTIAL CORRECTIVE ACTIONS LONGER TERM
	• Review of proper use or operation by compounding staff • Trends	• Staff communication	quality audits
CSP Quality	• Review facilities, engineering and environmental controls certifications • Review compounding process including supplies, components, & equipment used • Review personnel records of compounder(s) & QA audits of compliance • Review of analytical laboratory credentials & protocols • Trends	• Patient risk assessment & recall determination if CSPs dispensed prior to final verification • Investigation for other CSPs potentially impacted by quality issue; CSP recall consideration • Individual or team coaching or training • Staff communication	• SOP changes & staff communication • Additional training, competency, and/or quality audits
Complaints & Adverse Drug Reaction Reports	of all areas of sterile practice for possible contributory or causative factors; prioritize investigation by the most likely causes; ***see above***	• Risk assessment to current compounding operations & CSPs up to and including halting or restricting compounding operations, limiting BUDs to immediate use until issue resolved • Reassigning personnel involved pending investigation • Staff communication	Corrective actions appropriate to address the suspected or known root cause(s); ***see above*** • Enhanced QA/QC monitoring to ensure corrective actions have been effective • Staff communication

VI. REFERENCES

- United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
- United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.
- United States Pharmacopeial Convention, Inc. <1163> Quality Assurance in Pharmaceutical Compounding. Current version.

VII. STAKEHOLDERS

N/A

{{Watsonville Community Hospital	**Designated Person for Sterile Compounding**
Policy Number/ Version:	797- 2022 version
Policy Start Date:	Initial policy version/implementation

1. Overview and Scope

1.1 This policy describes the primary roles and responsibilities for the Designated Person(s) (DP) responsible for the oversite of sterile compounding processes and compliance where Compounded Sterile Preparations (CSP) are prepared within Watsonville Community Hospital.

2. Policy

2.1. [USP 797] Watsonville Community Hospital will designate one or more individuals (i.e., the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and all other functions pertaining to CSPs.

2.2. The DP for CSPs will have the following qualifications:

- Completion of CE hours in the area of compounding
- Recommended 3 years of experience preparing CSPs

3. Roles & Responsibilities

3.1 [USP 797] The Designated Person(s) for sterile compounding shall be the Director of Pharmacy.

- DP may assign designee(s) to assist with Sterile Compounding Program.
- Designee may be assigned by DP to assist with any of the procedures included in this policy.

3.2. [USP 797] The DP(s) is responsible for:

- Overall compliance with USP <797>, applicable federal and state laws and regulations and accreditation standards.
- Oversight of personnel training and competency for those involved in sterile compounding and handling and preparing CSPs
- Selection of components
- Monitoring and observing sterile compounding activities and taking immediate corrective action if deficient practices are observed.
- Ensuring standard operating procedures (SOPs) and/or policies are fully implemented, and that follow-up is carried out if problems, deviations, or errors are identified.
- Establishing, monitoring, and documenting procedures for the handling and storage of CSPs and/or components of CSPs.

3.3. Pharmacy Management is responsible for:

- Ensuring adequate personnel resources for training and adherence to Watsonville Community Hospital's Sterile Compounding procedures,
- Ensuring adequate equipment and facilities to comply with USP <797> standards,
- Coordinating with the Designated Person for Sterile Compounding for local site implementation, monitoring, or concerns.

4. Procedures

4.1 Training and Evaluation:

- [USP 797] The DP creates, implements, and oversees training of all compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties. The DP ensures that all persons who enter the sterile compounding area and/or handles CSPs complete training and demonstrate competency in maintaining the quality of the sterile compounding environment.
- [USP 797] The DP performs all training and observation associated with CSPs and/or designates an assigned trainer to complete these functions.

4.2 Personal Hygiene and Garbing:

- [USP 797] The DP evaluates if individuals with certain conditions should be excluded from the sterile compounding environment. Conditions that have a higher risk of contaminating the CSP and the environment are personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.
- [USP 797] The DP may permit individual personnel accommodations to hand hygiene and garbing as long as the quality of the CSP and the environment will not be affected; and will document accommodations as defined in the **Hand Hygiene and Garbing policy.**

4.3 Facility Design and Environmental Control:

- [USP 797] The DP ensures that each area where CSPs are prepared meets the classified air quality standard appropriate for the activities conducted in that area.
- [USP 797] The DP ensures that International Organization for Standardization (ISO) Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality.
- [USP 797] The DP determines the dynamic operating conditions for the sterile compounding environment. The dynamic operating conditions are reproduced during dynamic room certification testing.
    - Dynamic operating conditions are the conditions in the sterile compounding area in which personnel are present and simulating or performing sterile compounding. These conditions will reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the DP.
- [USP 797] The DP identifies and addresses other areas of risk related to placement and movement of materials within the compounding area to ensure the quality of the CSP and the environment will not be affected.

4.4 Certification and Recertification:

- [USP 797] The DP reviews all certification and recertification records to ensure that the classified environments meet the minimum requirements outlined in USP <797>.

4.5 Components:

- [USP 797] The DP assesses and selects acceptable and reliable sources if a component used in the compounding of CSPs cannot be obtained from a Food and Drug Administration (FDA)-registered facility.

4.6 Standard Operating Procedures (SOP)s:

- [USP 797] The DP ensures that SOPs are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function.
- [USP 797] The DP ensures that corrective actions are taken if problems, deviations, failures, or errors are identified, and documents corrective actions as necessary.
- [USP 797] The DP reviews SOPs at least every 12 months to ensure that they reflect current practices. The review is documented by DP.
- [USP 797] Any changes or alterations to an SOP are made only by a DP and must be documented.

4.7 Quality Assurance and Quality Control:

- [USP 797] The DP ensures that Watsonville Community Hospital has a formal, written Quality Assurance (QA) and Quality Control (QC) program.
- [USP 797] The written QA and QC program establishes a system of:
  - Adherence to procedures
  - Prevention and detection of errors and other quality problems
  - Evaluation of complaints and adverse events
  - Appropriate investigations and corrective action
- [USP 797] The DP reviews the overall QA and QC program once every 12 months and the results of the review are documented and appropriate action taken if necessary.

4.8 Complaint Handling:

- [USP 797] The DP reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.

4.9 Handling and storing CSPs:

- [USP 797] If there is a known excursion to temperatures either below or above the storage temperature limits for the CSP, the DP determines (e.g., by consulting literature or analytical testing) whether the CSP is expected to retain its integrity or quality. If this cannot be determined, the CSP is discarded.

5. Definitions

5.1 **Designated Person (DP)**: One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.

5.2 **Compounded Sterile Preparation (CSP)**: A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

6. Related Policies, Documents, References

6.1 United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 proposed version.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Patient Controlled Analgesia(PCA)	Policy #	PHARM1820
Responsible	Quality/Pharmacy Director	Revised/Reviewed	~~04/2021~~09/25/2023

I. PURPOSE

A. To provide monitoring and assessment guidelines for Registered Nursing (RN) staff to provide adequate Patient Controlled Analgesia (PCA) pain relief while maintaining satisfactory respiratory and ventilation status

II. POLICY

A. It is the policy of Watsonville Community Hospital (WCH) to provide equitable, timely, safe and effective pain management.
B. Any patient requiring the use of patient-controlled analgesia will be assessed and monitored by an RN including reliable and valid pain score, vital signs including heart rate, blood pressure, respiration and oxygen saturation in regular intervals as defined below.
C. Continuous End Tidal CO2 will be monitored when available.
D. Patient's level of sedation shall be monitored with the use of a reliable and validated sedation scoring tool
E. Patient and family education should be provided regarding pain scale, principles of PCA use and common side effects

III. DEFINITIONS

A. Continuous dose: The amount of analgesic administered continuously. Also referred to as Basal Dose
B. PCA dose: Patient administered dose
C. Clinician bolus dose: A bolus dose administered by a clinician when pain is inadequately managed with current PCA settings.
D. Lockout interval: Predetermined period during which the patient cannot initiate doses.

IV. PROCEDURE

A. Provider Orders

1. Review provider orders including medication, concentration, basal rate, loading dose, demand PCA dose, lockout interval, cumulative dose limit and basal rate
2. Check for medication allergies or sensitivities
3. Check for drugs that may potentiate the opioid or cause adverse effects of the opioid

B. Dispensing

1. PCA's will be available in automated dispensing cabinet (e.g., Pyxis Med Station)

C. Documentation

1. Independent verification and co-signature of the date, time, medication, medication concentration, basal rate, PCA dose, lockout interval, 4-hour maximum dose, starting volume after priming and with all changes thereafter required
2. Independent 2 RN verification and co-signature is required at the end of each 8-hour shift including total dose / volume infused, attempts, and actual and calculated reservoir volume

3. Pain assessment, nursing interventions and other adjunctive pain management per unit standards or more frequently as indicated
4. Patient's baseline and follow-up pain scores will be measured using validated and reliable scale
5. Patient's baseline and follow-up sedation scores will be measured using a validated and reliable scale
6. Patient education and reinforcement
7. Appearance and patency of the IV site

D. Patient Monitoring and Care

1. Assess and monitor patients' pain, pain quality, sedation scale including level of consciousness, respiratory rate and oxygen saturation after initial set up and every 30 minutes x 2, after any dose increase and every 4 hours and as needed.
2. Monitor IV line for patency, infiltration or signs of infection
3. Assess for the presence of side effects, such as nausea, pruritis, urinary retention or constipation
4. Encourage coughing and deep breathing every 2 hours
5. Recommend capnography, if available.
6. If respiratory rate < 10, stimulate patient and notify provider
7. If respiratory rate is below 8/minute, oxygen saturation is dropping and decreased level of consciousness, obtain order and give Narcan 0.4mg IV push; may repeat 0.4mg IV every 2 minutes. Notify physician
   a. Support respiratory status as necessary with an ambu bag until oxygen saturation and level of consciousness improve.
   b. If administration of Narcan required, increase monitoring to every 15 minutes x 1 hour, every 30 minutes x 1 hour, every 4 hours and as needed
   c. Do not administer additional opioids until physician notification and updated orders received

E. Outline of reportable conditions

1. Pain not controlled
2. Unrelieved nausea, vomiting, pruritis or somnolence.
3. Respiratory rate less than 10/minutes with increasing end tidal CO2, decreasing oxygen saturation, or increasing oxygen demands.
4. Allergic reaction.
5. Administration of naloxone.

V. REFERENCES

1. DynamicHealth Providing Patient-Controlled Analgesia
2. DynamicHealth Preventing Errors in Patient-Controlled Analgesia
3. The Joint Commission. National patient safety goals effective 2021 for the hospital program. January 2021.
   The Joint Commission
4. Lynn-McHale, W. D. J. (2017). Patient - Controlled Analgesia. In *AACN procedure for high-acuity, progressive, and critical care*. essay, Elsevier.

VI. STAKEHOLDERS

N/A

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: October 25, 2023

Report Type: Consent

Title: Short Term Loans Ratification

Recommendation: Pass a **Motion** ratifying Julie Peterson, CFO and Matko Vranjes, Interim CEO securing the short term loan arrangement from external partners, including potentially Salud Para La Gente, not to exceed $1.5 million dollars.

Contact: Julie Peterson, Chief Financial Officer

Executive Summary

The Pajaro Valley Health Care District Hospital Corporation desires the flexibility to arrange for short term loans on short notice when cash flow challenges threaten the Hospital's abilities to make payroll or AP disbursements. Given the nature of our business and the fact that we are subject to some liabilities of the prior ownership, it is necessary for the Hospital to make payments quickly to secure patient care supplies or pay past liabilities. The timing of these necessary payments does not always line up to the Hospital's ability to pay. Sometimes vendors are threatening to not provide needed patient care supplies until a pre-payment is made due to the credit risk of a company that has recently emerged from Bankruptcy. In some cases, the Department of Healthcare Services or other governmental agencies require payments for past cost report overpayments, quality assurance fees, or other normal course of business expenses. Sometimes the timing of these expenses is known and can be planned for. In other cases, the timing is unknown and when the request is received there is a short window for payment or to make alternative arrangements.

Background

On August 2, 2023, the PVHCD passed Motion no. 051-2023 authorizing Julie Peterson, CFO and Matko Vranjes, Interim CEO to negotiate and secure short term loan arrangements from external partners, including potentially Salud Para La Gente, not to exceed $1.5 million dollars.

Since emerging from Bankruptcy, the hospital has operated with limited working capital. On average we bring in about $2.3 million in cash collections each week. Every two weeks, the payroll, taxes and associated retirement payments are about $3.0 million dollars. On average, the normal Accounts Payable disbursements average about $1.5 million weekly. At the beginning of the month, certain payments, including a $400 thousand lease payment is due which can increase the Accounts Payable amount. Recently we have withheld Accounts Payable payments as the amount due exceeds the cash available, when managing cash to ensure payroll expenses are covered. Currently we have approximately $4.5 million in Accounts Receivable that is past due one week or more.

Analysis

A review of weekly Accounts Payable disbursements and bi-weekly payroll disbursements were compared to weekly cash collections. When cash deposits are received does not always align well with when disbursements are necessary. Additionally, there are certain large payments that are due above and beyond weekly disbursements. Given the timing Watsonville Community Hospital believes that the ability to enter into a short term bridge loan allows for a fast turnaround when cash is needed for unforeseen circumstances or any further delays in reimbursements due to the Hospital Corporation.

Financial Impact

The Hospital will have access up to $1.5 million for a short-term bridge loan from Salud Para La Gente for emergency needs. This would be a 3 unsecured loan at a 4.0% interest rate The authorization allows for quick turnaround on such a request. The Hospital will not immediately seek this loan unless needs dictate it.

The short-term bridge loan carries a promissory note to the borrower. Upon execution of a promissory note for any short term bridge loan, the CFO will report the action to the Board at the next regularly scheduled meeting.

Attachments:

A: PVHDHC Line of Credit Agreement dated October 1, 2023

LINE OF CREDIT AGREEMENT

$1,500,000.00 **Date: October 1, 2023**

FOR VALUE RECEIVED, Pajaro Valley Healthcare District Hospital Corporation (dba Watsonville Community Hospital) ("Borrower") promises to pay to the order of Salud Para La Gente ("Lender"), the principal sum of One and a Half Million Dollars ($1,500,000.00), or so much thereof as may be disbursed to or for the benefit of Borrower by Lender. With this Line of Credit Agreement (the "Agreement") it is the intent of Borrower and Lender hereunder to specify terms between Borrower and Lender whereby Borrower may borrow up to $1,500,000.00 from Lender upon written request. Each such request by Borrower shall specify the amount to be disbursed. Lender shall make such disbursement no later than five (5) business days of Lender's receipt of Borrower's written request, provided that the principal sum outstanding shall not exceed $1,500,000.00.

INTEREST & PRINCIPAL: The unpaid principal of this line of credit shall bear an interest rate of four percent (4%) per annum, compounded monthly. The principal balance of this Agreement, and all unpaid interest, shall be due and payable on December 31, 2023; however, once Borrower successfully secures a line of credit from Santa Cruz Community Bank ("SCCB LOC"), the outstanding loan principal on this Agreement and any accrued interest will be due and payable within three (3) days from the effective date of the SCCB LOC. Unless such a draw is made specifically for the purpose of paying off all outstanding principal and interest owed under this Agreement, no draw shall be made against the SCCB LOC until any outstanding principal and accrued interest on this Agreement is paid in full.

SECURITY: This debt incurred by Borrower under this Agreement shall be unsecured.

DEFAULT: Borrower shall be in default of this Agreement on the occurrence of any of the following events: (i) Borrower shall fail to meet its obligation to make the required principal or interest payments hereunder; (ii) Borrower shall make an election to wind up, dissolve, and liquidate, or otherwise approve corporate actions to cease as a going concern; (iii) Borrower shall make an assignment for the benefit of creditors or shall be unable to, or shall admit in writing its inability to, pay its debts as they become due; (iv) Borrower shall commence any case, proceeding, or other action under any existing or future law of any jurisdiction relating to bankruptcy, insolvency, reorganization or relief of debtors, or any such action shall be commenced against Borrower; (v) Borrower shall suffer a receiver to be appointed for it or for any of its property or shall suffer a garnishment, attachment, levy or execution.

REMEDIES: Upon default of this Agreement, Lender may declare the entire amount due and owing hereunder to be immediately due and payable. Lender may also use all remedies in law and in equity to enforce and collect the amount owed under this Agreement.

COLLECTION: Borrower agrees to pay all costs and expenses, including, without limitation, collection agency fees and expenses and reasonable attorneys' fees (whether or not suit is instituted), which Lender may incur in the exercise, preservation, or enforcement of its rights, powers, and remedies under this Agreement. Upon receipt of written demand, Borrower shall reimburse Lender for all such costs and expenses.

NO WAIVER BY LENDER: No failure on the part of Lender to exercise any right or remedy under this Agreement, whether before or after the occurrence of a default, shall constitute a

waiver thereof, and no waiver of any past default shall constitute waiver of any future default or of any other default.

WAIVER BY BORROWER: Borrower hereby waives demand, presentment, notice of dishonor, diligence in collecting, grace and notice of protest.

SEVERABILITY: If a court of competent jurisdiction holds any provision of this Agreement to be illegal, unenforceable, or invalid in whole or in part for any reason, the validity and enforceability of the remaining provisions, or portions of them, will not be affected.

GOVERNING LAW: This Agreement shall be governed by and construed under the laws of the State of California. The parties agree that Santa Cruz County is the proper jurisdiction for any action to enforce this Agreement.

TIME: Time is of the essence for every obligation under this Agreement.

AMENDMENT: This Agreement may not be changed orally but may be amended or altered only by prior written agreement signed by both Borrower and Lender.

BINDING ON SUCCESSORS: Borrower shall not assign or otherwise transfer this Agreement or its obligations hereunder without Lender's written consent. The covenants, terms, and conditions contained in this Agreement apply to and bind the permitted successors and assigns of Borrower.

HOLDER IN DUE COURSE: Lender shall not have the right to sell, assign, or otherwise transfer, either in part or in its entirety, this Agreement or any other instrument evidencing or securing the indebtedness of this Agreement without Borrower's consent.

[*Signature page to follow.*]

IN WITNESS WHEREOF, the parties hereto have executed this Line of Credit Agreement effective as of the date written above.

BORROWER: PAJARO VALLEY HEALTHCARE DISTRICT HOSPITAL CORPORATION (DBA WATSONVILLE COMMUNITY HOSPITAL)

Date: 9.27.23

LENDER: SALUD PARA LA GENTE

Donna Young
Donna Young (Sep 27, 2023 17:50 PDT)

Date: Sep 27, 2023

Line of Credit Agreement - Pajaro Valley Healthcare District Hospital Corporation (WCH)

Final Audit Report 2023-09-28

Created:	2023-09-27
By:	Amy Hsiung (ahsiung@splg.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAr3wU9XSHAkRYbyE-iO9_vzsx9ao0gQOI

"Line of Credit Agreement - Pajaro Valley Healthcare District Hospital Corporation (WCH)" History

Document created by Amy Hsiung (ahsiung@splg.org)
2023-09-27 - 10:58:55 PM GMT

Document emailed to dyoung@splg.org for signature
2023-09-27 - 11:10:28 PM GMT

Email viewed by dyoung@splg.org
2023-09-28 - 0:50:09 AM GMT

Signer dyoung@splg.org entered name at signing as Donna Young
2023-09-28 - 0:50:29 AM GMT

Document e-signed by Donna Young (dyoung@splg.org)
Signature Date: 2023-09-28 - 0:50:31 AM GMT - Time Source: server

Agreement completed.
2023-09-28 - 0:50:31 AM GMT

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: October 25, 2023

Report Type: Consent

Title: Pajaro Valley Health Care District Hospital Corporation (PVHCDHC) Board Meeting 2024 Calendar

Recommendation: Pass a Motion approving the PVHCDHC board and committee meetings calendar for 2024 as regular meetings.

Contact: Matko Vranjes, Interim Chief Executive Officer

Analysis

As required per The Pajaro Valley Health Care District Hospital Corporation bylaws adopted on January 25, 2023, the proposed calendar reflects a meeting frequency of “at least monthly” (Article 4, Section 4.5 and will continue this frequency in 2024. The Board may determine “the time for regular meetings of any committee” (Article VI, Section 6.4a) and the proposed meeting frequency for Strategic Planning and Marketing, Employee Engagement, and Quality and Patient Safety is quarterly, and the proposed meeting frequency for Finance is monthly. The dates and times of the Hospital Corporation and Committee meetings are held in conjunction with The Pajaro Valley Health Care District meetings per the attached calendar.

Financial Impact: None

Attachments:

A: 2024 PVHCDHC Meeting Dates Rev 100623

2024 Boards and Standing Committees: Meeting Schedule

Month	**District** *Board* (Matko Vranjes, CEO)	**Corporation** *Board* *Open and Closed* *Wednesdays* (Matko Vranjes, CEO)	**Finance** *Standing Committee* *Tuesday* (Julie Peterson)	**Strategic Planning and Marketing** *Standing Committee* *Tuesday* (Matko Vranjes, CEO)	**Employee Engagement** *Standing Committee* *Wednesdays* (Allyson Hauck)	**Quality and Patient Safety** *Standing Committee* *Wednesdays* (Sherri Torres)
January 2024	01/31 @ 6pm	01/31 @ 5pm	1/30 @ 12 Noon			01/17 @ 12 noon
February 2024	02/28 @ 6pm	02/28 @ 5pm	2/27@ 12 Noon		02/21 @ 12 noon	
March 2024	03/27 @ 6pm	03/27 @ 5pm	03/26 @ 12 Noon	03/21 @ 12 noon		
April 2024	04/24 @ 6pm	04/24 @ 5pm	04/23 @ 12 Noon			04/17 @ 12 noon
May 2024	05/29 @ 6pm	05/29 @ 5pm	05/28 @ 12 Noon		05/15 @ 12 noon	
June 2024	06/26 @ 6pm	06/26 @ 5pm	06/25 @ 12 Noon	06/19 @ 12 noon		
July 2024	07/31 @ 6pm	07/31 @ 5pm	07/30 @ 12 Noon			07/17 @ 12 noon
August 2024	08/28 @ 6pm	08/28 @ 5pm	08/27 @ 12 Noon		08/21 @ 12 noon	
September 2024	09/25 @ 6pm	09/25 @ 5pm	09/24 @ 12 Noon	09/18 @ 12 noon		
October 2024	10/30 @ 6pm	10/30 @ 5pm	10/29 @ 12 Noon			10/16 @ 12 noon
November 2024	11/20 @ 6pm*	11/20 @ 5pm*	11/19 @ 12 Noon		11/20 @ 4pm*	
December 2024	12/18 @ 6pm*	12/18 @ 5pm*	12/17 @ 12 Noon	12/18 @ 4pm*		

*Denotes other than standard meeting date or time due to holiday

10/06/2023

2024 Boards and Standing Committees: Meeting Schedule

Board Meeting Deadlines for Report Submission

	PAJARO VALLEY HEALTH CARE DISTRICT	PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION				
Month	District *Board* *Wednesday*	Corporation *Board* *Wednesday*	***Draft or Final Reports Submitted to Clerk for Assembley*** ***Friday***	***Draft Agenda and Document Status to LT for Review*** ***Monday***	***Final Report to Clerk for Polish and Publication*** ***Wednesday***	***Hard Deadline for Posting and Publication*** ***Thursday***
January 2024	01/31 @ 6pm	01/31 @ 5pm	01/19 (5pm)	01/22 (5pm)	01/24 (5pm)	01/25 (5pm)
February 2024	02/28 @ 6pm	02/28 @ 5pm	02/16 (5pm)	02/19 (5pm)	02/21 (5pm)	02/24 (5pm)
March 2024	03/27 @ 6pm	03/27 @ 5pm	03/15 (5pm)	03/18 (5pm)	03/20 (5pm)	03/21 (5pm)
April 2024	04/24 @ 6pm	04/24 @ 5pm	04/12 (5pm)	04/15 (5pm)	04/17 (5pm)	04/18 (5pm)
May 2024	05/29 @ 6pm	05/29 @ 5pm	05/17 (5pm)	05/20 (5pm)	05/22 (5pm)	05/23 (5pm)
June 2024	06/26 @ 6pm	06/26 @ 5pm	06/14 (5pm)	06/17 (5pm)	06/19 (5pm)	06/20 (5pm)
July 2024	07/31 @ 6pm	07/31 @ 5pm	07/19 (5pm)	07/22 (5pm)	07/24 (5pm)	07/25 (5pm)
August 2024	08/28 @ 6pm	08/28 @ 5pm	08/16 (5pm)	08/19 (5pm)	08/21 (5pm)	08/22 (5pm)
September 2024	09/25 @ 6pm	09/25 @ 5pm	09/13 (5pm)	09/16 (5pm)	09/18 (5pm)	09/19 (5pm)
October 2024	10/30 @ 6pm	10/30 @ 5pm	10/18 (5pm)	10/21 (5pm)	10/23 (5pm)	10/24 (5pm)
November 2024	11/20 @ 6pm	11/20 @ 5pm	11/8 (5pm)	11/11 (5pm)	11/13 (5pm)	11/14 (5pm)
December 2024	12/18 @ 6pm	12/18 @ 5pm	12/13 (5pm)	12/16 (5pm)	12/18 (5pm)	12/19 (5pm)
January 2025	01/29 @ 6pm	01/29 @ 5pm	01/17 (5pm)	01/20 (5pm)	01/22 (5pm)	01/23 (5pm)

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: October 25, 2023
Report Type: Discussion

Title: Medical Committees Reports October 2023

Recommendation: Pass a **Motion** approving the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of October 2023.

Contact: Clay Angel, M.D., Chief of Staff, Chair, Medical Executive Committee

Analysis
At each board meeting the board receives reports from the Medical Executive Committee including the Credentials Report and the Interdisciplinary Practice Credentials Report.

Financial Impact: None.

Attachments:
Medical Executive Committee Report – October 2023 Credentials Report, Interdisciplinary Practice Credentials Report

WATSONVILLE COMMUNITY HOSPITAL

Medical Executive Committee Summary – October 25, 2023
ITEMS FOR BOARD APPROVAL

Credentials Committee

INITIAL APPOINTMENTS: (1)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Parson, Algenon MD	Anesthesiology / Provisional	Surgery	Anesthesia, Adult, Pediatric, OB	10/26/2023-09/30/2025

REAPPOINTMENTS: (8)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Albright, Joseph, DPM	Podiatry / Active	Surgery	Podiatry & Fluoroscopy	10/28/2023-09/30/2025
Aratow-Gallardo, Natalie, DO	Family Medicine Hospitalist / Active	Medicine	Critical Care, Non-Intensivist; Medicine	11/01/2023-10/31/2025
Brandt, Ryan, MD	Interventional Cardiology / Active	Medicine	Cardiovascular Disease	11/01/2023-10/31/2025
Kim, Alyn, MD	Otolaryngology / Consulting	Surgery	Otolaryngology	11/01/2023-10/31/2025
Mak, Waii, MD	Internal Medicine Hospitalist / Active	Medicine	Critical Care, Non-Intensivist; Medicine	11/01/2023-10/31/2025
Markel, Peter, MD	Emergency Medicine / Active	Emergency Medicine	Emergency Medicine; Sedation	11/01/2023-10/31/2025
Marshall, Melinda, MD	OB/GYN / Active	OB/GYN	OB/GYN	11/01/2023-10/31/2025
Mehulic, Suarna, MD	Family Medicine Hospitalist / Active	Medicine	Critical Care, Non-Intensivist; Medicine	10/28/2023-09/30/2025

MODIFICATION / ADDITION OF PRIVILEGES: (3)

NAME	SPECIALTY / STATUS	Privileges
Guan, Yuxi, DPM	Podiatry / Provisional	Wound Care
Khademi, Ali, DO	Gastroenterology / Active	Flurosocopy
Redwine, Jonathon, MD	General Surgery / Active	Robotic Surgery Privileges

STAFF STATUS MODIFICATIONS: (6)

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Albright, Joseph, DPM	Podiatry / Provisional	Advance to Active Staff Proctoring Requirement met
Brant, Sarah, MD	General Surgery / Active	Release from Robotic Surgery Proctoring Proctoring Requirement Met
De, Ajanta, MD	Cardiovascular Disease / Active	Release from Wound Center Proctoring Proctoring Requirement Met

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Mehulic, Suarna, MD	Family Medicine Hospitalist / Provisional	Advance to Active Staff
Choe, Jessica, MD	Teleneurology / Provisional	Voluntary Resignation, 10/02/2023
Kim, Brandon, DPM	Podiatry / Applicant	Voluntary withdrew application, 09/26/2023

TEMPORARY PRIVILEGES: (4)

NAME	SPECIALTY / DEPARTMENT	DATES
Guan, Yuxi, DPM	Podiatry / Surgery	Wound Care Privileges 10/12/2023 – 10/26/2023
Parson, Algenon MD	Anesthesiology / Surgery	Anesthesia Privileges 10/13/2023 – 10/26/2023
Redwine, Jonathon, MD	General Surgery / Surgery	Robotic Surgery Privileges 10/13/2023 – 10/26/2023
Telefus, Phillip, MD	Anesthesiology / Surgery	Anesthesia Privileges 10/05/2023 – 10/20/2023

INTERDISCIPLINARY PRACTICE CREDENTIALS REPORT

Initial Appointment: (1)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Moran, Patrick, CRNA	Nurse Anesthetist / Allied Health Professional	Surgery	Certified Registered Nurse Anesthetist, Adult, Pediatric, OB	10/26/2023-09/30/2025

REAPPOINTMENT: (1)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
O'Halloran, Ellen, PA-C	Physician Assistant / Allied Health Professional	Emergency Medicine	Physician Assistant, Emergency	11/01/2023-10/31/2025

Temporary Privileges: (0)

NAME	SPECIALTY / DEPARTMENT	DATES
None		

STAFF STATUS MODIFICATIONS: (2)

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Gamble, Lisa, PA-C	Physician Assistant / Emergency Medicine	Release from Physician Assistant Emergency Medicine Core Privilege proctoring. Continue Advanced Procedure proctoring
Weiner, Haley, PA-C	Physician Assistant / Emergency Medicine	Release from Physician Assistant Emergency Medicine Core Privilege proctoring. Continue Advanced Procedure Proctoring

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: October 25, 2023

Report Type: Discussion

Title: Watsonville Community Hospital (WCH) Food Market Pilot Program

Recommendation: Receive and file update on the Second Harvest Foodbank in conjunction with WCH as is done throughout the state to partner with healthcare providers to work upstream in addressing the social determinants of health.

Contact: Matko Vranjes, Interim CEO

Analysis

Recognizing that Watsonville Community Hospital is a safety net hospital servicing the predominant Latin/x population of the Pajaro Valley, Second Harvest Food Bank is joining other food bank from throughout the state and the nation to partner with healthcare providers to work upstream in addressing the social determinants of health, like food insecurity, to optimize health outcomes.

Working in partnership, Second Harvest Food Bank and Watsonville Community Hospital, will offer access to healthy nourishment for patients in need of access to healthy food such as produce, grains, legumes, and the like in a new food market to be housed within the hospital. Additionally, Second Harvest will provide direct-to-client services such as home delivery of healthy nourishment, CalFresh enrollment, CalWorks enrollment, and nutrition education. We envision the unfolding of these and other specialized services over the course of the next two years. Of particular interest is the development of a Maternal prenatal and child's nutrition program, particularly as Watsonville Community Hospital is home to the highest percentages of births in the Pajaro Valley.

Financial Impact: None

Attachments:

A: WCH Food Market Pilot Program Description

Watsonville Community Hospital Pantry Pilot Program Description

Program Name: Nourish – Healthy Food for Your Table

Background and Data: In 2021, National Institute of Health found that food insecurity and lack of access to affordable nutritious food are associated with increased risk for multiple chronic conditions such as diabetes, obesity, heart disease, mental health disorders and other chronic conditions. Their research found that food insecurity disproportionately affects individuals from racial and ethnic minorities and socioeconomically disadvantaged populations. Factors such as affordability, accessibility and neighborhood infrastructure are the predominant influences of food and nutrition insecurity. These are known as Social Determinants of Health.

Local data signals that Diabetes in adults is highest in the Pajaro Valley inclusive of the communities of Freedom (95019), Watsonville & Royal Oaks (95076), parts of North Monterey County (95012) and Live Oak (95010). Figure 1 demonstrates that the 95076-zip code has an 11.9% rate of diabetes among adults, compared to 5.5% in Boulder Creek (95006) and 7.2% in Santa Cruz (95062).

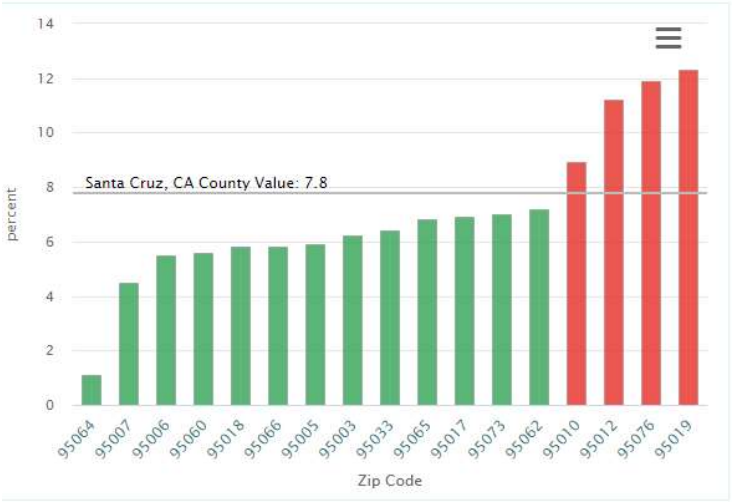


Figure 1 Adults with diabetes by zip code (Data Share Santa Cruz County)

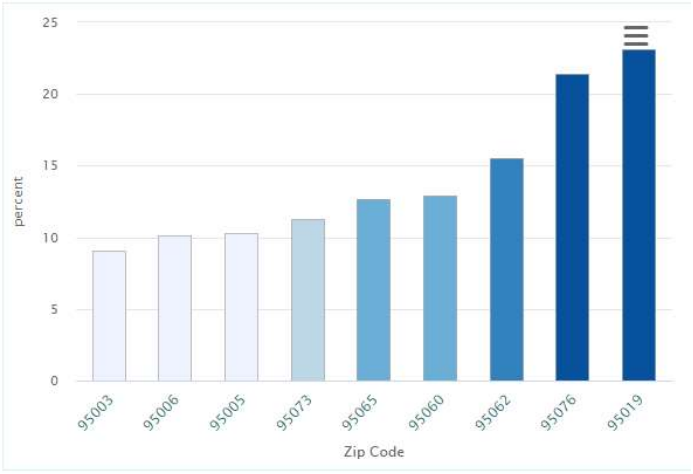


Figure 2 Children who are Overweight for Age (Santa Cruz Data Share)

The percentage of children who are overweight for their age follows a similar pattern to the rate of diabetes among adults. Zip codes 95019 (23.1%) and 95076 (21.4%) have higher percentages of overweight children in Santa Cruz County. Unfortunately, other chronic conditions such as heart disease follow a similar pattern as those tend to result over time due to the presence of these health conditions.

Furthermore, local data shows that food insecure adults have higher healthcare costs, likely associated with poor health outcomes related to food insecurity. In Santa Cruz County, food insecure adults spend approximately $50 million on additional healthcare costs.

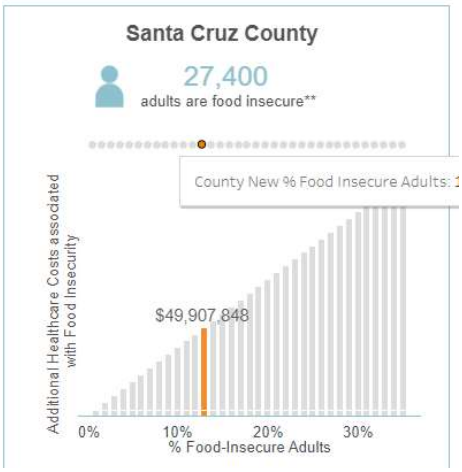


Figure 3 Additional Healthcare Costs for food insecure adults in County

Pilot Proposal: Recognizing that Watsonville Community Hospital is a safety net hospital servicing the predominant Latin/x population of the Pajaro Valley, Second Harvest Food Bank is joining other food bank from throughout the state and the nation to partner with healthcare providers to work upstream in addressing the social determinants of health, like food insecurity, to optimize health outcomes.

Working in partnership, Second Harvest Food Bank and Watsonville Community Hospital, will offer access to healthy nourishment for patients in need of access to healthy food such as produce, grains, legumes, and the like in a new food market to be housed within the hospital. Additionally, Second Harvest will provide direct-to-client services such as home delivery of healthy nourishment, CalFresh enrollment, CalWorks enrollment, and nutrition education. We envision the unfolding of these and other specialized services over the course of the next two years. Of particular interest is the development of a Maternal prenatal and child's nutrition program, particularly as Watsonville Community Hospital is home to the highest percentages of births in the Pajaro Valley. This approach aligns with recent recommendations of the American Academy of Pediatrics who are advocating that healthcare practitioners refer expecting mothers and their newborn children to existing services for nutrition support, particularly for pregnant and breastfeeding women, infants, and toddlers (Scharzenerg, Sarah, MD, et.all, AAP Publication, 2018).

Objectives: Objectives of this pilot program include:

1. Co-create a food insecurity screening and referral process
2. Engage WCH appropriate personnel to encourage participation of patients
3. Increase food security among participants
4. Implement a case management service for food security for expecting mothers and new mothers

Target Audience: WCH-Labor and Delivery - new mothers and babies regardless of income
Location: Watsonville Community Hospital - former gift shop
Pantry Hours: 12:30 pm -5:30 pm
Staffing for Food Market: Community Outreach Personnel -SHFB

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: October 25, 2023

Report Type: Discussion

Title: Santa Cruz County Pediatrics Crisis Stabilization

Recommendation: Receive and file update from Matko Vranjes, Interim CEO on Watsonville County Hospital (WCH) partnership with the County of Santa Cruz Health Services Agency Behavioral Health Services division (Santa Cruz BHD) to accept minors detained on a §5585 hold, under EMTALA, until a designated receiving facility is completed.

Contact: Matko Vranjes, Interim CEO

Analysis

Beginning on November 1, 2023, Watsonville Community Hospital (Watsonville) and the County of Santa Cruz Health Services Agency Behavioral Health Services division (Santa Cruz BHD) will issue a MOU in support of Santa Cruz County minors experiencing a mental health crisis and/or behavioral health condition. This MOU calls for Santa Cruz BHD to provide a contract provider team comprised of a licensed behavioral health clinician and an unlicensed mental health interventionist to provide behavioral health services to minor patients placed on a §5585 hold and diverted to the Watsonville ED under the EMTALA (Emergency Medical Treatment & Labor Act). A §5585 hold refers to the Welfare and Code under California State Law, which allows involuntary detainment of a minor experiencing a mental health crisis for a 72-hour psychiatric hospitalization. Santa Cruz BHD and contractor shall be exclusively responsible for directly billing patients for Behavioral Health services provided by contractor and MERT pursuant this MOU. No compensation from Watsonville is payable under this MOU. Watsonville ED will provide and bill for medical evaluation, medical treatment, and medical clearance for any minor on a §5585 hold, in accordance with EMTALA.

Financial Impact: None.

Attachments:

A: SCC Pediatrics Crisis Stabilization MOU 09.28.2023

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (MOU) is made and entered into effective as of November 1, 2023 (Effective Date) by and between Watsonville Community Hospital (Watsonville), a California nonprofit public benefit corporation and the County of Santa Cruz Health Services Agency Behavioral Health Services division (Santa Cruz BHD).

RECITALS

A. Watsonville operates an emergency department ("ED") which provides emergent medical services to the residents of Santa Cruz County (and others), including minors experiencing a mental health crisis and/or behavioral health condition, placed on a §5585 hold, and diverted to the ED under EMTALA (Emergency Medical Treatment & Labor Act).

B. Currently there is no designated receiving facility in Santa Cruz County for minors who are placed on a §5585 hold.

C. Without a designated receiving facility, minors are diverted and boarded at one of two emergency departments in Santa Cruz County until they are placed in a psychiatric health facility out of county.

D. Watsonville is willing to partner with Santa Cruz BHD to accept minors detained on a §5585 hold, under EMTALA, until a designated receiving facility is completed.

E. In conjunction with medical services provided by Watsonville, Santa Cruz BHD will provide assessment, intervention, safety planning, treatment coordination and recommendations, via a contract provider within the ED on a daily basis from 8AM-8PM.

F. When an appropriate safety plan has been arranged the BHD's Mobile Emergency Response Team (MERT) will consult with ED staff and the contracted provider and rescind the §5585 hold.

G. If the §5585 hold is upheld, the BHD's contracted provider will assist in making arrangements for placement at a psychiatric health facility.

H. The parties agree that this partnership between Watsonville ED and Santa Cruz BHD will be beneficial to the community, reducing undue stress on minors and their support systems, decrease in-patient placements, improve patient outcomes and quality of life, and decrease the strain on the County Emergency Medical System (EMS).

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the parties agree as follows:

1. During the hours of 8AM-8PM, (daily, seven-days per week, exclusive of holidays) Santa Cruz BHD will provide a contract provider team (contractor) comprised of a licensed behavioral health clinician and an unlicensed mental health interventionist to provide behavioral health services to minor patients at Watsonville ED within one (1) hour of a minor patient arriving on a §5585 hold.

2. Once onsite at the Watsonville ED, the contractor will provide the following services as clinically appropriate:
    a. Maintain direct line of sight on minors on a §5585 hold;
    b. Evaluate minors on a §5585 hold inclusive of presenting issue, psychosocial evaluation, mental status examination, diagnosis, safety and risk assessment and level of care recommendation;
    c. Direct consultation with patient's family members or guardians to the extent allowed under applicable privacy law;
    d. Consultation with Watsonville ED providers regarding assessment and level of care determination; and
    e. Provide information to MERT clinicians to support rescinding 5585 hold or assist ED staff with placement at a psychiatric health facility.

3. Santa Cruz BHD and contractor shall be exclusively responsible for directly billing patients for services provided by contractor and MERT pursuant to this MOU. No compensation from Watsonville is payable under this MOU.

4. Watsonville ED will provide:

    a. Medical evaluation, medical treatment, and medical clearance for any minor on a §5585 hold, in accordance with EMTALA.

5. *We will need a piece about Watsonville providing a sitter from 8PM-8AM and potential additional staffing ratio that Santa Cruz BHD will reimburse.*

6. The initial term of this MOU shall be from the Effective date through December 31, 2025. In the event that either parties desires to withdraw from this MOU, at least sixty (60) days written notice shall be given to the other party.

7. *We will insert clause about Santa Cruz BHD and Contractor being self insured…*

8. Both parties shall maintain full and accurate records with respect to all matters covered under this MOU. To the extent allowed in accordance with confidentiality and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") limitations, the parties may request periodic reports from the other to facilitate their respective areas of treatment and care.

9. The parties shall comply with HIPAA as well as applicable provisions of state law including, without limitation, the California Medical Information Act ("CMIA"). The parties shall not use identifying information about patients for any other purpose other than carrying out each party's respective obligations under the MOU. Each Party shall be responsible for the confidentiality of their own documents, files, and charts. Each party shall notify the other within 24 hours of becoming aware of any breach of the confidentiality requirements set forth herein and in applicable law.

10. Any amendments to this MOU shall be made in writing and signed and dated by the parties.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: October 25, 2023

Report Type: Discussion

Title: Update by Interim Chief Executive Officer (CEO)

Recommendation: Receive and file update from Matko Vranjes, Interim CEO

Contact: Matko Vranjes, Interim CEO

Analysis

At each board meeting the CEO provides the board and the public an oral update on various matters.

Financial Impact: None

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: Octobe 25, 2023

Report Type: Discussion

Title: Chief Financial Officer (CFO) Monthly Financial Performance and Budget Update

Recommendation: Receive and file update from Julie Peterson, Chief Financial Officer

Contact: Julie Peterson, Chief Financial Officer

Analysis

At each board meeting the CFO provides the board and the public an update on Financial Performance.

Financial Impact: See attached report.

Attachments

A: Financial Performance Report

WATSONVILLE COMMUNITY HOSPITAL
2023 CONSOLIDATED TRENDED BALANCE SHEET
($ in 000's)

	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23
Assets									
Cash	$ 5,982	$ 6,078	$ 1,916	$ 3,958	$ 3,576	$ 2,081	$ 2,852	$ 3,296	$ 973
A/R	43,166	43,452	42,474	39,084	39,504	41,108	57,266	57,769	61,464
Less: Allowance for BD	(8,134)	(7,325)	(6,587)	(6,365)	(7,298)	(7,420)	(21,342)	(22,157)	(23,239)
Supplies	2,079	2,073	2,118	2,069	2,058	2,056	2,024	2,027	2,023
Prepaid Expenses	1,185	1,209	1,104	1,096	1,028	831	951	775	557
Other Current Assets	722	1,195	2,551	2,271	2,217	2,757	2,347	2,260	2,267
Total Current Assets	$ 45,000	$ 46,682	$ 43,576	$ 42,113	$ 41,085	$ 41,413	$ 44,098	$ 43,970	$ 44,045
Net PP&E	35,245	35,168	35,150	35,074	34,999	34,933	34,863	34,849	34,787
Operating Lease ROU, Net	1,676	1,634	1,491	1,449	1,408	1,367	1,326	1,284	1,242
Notes Receivable									
Deposits	5	5	5	5	5	5	5	5	5
Unamortized Loan Costs	50	50	50	50	50	50	50	50	50
Physician Recruitment Costs	-	-	-	-	-	-	-		
Deferred MIS Charges	698	631	562	496	431	367	349	340	331
Goodwill (Placeholder)	(20,666)	(20,551)	(20,963)	(20,963)	(20,963)	(20,963)	(19,771)	(19,771)	(19,771)
Total Other Assets	$ (18,237)	$ (18,231)	$ (18,855)	$ (18,963)	$ (19,069)	$ (19,174)	$ (18,041)	$ (18,092)	$ (18,143)
Total Assets	$ 62,008	$ 63,619	$ 59,871	$ 58,224	$ 57,015	$ 57,172	$ 60,920	$ 60,727	$ 60,689
Liabilities and Equity									
Current maturities of LTD	$ (47)	$ (57)	$ (68)	$ (79)	$ (90)	$ (105)	$ (113)	$ (117)	$ (122)
Accounts Payable	6,622	7,194	7,009	7,361	6,855	7,478	9,746	9,607	10,338
Accrued Emp. Comp.	9,401	10,052	7,793	8,535	8,112	8,160	9,171	7,124	7,447
Operating Lease - Current	30	20	319	324	307	448	433	428	423
Other Accrued Liabilities	5,844	7,716	7,006	5,955	6,073	6,350	7,223	10,351	10,843
Total Current Liabilities	$ 21,850	$ 24,925	$ 22,059	$ 22,096	$ 21,257	$ 22,331	$ 26,460	$ 27,393	$ 28,929
Deferred Credits and Other Long-term Liabilities	6,935	6,880	6,405	6,318	6,133	6,116	6,131	5,755	5,721
Operating Lease Liabilities	1,693	1,655	1,194	1,159	1,124	940	904	868	831
Long Term Debt	39,836	39,847	40,358	40,369	40,379	40,388	41,686	41,618	41,560
Total Liabilities	$ 70,314	$ 73,307	$ 70,016	$ 69,942	$ 68,893	$ 69,775	$ 75,181	$ 75,634	$ 77,041
Stockholders' Equity	(8,306)	(9,688)	(10,145)	(11,718)	(11,878)	(12,603)	(14,261)	(14,907)	(16,352)
Total Liabilities and Equity	$ 62,008	$ 63,619	$ 59,871	$ 58,224	$ 57,015	$ 57,172	$ 60,920	$ 60,727	$ 60,689

Watsonville Community Hospital
Income Statement
For The Month of September, 30, 2023

CURRENT PERIOD					YTD			
Sep-23	BUDGET	VARIANCE	% VARIANCE		ACTUAL	BUDGET	VARIANCE	% VARIANCE
				Operating Revenues				
28,293,972	35,564,005	(7,270,033)	-20.4%	Inpatient Revenue	268,352,337	315,310,279	(46,957,942)	-14.9%
51,700,100	52,904,433	(1,204,333)	-2.3%	Outpatient Revenue	474,923,401	450,804,562	24,118,839	5.4%
79,994,072	**88,468,439**	**(8,474,367)**	**-9.6%**	**Total gross patient revenue**	**743,275,738**	**766,114,841**	**(22,839,103)**	**-3.0%**
				Deductions From Revenue:				
70,005,070	76,771,152	(6,766,082)	-8.8%	Contractual Allowances	642,468,171	666,166,769	(23,698,598)	-3.6%
(1,599,179)	(1,599,179)		0.0%	QAF	(14,392,613)	(14,392,613)		0.0%
(128,059)	(128,059)		0.0%	Disproportionate Share DSH	(1,152,527)	(1,152,527)		0.0%
68,277,832	**75,043,914**	**(6,766,082)**	**-9.0%**	**Total Deductions From Rev**	**626,923,031**	**650,621,629**	**(23,698,598)**	**-3.6%**
11,716,240	**13,424,525**	**(1,708,285)**	**-12.7%**	**Net Revenue**	**116,352,707**	**115,493,212**	**859,495**	**0.7%**
1,173,348	113,849	1,059,499	930.6%	Provision for Bad Dbt	15,872,922	979,460	14,893,462	1520.6%
10,542,892	**13,310,676**	**(2,767,784)**	**-20.8%**	**Collectible Patient Revenue**	**100,479,785**	**114,513,752**	**(14,033,967)**	**-12.3%**
18,011	113,024	(95,013)	-84.1%	Other Revenue	3,112,842	1,028,519	2,084,323	202.7%
10,560,903	**13,423,700**	**(2,862,797)**	**-21.3%**	**Total Net Operational Revenue**	**103,592,627**	**115,542,271**	**(11,949,644)**	**-10.3%**
				Operating Expenses				
5,500,901	5,812,752	(311,851)	-5.4%	Salaries & Wages	50,247,405	50,289,957	(42,552)	-0.1%
1,746,300	1,971,538	(225,238)	-11.4%	Benefits	15,036,873	17,940,995	(2,904,122)	-16.2%
588,542	480,000	108,542	22.6%	Contract Labor	5,410,036	4,826,000	584,036	12.1%
7,835,743	**8,264,290**	**(428,547)**	**-5.2%**	**Subtotal Salaries Wages & Benefits**	**70,694,314**	**73,056,951**	**(2,362,637)**	**-3.2%**
626,856	816,758	(189,902)	-23.3%	Medical Spec Fees	5,803,137	7,432,496	(1,629,359)	-21.9%
763,919	950,752	(186,833)	-19.7%	Supplies	7,802,861	8,225,583	(422,722)	-5.1%
92,447	100,828	(8,381)	-8.3%	Repairs & Maintenance	924,812	917,539	7,273	0.8%
178,321	160,394	17,927	11.2%	Utilities	1,893,922	1,459,589	434,333	29.8%
960,674	749,816	210,858	28.1%	Purchased Services	10,209,123	11,363,230	(1,154,107)	-10.2%
172,504	189,964	(17,460)	-9.2%	Lease Cost and Rent	1,230,141	1,728,671	(498,530)	-28.8%
181,120	263,544	(82,424)	-31.3%	Prop Taxes & Ins	1,763,341	2,398,252	(634,911)	-26.5%
548	-	548		Marketing	4,663	-	4,663	
-	-			Management Fees	-	150,000	(150,000)	-100.0%
635,872	828,596	(192,724)	-23.3%	Other Operating Exp	5,953,828	8,441,631	(2,487,803)	-29.5%
11,448,004	**12,324,943**	**(876,939)**	**-7.1%**	**Total Operating Exp**	**106,280,142**	**115,173,942**	**(8,893,800)**	**-7.7%**
(887,101)	**1,098,757**	**(1,985,858)**	**-180.7%**	**EBITDA**	**(2,687,515)**	**368,330**	**(3,055,845)**	**-829.6%**
-	-			Depreciation and Amortization	-	-		
11,295	6,694	4,601	68.7%	Interest	56,834	131,296	(74,462)	-56.7%
11,295	**6,694**	**4,601**	68.7%	**Total Other Expenses**	**56,834**	**131,296**	**(74,462)**	-56.7%
(898,396)	**1,092,063**	**(1,990,459)**	-182.3%	**Net Income/Loss from Operations**	**(2,744,349)**	**237,033**	**(2,981,382)**	-1257.8%

Watsonville Community Hospital
Consolidated Income Statement
For The Month of September, 30, 2023

CURRENT PERIOD					YTD			
Sep-23	BUDGET	VARIANCE	% VARIANCE		ACTUAL	BUDGET	VARIANCE	% VARIANCE
				Operating Revenues				
28,293,972	35,564,005	(7,270,033)	-20.4%	Inpatient Revenue	268,352,337	315,310,279	(46,957,942)	-14.9%
52,271,444	53,411,001	(1,139,557)	-2.1%	Outpatient Revenue	479,662,133	455,169,495	24,492,638	5.4%
80,565,416	**88,975,006**	**(8,409,590)**	**-9.5%**	**Total gross patient revenue**	**748,014,470**	**770,479,774**	**(22,465,304)**	**-2.9%**
				Deductions From Revenue:				
70,351,734	77,052,309	(6,700,575)	-8.7%	Contractual Allowances	645,362,223	668,583,955	(23,221,733)	-3.5%
(1,599,179)	(1,599,179)		0.0%	QAF	(14,392,613)	(14,392,613)		0.0%
(128,059)	(128,059)		0.0%	Disproportionate Share DSH	(1,152,527)	(1,152,527)		0.0%
68,624,496	**75,325,071**	**(6,700,575)**	**-8.9%**	**Total Deductions From Rev**	**629,817,083**	**653,038,816**	**(23,221,733)**	**-3.6%**
11,940,920	**13,649,934**	**(1,709,014)**	**-12.5%**	**Net Revenue**	**118,197,387**	**117,440,958**	**756,429**	**0.6%**
1,184,922	116,398	1,068,524	918.0%	Provision for Bad Dbt	15,900,817	1,001,489	14,899,328	1487.7%
10,755,998	**13,533,536**	**(2,777,538)**	**-20.5%**	**Collectible Patient Revenue**	**102,296,570**	**116,439,469**	**(14,142,899)**	**-12.1%**
91,261	132,138	(40,877)	-30.9%	Other Revenue	3,735,267	1,202,454	2,532,813	210.6%
10,847,259	**13,665,674**	**(2,818,415)**	**-20.6%**	**Total Net Operational Revenue**	**106,031,837**	**117,641,924**	**(11,610,087)**	**-9.9%**
				Operating Expenses				
5,744,163	6,047,587	(303,424)	-5.0%	Salaries & Wages	52,444,612	52,735,393	(290,781)	-0.6%
1,790,163	2,024,328	(234,165)	-11.6%	Benefits	15,435,391	18,484,492	(3,049,101)	-16.5%
588,542	480,000	108,542	22.6%	Contract Labor	5,410,036	4,826,000	584,036	12.1%
8,122,868	**8,551,915**	**(429,047)**	**-5.0%**	**Subtotal Salaries Wages & Benefits**	**73,290,039**	**76,045,885**	**(2,755,846)**	**-3.6%**
644,066	818,897	(174,831)	-21.3%	Medical Spec Fees	5,908,161	7,555,780	(1,647,619)	-21.8%
765,986	952,003	(186,017)	-19.5%	Supplies	7,860,582	8,285,492	(424,910)	-5.1%
92,481	100,945	(8,464)	-8.4%	Repairs & Maintenance	944,037	918,602	25,435	2.8%
179,583	161,189	18,394	11.4%	Utilities	1,904,792	1,469,695	435,097	29.6%
988,515	783,366	205,149	26.2%	Purchased Services	10,306,334	11,667,537	(1,361,203)	-11.7%
196,368	210,148	(13,780)	-6.6%	Lease Cost and Rent	1,446,930	1,899,181	(452,251)	-23.8%
188,173	269,734	(81,561)	-30.2%	Prop Taxes & Ins	1,839,097	2,490,832	(651,735)	-26.2%
548	4,167			Marketing	4,663	37,500	(32,837)	-87.6%
637,112	833,439	(196,327)	-23.6%	Other Operating Exp	5,979,954	8,631,696	(2,651,742)	-30.7%
11,815,700	**12,685,804**	**(870,104)**	**-6.9%**	**Total Operating Exp**	**109,484,589**	**119,002,198**	**(9,517,609)**	**-8.0%**
(968,441)	**979,870**	**(1,948,311)**	**-198.8%**	**EBITDA**	**(3,452,752)**	**(1,360,275)**	**(2,092,477)**	**153.8%**
134,380	96,693	37,687	39.0%	Depreciation and Amortization	833,336	869,392	(36,056)	-4.1%
342,576	393,152	(50,576)	-12.9%	Interest	3,336,222	3,609,423	(273,201)	-7.6%
476,956	**489,845**	**(12,889)**	-2.6%	**Total Other Expenses**	**4,169,558**	**4,478,816**	**(309,258)**	-6.9%
(1,445,397)	**490,025**	**(1,935,422)**	-395.0%	**Net Income/Loss from Operations**	**(7,622,310)**	**(5,839,090)**	**(1,783,220)**	30.5%

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Report

Meeting Date: October 25, 2023

Report Type: Discussion

Title: Pajaro Valley Health Care District and Pajaro Valley Health Care District Hospital Corporation Consolidated Audit Report

Recommendation: Pass a **Motion** approving the Pajaro Valley Health Care District Hospital Corporation and the Pajaro Valley Healthcare District audit findings for the period of September 01, 2022, through December 31, 2022.

Contact: Julie Peterson, Chief Financial Officer

Executive Summary

Presentation of audited financial statements and other financial information for the Pajaro Valley Health Care District, conducted by JWT & Associates, LLP, Certified Public Accountant for the period of September 01, 2022, through December 31, 2022. In addition, a high-level discussion of related Balance Sheet adjustments for the same time period.

Background

Per the requirements of the Pajaro Valley Health Care District (PVHCD) as outlined in the bylaws Article V, Section 4, the Finance Committee will manage the audit process of the books and accounts on an annual basis.

Attachments:

A: Audited Financial Statements and Other Financial Information for the Pajaro Valley Health Care District

Audited Financial Statements
and Other Financial Information

PAJARO VALLEY
HEALTH CARE DISTRICT

December 31, 2022

JWT & Associates, LLP
Certified Public Accountant

Pajaro Valley Health Care District

Audited Financial Statements and Other Financial Information

December 31, 2022

JWT & Associates, LLP

Advisory Assurance Tax

1111 East Herndon, Suite 211, Fresno, California 93720
Voice: (559) 431-7708 Fax:(559) 431-7685

Report of Independent Auditors

The Board of Directors
Pajaro Valley Health Care District
Watsonville, California

Opinions

We have audited the accompanying financial statements of the business-type activities and the discretely presented component unit of the Pajaro Valley Health Care District (the District), as of and for the year ended December 31, 2022, and the related notes to the financial statements, which collectively comprise the District's basic financial statements as listed in the table of contents.

In our opinion, the financial statements referred to above present fairly, in all material respects, the respective financial positions of the business-type activities and the discretely presented component unit of the District, as of December 31, 2022, and the respective changes in financial position, and, where applicable, cash flows thereof for the year then ended in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinions

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are required to be independent of the District, and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audits. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinions.

Responsibilities of Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the District’s ability to continue as a going concern for twelve months beyond the financial statement date, including any currently known information that may raise substantial doubt shortly thereafter.

Auditor’s Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with generally accepted auditing standards will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions,

misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with generally accepted auditing standards, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the District's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the District's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control-related matters that we identified during the audit.

Required Supplementary Information

Accounting principles generally accepted in the United States of America require that the management's discussion and analysis be presented to supplement the basic financial statements. Such information is the responsibility of management and, although not a part of the basic financial statements, is required by the Governmental Accounting Standards Board who considers it to be an essential part of financial reporting for placing the basic financial statements in an appropriate operational, economic, or historical context. We have applied certain limited procedures to the required supplementary information in accordance with auditing standards generally accepted in the United States of America, which consisted of inquiries of management about the methods of preparing the information and comparing the information for consistency with management's responses to our inquiries, the basic financial statements, and other knowledge we obtained during our audits of the basic financial statements. We do not express an opinion or provide any assurance on the information because the limited procedures do not provide us with sufficient evidence to express an opinion or provide any assurance.

JWT & Associates, LLP

Fresno, California
October 25, 2023

Pajaro Valley Health Care District

Management's Discussion and Analysis

For the Year Ended December 31, 2022

Management of the Pajaro Valley Health Care District (the District) has prepared this annual discussion and analysis in order to provide an overview of performance for the fiscal year ended December 31, 2022 in accordance with the Governmental Accounting Standards Board Statement No. 34, Basic Financials Statements; Management's Discussion and Analysis for State and Local Governments. The District wholly owns the Pajaro Valley Health Care District Hospital Corporation dba Watsonville Community Hospital (the Hospital). Together they are referenced as the Combined Unit. The intent of this document is to provide additional information on the Combined Unit's financial performance as a whole and a prospective look at revenue, operating expenses and capital development plans. This discussion should be reviewed in conjunction with the audited financial statements for the fiscal year ended December 31, 2022 and accompanying notes to the financial statements to enhance one's understanding of the Combined Unit's financial performance. Being the first year of operation, there is no prior year analysis.

Introduction

The Combined Unit offers readers of our financial statements this narrative overview and analysis of our financial activities for the year ended December 31, 2022. We encourage readers to consider the information presented here in conjunction with the Combined Unit's financial statements, including the notes thereto.

The Combined Unit is governed by a five-member elected board of directors. Day-to-day operations are managed by the General Manager. The Combined Unit employed 593 employees on December 31, 2022 and had an annual payroll of approximately $17M, not including benefits.

Required Financial Statements

The Combined Unit's financial statements offer short-term and long-term information about its activities. The statement of net position includes all of the Combined Unit's assets and liabilities at December 31, 2022 and provides information about the nature and amounts of investments in resources (assets) and the obligations to Combined Unit creditors (liabilities). The statement of net position also provide the basis for evaluating the capital structure of the Combined Unit and assessing the liquidity and financial flexibility of the Combined Unit.

All revenue and expenses for years ended December 31, 2022 are accounted for in the statement of revenue, expenses and changes in net position. The statement can be used to determine whether the Combined Unit has successfully recovered all of its costs through its patient service revenue and other revenue sources. Revenue and expenses are reported on an accrual basis, which means the related cash could be received or paid in a subsequent period.

The final required statement is the statement of cash flows. This statement reports cash receipts, cash payments and net changes in cash resulting from operations, investing and financial activities for the years ended December 31, 2022. They also provide answers to such questions as where did cash come from, what was cash used for and what was the change in the cash balance during the reporting period.

Pajaro Valley Health Care District

Management's Discussion and Analysis

For the Year Ended December 31, 2022

Financial Analysis of the Combined Unit

The Combined Unit's net position, the difference between assets and liabilities, is a way to measure financial health or financial position. Over time, sustained increases or decreases in the Combined Unit's net position are one indicator of whether its financial health is improving or deteriorating. However, other nonfinancial factors such as changes in economic condition, population growth and new or revised government regulations and legislation should also be considered. In 2022, the Combined Unit's net position increased by approximately $9.7M largely due to an extraordinary gain (see footnotes).

Financial Summary

- Total assets ended at $73.9 million being largely comprised of net patient AR ($21.3M) and lease assets ($34.8M). Total cash and cash equivalents at year end were $8.7 million (see the Statements of Cash Flows for changes).
- Current assets ended at $36.1M compared to current liabilities which ended at $21.7M. The current ratio for this year was 1.66.
- Net operating revenues were $33.8M and operating expenses were $45.1M. There was an operating loss of $10.9M
- The increase in net position was $9.7M due to an extraordinary gain of $20.7M. See footnotes for more information.

Items Affecting Operations

The challenges facing the Combined Unit this fiscal period were largely similar, although varying in degree of intensity, to those issues facing the health care industry in general and for rural health care facilities in particular. Where the immediate environment and circumstances uniquely influence the Combined Unit, these areas are also highlighted in the discussion below:

- Reimbursement: Medicare and Medi-Cal programs continue to look for ways to reduce reimbursement.
- Labor: Physician positions continue to be difficult to recruit in rural areas.
- Hospital emerged from bankruptcy and was purchased by The District on September 1, 2022, with limited working capital. The District continues to work through transition activities to stabilize operations.

Items Affecting Operations (continued)

- The Hospital Corporation renegotiated all major payor contracts to improve reimbursement. As of December 31, 2022, only one was implemented and the remaining were implemented in 2023.

- The Hospital faces challenges recruiting staff due to the high cost of living in the area and thus relies on contracted resources to supplement staffing. These resources come at a higher cost.

- The District leases hospital real estate from Medical Properties Trust. The Hospital operations must cover this lease payment along with all deficits of The District.

In summary, the external environment continues to challenge rural healthcare providers in particular, with continuing declines in reimbursement, increases in uncompensated care and ongoing labor and health insurance issues. The Combined Unit strives to improve relationships within our community through collaboration with community leaders and service groups, outreach to neighboring healthcare facilities, improving access to care and recruitment of quality medical providers.

The Combined Unit's employees are working together to continue to find ways to make progress on improving how the Combined Unit organizes and processes work in such a way that it continues to improve patient care and service to its patients and community, while striving to improve its financial position and overall fiscal performance.

Pajaro Valley Healthcare District

Combined Statement of Net Position

December 31, 2022

Assets	
Current Assets	
Cash and cash equivalents	$ 8,660,568
Patient accounts receivable, net of allowances	21,266,511
Other accounts receivable	1,498,921
Inventories	2,158,403
Prepaid expenses and other current assets	2,510,580
Total current assets	36,094,983
Capital assets, net of accumulated depreciation	3,015,808
Lease assets	34,759,953
Total assets	73,870,744
Liabilities and Net Position	
Current liabilities	
Current maturities of debt borrowings	1,702,035
Accounts payable and accrued expenses	6,922,004
Accrued payroll and related liabilities	8,641,862
Estimated third party payor settements	1,597,184
IBNR self funded health benefits	2,787,581
Total current liabilities	21,650,666
Debt borrowings, net of current maturities	7,478,951
Lease liabilities	35,023,963
Total liabilities	64,153,580
Net position	
Invested in capital assets, net of related debt	2,891,822
Restricted	2,600,000
Unrestricted	4,225,342
Total net position	9,717,164
Total liabilities and net position	$ 73,870,744

See accompanying notes to the financial statements

Pajaro Valley Healthcare District

Combined Statement of Revenues, Expenses and Changes in Net position

For The Year Ended December 31, 2022

Operating revenues	
Net patient service revenues	$ 33,308,250
Other operating revenues	532,944
Total operating revenues	33,841,194
Operating expenses	
Salaries & Wages	17,381,952
Benefits	6,100,838
Contract Labor	2,414,616
Supplies	3,688,032
Medical Spec Fees	2,876,058
Purchased Services	5,579,962
Lease Cost and Rent	1,649,758
Repairs & Maintenance	316,371
Utilities	712,745
Depreciation and amortization	384,786
Other Operating Exp	2,906,562
Prop Taxes & Ins	731,821
Interest	320,538
Total operating expenses	45,064,039
Operating income (loss)	(11,222,845)
Nonoperating revenues	
Rental income	277,387
Total nonoperating revenues (expenses)	277,387
Net income/(loss) before extraordinary item	(10,945,458)
Extraordinary income	20,662,622
Increase/(decrease) in net position	9,717,164
Net position, beginning of the year	-
Net position, end of year	$ 9,717,164

See accompanying notes to the financial statements

Pajaro Valley Healthcare District

Combined Statement of Cash Flows

For The Year Ended December 31, 2022

Cash flows from operating activities	
Cash received for operations	$ 12,352,408
Cash payments to suppliers and contractors	(18,622,904)
Cash payments to employees and benefit programs	(12,053,347)
Net cash provided by operating activities	(18,323,843)
Cash flows from noncapital financing activities	
Extraordinary income	20,662,622
Net cash provided by noncapital financing activities	20,662,622
Cash flows from investing activities	
Purchases of property, plant & equipment	(3,136,584)
Rental income	277,387
Net cash used in investing activities	(2,859,197)
Cash flows from financing activities	
Proceeds from debt borrowings	9,180,986
Net cash provided by financing activities	9,180,986
Increase in cash and cash equivalents	8,660,568
Cash and cash equivalents at beginning of year	-
Cash and cash equivalents at end of year	$ 8,660,568

See accompanying notes to the financial statements

Pajaro Valley Healthcare District

Combined Statement of Cash Flows (continued)

For The Year Ended December 31, 2022

Reconciliation of operating income (loss) to net cash provided by operating activities	
Operating income	$ (11,222,845)
Adjustments to reconcile operating income to net cash provided by operating activities	
Depreciation	384,786
Changes in operating assets and liabilities	
Receivables	(22,765,432)
Inventories	(2,158,403)
Prepaid expenses and other current assets	(2,510,580)
Accounts payable and accrued expenses	6,922,004
Accrued payroll and related expenses	8,641,862
Estimated third party payor settements	1,597,184
IBNR self funded health benefits	2,787,581
Net cash provided by operating activities	$ (18,323,843)

See accompanying notes to the financial statements

Pajaro Valley Health Care District

Notes to the Financial Statements

For the Year Ended December 31, 2022

NOTE 1 - ORGANIZATION AND ACCOUNTING POLICIES

Organization: Pajaro Valley Health Care District, (the District) is a public entity organized under Local District Law as set forth in the Health and Safety Code of the State of California. The District is a political subdivision of the State of California and is generally not subject to federal or state income taxes. The District is governed by a five-member Board of Directors, elected from within the district to specified terms of office. The District is located in Watsonville, California. The District wholly owns the Pajaro Valley Health Care District Hospital Corporation dba Watsonville Community Hospital (the Hospital). The Hospital is a 501(c)(3) component unit of the District and operates a 106 -bed acute care hospital and other patient services. The District's mission is to provide health care services primarily to individuals who reside in the local geographic area. A combining statement presenting both District and Hospital operations is presented in the supplementary information to these combined financial statements.

The District and the Hospital were both created to purchase the operations and certain assets of the Watsonville Community Hospital (WCH) and operate the hospital facility. WCH assets were acquired in September of 2022.

The District has a Professional Services Agreement (PSA) with Coastal Health Partners (CHP). CHP is incorporated under the laws of the State of California and operates as a corporation. This agreement calls for CHP to provide physicians to the District 1206(b) clinic. The District provides support staff to CHP through the Hospital and passes those expenses onto the District Clinic.

The Combined Unit (the District and the Hospital) maintains its financial records in conformity with guidelines set forth by the Local Health Care District Law and the Office of Statewide Health Planning and Development of the state of California.

Basis of Preparation: The accounting policies and financial statements of the Combined Unit generally conform with the recommendations of the audit and accounting guide, *Health Care Organizations*, published by the American Institute of Certified Public Accountants. The financial statements are presented in accordance with the pronouncements of the Governmental Accounting Standards Board (GASB). For purposes of presentation, transactions deemed by management to be ongoing, major or central to the provision of health care services are reported as operational revenues and expenses.

The Combined Unit uses proprietary fund accounting. Revenues and expenses are recognized on the accrual basis using the economic resources measurement focus. Based on GASB Statement Number 20, *Accounting and Financial Reporting for Proprietary Funds and Other Governmental Entities That Use Proprietary Fund Accounting*, as amended, the District has elected to apply the provisions of all relevant pronouncements of the Financial Accounting Standards Board (FASB), including those issued after November 30, 1989, that do not conflict with or contradict GASB pronouncements.

NOTE 1 - ORGANIZATION AND ACCOUNTING POLICIES (continued)

Financial Statement Presentation: The Combined Unit applies the provisions of GASB 34, *Basic Financial Statements - and Management's Discussion and Analysis - for State and Local Governments* (Statement 34), as amended by GASB 37, *Basic Financial Statements - and Management's Discussion and Analysis - for State and Local Governments: Omnibus*, and Statement 38, *Certain Financial Statement Note Disclosures*. Statement 34 established financial reporting standards for all state and local governments and related entities. Statement 34 primarily relates to presentation and disclosure requirements. The impact of this change was related to the format of the financial statements; the inclusion of management's discussion and analysis; and the preparation of the statement of cash flows on the direct method. The application of these accounting standards had no impact on the total net assets.

Management's Discussion and Analysis: Statement 34 requires that financial statements be accompanied by a narrative introduction and analytical overview of the Combined Unit's financial activities in the form of "management's discussion and analysis" (MD&A). This analysis is similar to the analysis provided in the annual reports of organizations in the private sector.

Use of Estimates: The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents: Cash and cash equivalents include deposits with financial institutions and investments in highly liquid debt instruments with an original maturity of three months or less. Cash and cash equivalents exclude amounts whose use is limited by board designation or by legal restriction.

Patient Accounts Receivable: Patient accounts receivable consists of amounts owed by various governmental agencies, insurance companies and private patients. The Combined Unit manages its receivables by regularly reviewing the accounts, inquiring with respective payors as to collectability and providing for allowances on their accounting records for estimated contractual adjustments and uncollectible accounts. Significant concentrations of patient accounts receivable are discussed further in the footnotes.

Supplies: Inventories are consistently reported from year to year at cost determined by average costs and replacement values which are not in excess of market. The Combined Unit does not maintain levels of inventory values such as those under a first-in, first out or last-in, first out method.

NOTE 1 - ORGANIZATION AND ACCOUNTING POLICIES (continued)

Capital Assets: Capital assets consist of property and equipment and are reported on the basis of cost, or in the case of donated items, on the basis of fair market value at the date of donation. Routine maintenance and repairs are charged to expense as incurred. Expenditures which increase values, change capacities, or extend useful lives are capitalized. Depreciation of property and equipment and amortization of property under capital leases are computed by the straight-line method for both financial reporting and cost reimbursement purposes over the estimated useful lives of the assets, which range from 10 to 30 years for buildings and improvements, and 3 to 15 years for equipment. The Combined Unit periodically reviews its capital assets for value impairment. As of December 31, 2022 the Combined Unit has determined that no capital assets are impaired.

Compensated Absences: The employees of the Combined Unit earn vacation, paid time off, holiday and float benefits at varying rates. These accrual rates are determined based on the employee's years of service, full time equivalent (FTE) status, and union affiliation. This benefit can accumulate up to specified maximum levels. Accumulated vacation, paid time off, holiday, and float benefits are paid to an employee upon either termination or retirement. The combined liability for vacation, paid time off, holiday, and float liabilities as of December 31, 2022 totaled $4,137,292.

Some employees also have a Legacy bank of hours that can be utilized, once they have exhausted all other accruals, and is payable at one half of their hourly rate of pay upon termination or retirement. The liability for these hours as of December 31, 2022 totaled $982,045.

Risk Management: The Combined Unit is exposed to various risks of loss from torts; theft of, damage to, and destruction of assets; business interruption; errors and omissions; employee injuries and illnesses; natural disasters; and medical malpractice. Commercial insurance coverage is purchased for claims arising from such matters.

Net position: Net position is presented in three categories. The first category of net position is "invested in capital assets, net of related debt". This category of net position consists of capital assets (both restricted and unrestricted), net of accumulated depreciation and reduced by the outstanding principal balances of any debt borrowings that were attributable to the acquisition, construction, or improvement of those capital assets.

The second category is "restricted" net position. This category consists of externally designated constraints placed on assets by creditors (such as through debt covenants), grantors, contributors, law or regulations of other governments or government agencies, or law or constitutional provisions or enabling legislation. The third category is "unrestricted" net position. This category consists of net position that does not meet the definition or criteria of the previous two categories.

NOTE 1 - ORGANIZATION AND ACCOUNTING POLICIES (continued)

Net Patient Service Revenues: Net patient service revenues are reported in the period at the estimated net realized amounts from patients, third-party payors and others including estimated retroactive adjustments under reimbursement agreements with third-party programs. Normal estimation differences between final reimbursement and amounts accrued in previous years are reported as adjustments of current year's net patient service revenues.

Financial Assistance: The Hospital offers a financial assistance policy for its patients. The financial assistance policy describes the Hospital's policy for both charity care (free care) and discounted care, and the process for patients who need help paying for their emergency and medically necessary care. The intent of this policy is to satisfy the requirements of Section 501(r) of the Internal Revenue Code and California Health and Safety Code sections 127400 to 127446.Because the Combined Unit does not pursue collection of amounts determined to qualify as charity care, they are not reported as net patient service revenues. Services provided are recorded as gross patient service revenues and then written off entirely as an adjustment to net patient service revenues.

Operating Revenues and Expenses: The Combined Unit's statement of revenues, expenses and changes in net assets distinguishes between operating and non-operating revenues and expenses. Operating revenues result from exchange transactions associated with providing health care services, which is the Combined Unit's principal activity. Operating expenses are all expenses incurred to provide health care services, other than financing costs. Non-operating revenues and expenses are those transactions not considered directly linked to providing health care services.

Income taxes: The District operates under the purview of the Internal Revenue Code, Section 115, and corresponding California Revenue and Taxation Code provisions. As such, it is not subject to state or federal taxes on income. However, income from the unrelated business activities of the District may be subject to income taxes.

The Hospital is exempt from income taxes under Section 501(c)(3) of the Internal Revenue Code (IRC). Thus, no provision for income taxes is included in the accompanying financial statements. The Hospital follows the accounting guidance for accounting for uncertainty in income taxes. The Hospital is subject to federal and state income taxes to the extent it has unrelated business income. In accordance with the guidance for uncertainty in income taxes, management has evaluated its material tax positions and determined that there are no income tax effects with respect to its financial statements. The Hospital is subject to examination by federal or state authorities within the three-year statute of limitations applied to tax filings. The Hospital management has not been notified of any impending examination and no examinations are currently in process.

NOTE 1 - ORGANIZATION AND ACCOUNTING POLICIES (continued)

Recently Adopted Accounting Pronouncement: In June 2017 the Governmental Accounting Standards Board released GASB 87 regarding changes in the way leases are accounted for. GASB 87 superseded GASB 13 and GASB 62 and more accurately portrays lease obligations by recognizing lease assets and lease liabilities on the statement of net position and disclosing key information about leasing arrangements. GASB 87 increases the usefulness of financial statements by requiring recognition of certain operating lease obligations to recognize the inflows of resources based upon the provisions of the lease contracts. The Combined Unit has adopted GASB 87 effective September 1, 2022, in accordance with the timetable established by GASB 87.

Other new GASB pronouncements recently issued were GASB's 84 (Fiduciary Activities) 88 (Certain Disclosures Related to Debt, including Direct Borrowings and Direct Placements) 89 (Accounting for Interest Cost Incurred Before the End of a Construction Period) and 91 (Conduit Debt Obligation) have been analyzed by Combined Unit management and have been determined to have no impact upon the financial statements.

Revenue Recognition: As previously stated, net patient service revenues are reported at amounts that reflect the consideration to which the Combined Unit expects to be entitled in exchange for patient services. These amounts are due from patients, third-party payors (including health insurers and government programs), and others and include variable consideration for retroactive revenue adjustments due to settlement of third-party payor audits, reviews, and investigations. Generally, the Combined Unit bills the patients and third-party payors several days after the patient receives healthcare services at the Combined Unit. Revenue is recognized as services are rendered.

The Combined Unit has agreements with third-party payors that provide for payments to the Combined Unit at amounts different from its established rates. Payment arrangements include prospectively determined rates per day, discharge or visit, reimbursed costs, discounted charges and per diem payments. Retroactive adjustments are accrued on an estimated basis in the period the related services are rendered and adjusted in future periods as final settlements are determined.

NOTE 2 – CASH AND CASH EQUIVALENTS

As of December 31, 2022, the Combined Unit had deposits in a financial institution of $8,660,568. All of these funds are in the form of cash and cash equivalents, which were collateralized in accordance with the California Government Code ("CGC"), except for $250,000 per account that is federally insured.

Under the provisions of the CGC, California banks and savings and loan associations are required to secure the Combined Unit's deposits by pledging government securities as collateral. The market value of pledged securities must equal at least 110% of the Combined Unit's deposits. California law also allows financial institutions to secure Combine Unit deposits by pledging first trust deed mortgage notes having a value of 150% of the Combined Unit's total deposits. The pledged securities are held by the pledging financial institution's trust department in the name of the Combined Units.

NOTE 2 – CASH AND CASH EQUIVALENTS (continued)

Combined Unit investment policies allow investments in U.S. Government securities and state and local agency funds which invest in U.S. Government securities. These investments, when present, are stated at quoted market values. Changes in market value between years are reflected as a component of investment income in the accompanying statement of revenues, expenses, and changes in net position.

NOTE 3 - NET PATIENT SERVICE REVENUES AND REIMBURSEMENT PROGRAMS

The Combined Unit renders services to patients under contractual arrangements with the Medicare and Medi-Cal programs, commercial insurance companies, health maintenance organizations (HMOs) and preferred provider organizations (PPOs). Patient service revenues from these programs approximate 98% of gross patient service revenues for the year ended December 31, 2022.

The Medicare Program reimburses the Hospital on a cost basis payment system for inpatient and outpatient hospital services. The cost-based reimbursement is determined based on filed Medicare cost reports. Clinic services are reimbursed based on fee schedules.

The Combined Unit contracts to provide services to Medi-Cal, HMO and PPO inpatients on negotiated rates. Certain outpatient reimbursement is subject to a schedule of maximum allowable charges for Medi-Cal and to a percentage discount for HMOs and PPOs.

Both the Medicare and Medi-Cal program's administrative procedures preclude final determination of amounts due to the Combined Unit for services to program patients until after patients' medical records are reviewed and cost reports are audited or otherwise reviewed by and settled with the respective administrative agencies. The Medicare and Medi-Cal cost reports are subject to audit and possible adjustment. Management is of the opinion that no significant adverse adjustment to the recorded settlement amounts will be required upon final settlement.

Medicare and Medi-Cal revenue accounted for approximately 63% of the Combined Unit’s net patient revenues for the year ended December 31, 2022. Laws and regulations governing the Medicare and Medi-Cal programs are extremely complex and subject to interpretation. As a result, there is at least a reasonable possibility that recorded estimates will change by a material amount in the near term.

NOTE 4 - CONCENTRATION OF CREDIT RISK

The Combined Unit grants credit without collateral to its patients and third-party payors. Patient accounts receivable from government agencies represent the only concentrated group of credit risk for the Combined Unit and management does not believe that there is any credit risk associated with these governmental agencies. Contracted and other patient accounts receivable consist of various payors including individuals involved in diverse activities, subject to differing economic conditions and do not represent any concentrated credit risks to the Combined Unit. Concentration of patient accounts receivable at December 31, 2022, were as follows:

	2022
Medicare	$ 33,608,188
Medi-Cal	45,145,391
Other third party payors	59,234,298
Self pay and other	11,100,868
Gross patient accounts receivable	149,088,745
Less allowances for contractual adjustments and bad debts	(127,822,234)
Net patient accounts receivable	$ 21,266,511

NOTE 5 - CAPITAL ASSETS

Capital assets as of December 31, 2022 were comprised of the following:

	Balance at 12/31/2021	Transfers & Additions	Transfer & Retirements	Balance at 12/31/2022
CIP	$ -	$ 965,266	$ -	$ 965,266
Equipment	-	1,738,255	-	1,738,255
Software	-	1,038,183	-	1,038,183
Totals at historical cost	-	3,741,704	-	3,741,704
Less accumulated depreciation	-	(725,896)	-	(725,896)
Capital assets, net	$ -	$ 3,015,808	$ -	$ 3,015,808

NOTE 6 - DEBT BORROWINGS

Long-term debt consists of a note payable, a line of credit, and finance lease agreements as follows:

District debt		
The District has a note payable with the County of Santa Cruz, for the purpose of funding a Letter of Credit with the Santa Cruz County Bank, which is a requirement of the Hospital lease agreement. Interest at 0% with principal payments in the amount of $500,000 due bi-annually on June 30th and December 31st. The first payment is due on June 30, 2023, with final payment due on December 31st, 2025.	$	2,700,000
Total District debt:		2,700,000
Hospital debt		
Note payable to the David and Lucille Packard Foundation; the Hospital is a co-borrower on a note payable collatoralized by community pledges to the Pajaro Valley Healthcare District Project (the Project). As community pledges are received, the Project will make annual principal payments, with the first payment due on March 31, 2023, and the final payment due on January 31, 2026. The Hospital will relieve the debt and recognize revenue as principal payments are made by the Project. Interest at 0.5% will be paid by the Hospital bi-annually on March 31st and September 30th, with the final payment due on January 31, 2026.		6,357,000
Multiple finance leases; imputed interest ranging from 10-11%; monthly lease payments ending in August of 2024:		123,986
Total Hospital debt:		6,480,986
Total debt borrowings		9,180,986
Less current maturities		(1,702,035)
Debt borrowings, net of current maturities	$	7,478,951

NOTE 7 - RETIREMENT PLANS

The Hospital sponsors two 401(a) defined contribution retirement plans for employer contributions: one for service and maintenance employees payable on a calendar year-end that contributes 6% or higher depending on years of service of gross annual earnings; the second 401(a) plan covers other non-management, non-highly compensated employees and contributes 6% of gross earnings bi-weekly. The Hospital also sponsors a 457(b) deferred compensation plan for employee contributions, withheld from bi-weekly earnings.

Accrued payroll and related liabilities include $174,217 of 401(a) employer liabilities, calculated from the final two pay period of the year and contributed to the plan in January of 2023. 401(a) liabilities for SEIU employees was around $1,000 as of December 31, 2022.

NOTE 8 - COMMITMENTS AND CONTINGENCIES

Operating leases: The Combined Unit leases various equipment and facilities under operating leases expiring at various dates. Total building and equipment rent expense for the year ended December 31, 2022, was $1,571,712. Future minimum lease payments for the succeeding years under operating leases as of December 31, 2022, other than those disclosed in Note 9, that have remaining terms in excess of one year are not material.

Construction-in-Progress: As of December 31, 2022, the Combined Unit had $965,266 in construction-in-progress for the Cardio Cath Lab. Approximately $25,000 in remobilization fees are remaining to complete construction. Funds for these fees will come from earnings.

Litigation: The Combined Unit may from time-to-time be involved in litigation and regulatory investigations which arise in the normal course of doing business. As of December 31, 2022, management is not aware of any legal matters or potential regulatory investigations.

Medical Malpractice Insurance: The Combined Unit maintains commercial malpractice liability insurance coverage under a claims made and reported policy covering losses up to $15 million per claim and $25 million in the aggregate for all claims, subject to a deductible of $150,000 Indemnity & Expense each claim. The District plans to maintain the insurance coverage by renewing its current policy, or by replacing it with equivalent insurance.

Workers Compensation Program: The Hospital workers compensation policy is through travelers and renews in Oct 2023. Annual premium is $1,755,002. The district workers compensation policy is also through travelers and renews in Oct 2024. The annual premium is $17,775.

NOTE 8 - COMMITMENTS AND CONTINGENCIES (continued)

Health Insurance Portability and Accountability Act: The Health Insurance Portability and Accountability Act (HIPAA) was enacted August 21, 1996, to ensure health insurance portability, reduce health care fraud and abuse, guarantee security and privacy of health information, and enforce standards for health information. Organizations are subject to significant fines and penalties if found not to be compliant with the provisions outlined in the regulations. Management believes the Combined Unit is in compliance with HIPAA as of December 31, 2022.

Regulatory Environment: The Combined Unit is subject to several laws and regulations. These laws and regulations include matters such as licensure, accreditation, government health care program participation requirements, reimbursement for patient services, and Medicare and Medi-Cal fraud and abuse. Government activity has increased with respect to possible violations of statues and regulations by health care providers. Violations of these laws and regulations could result in expulsion from government health care programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Combined Unit is in compliance with all applicable government laws and regulations and is not aware of any future actions or unasserted claims at this time.

NOTE 9 - LEASES

The Combined Unit has multiple equipment and building leases. The District leases the building and land for the Hospital from Medical Properties Trust, Inc with a remaining term of 321 months and an annual increase to base rent of 2%. The District also leases office space for a urology center near the Hospital. This lease has 91 months remaining and a fixed monthly payment during the term. All other lease arrangements are either immaterial or have a term of 12 months or less.

Neither lease has a readily determinable discount rate. The estimated borrowing rate for the Hospital building and land and for the urology center is 9.5%. The urology center lease requires payment of common area maintenance, which represent the majority of variable lease costs. Variable lease costs are excluded from the present value of lease obligations. The District's lease agreements do not contain any material restrictions, covenants, or any material residual value guarantees.

NOTE 9 – LEASES (continued)

Lease related assets and liabilities as of December 31, 2022 consist of the following:

Lease assets:	2022
MPT	$ 33,042,270
Urology center	554,503
Other	1,163,180
Total lease assets	$ 34,759,953

Lease liabilities:	2022
MPT	$ 33,300,104
Urology center	557,177
Other	1,166,684
Total lease liabilities	$ 35,023,965

Total operating lease expense for the year ended December 31, 2022 was $1,571,712. Future minimum rental payments required under operating lease obligations as of December 31, 2022 are summarized as follows:

Years ending December 31,	
2023	$ 3,542,186
2024	3,544,634
2025	3,385,886
2026	3,192,676
Thereafter	89,221,468
Total	102,886,850
Less imputed interest	(67,862,885)
Present value of lease liabilities	$ 35,023,965

NOTE 10 – EXTRAORDINARY ITEM

For the year ended December 31, 2022, the Combined Unit recognized an extraordinary gain of $20,662,622. This extraordinary gain was generated as a result of acquiring the operations and certain assets of the Watsonville Community Hospital in September 2022. The District purchased the Hospital at a discounted price out of bankruptcy, which generated the gain.

NOTE 11 – SUBSEQUENT EVENTS

Management evaluated the effect of subsequent events on the combined financial statements through October 25, 2023, the date the combined financial statements are issued, and determined that there are no material subsequent events that have not been disclosed.

SUPPLEMENTARY SCHEDULES

Pajaro Valley Healthcare District

Combining Statement of Net Position

December 31, 2022

	District	Hospital	Eliminations	Total
Assets				
Current Assets				
Cash and cash equivalents	$ 2,748,593	$ 5,911,975	$ -	$ 8,660,568
Patient accounts receivable, net of allowances	3,242	21,263,269	-	21,266,511
Other accounts receivable	-	1,498,921	-	1,498,921
Inventories	15,409	2,142,994	-	2,158,403
Prepaid expenses and other current assets	581,562	1,929,018	-	2,510,580
Total current assets	3,348,806	32,746,177	-	36,094,983
Capital assets, net of accumulated depreciation	2,885,858	129,950	-	3,015,808
Lease assets	33,721,877	1,038,076	-	34,759,953
Due from district	-	3,205,566	(3,205,566)	-
Total assets	39,956,541	37,119,769	(3,205,566)	73,870,744
Liabilities and Net Position				
Current liabilities				
Current maturities of debt borrowings	-	1,702,035	-	1,702,035
Accounts payable and accrued expenses	412,552	6,509,452	-	6,922,004
Accrued payroll and related liabilities	231,003	8,410,859	-	8,641,862
Estimated third party payor settements	-	1,597,184	-	1,597,184
IBNR self funded health benefits	-	2,787,581	-	2,787,581
Total current liabilities	643,555	21,007,111	-	21,650,666
Debt borrowings, net of current maturities	2,700,000	4,778,951	-	7,478,951
Lease liabilities	33,987,142	1,036,821	-	35,023,963
Due to hospital	3,205,566	-	(3,205,566)	-
Total liabilities	40,536,263	26,822,883	(3,205,566)	64,153,580
Net position				
Invested in capital assets, net of related debt	2,885,858	5,964	-	2,891,822
Restricted	2,600,000	-	-	2,600,000
Unrestricted	(4,803,145)	9,028,487	-	4,225,342
Total net position	682,713	9,034,451	-	9,717,164
Total liabilities and net position	$ 41,218,976	$ 35,857,334	$ (3,205,566)	$ 73,870,744

See accompanying notes to the financial statements

Pajaro Valley Healthcare District

Combining Statement of Revenues, Expenses and Changes in Net position

For The Year Ended December 31, 2022

	District	Hospital	Eliminations	Total
Operating revenues				
Net patient service revenues	$ 451,860	$ 32,856,390	$ -	$ 33,308,250
Other operating revenues	754,870	87,518	(309,444)	532,944
Total operating revenues	1,206,730	32,943,908	(309,444)	33,841,194
Operating expenses				
Salaries & Wages	919,690	16,462,262	-	17,381,952
Benefits	175,378	5,925,460	-	6,100,838
Contract Labor	-	2,414,616	-	2,414,616
Supplies	25,443	3,662,589	-	3,688,032
Medical Spec Fees	37,514	2,838,544	-	2,876,058
Purchased Services	480,077	5,099,885	-	5,579,962
Lease Cost and Rent	1,353,548	296,210	-	1,649,758
Repairs & Maintenance	96	316,275	-	316,371
Utilities	5,848	706,897	-	712,745
Depreciation and amortization	384,786	-	-	384,786
Other Operating Exp	49,608	2,856,954	-	2,906,562
Prop Taxes & Ins	28,644	703,177	-	731,821
Interest	273,907	46,631	-	320,538
Total operating expenses	3,734,539	41,329,500	-	45,064,039
Operating income (loss)	(2,527,809)	(8,385,592)	(309,444)	(11,222,845)
Nonoperating revenues (expenses)				
Rental income	277,387	-	-	277,387
Management fees	(309,444)	-	309,444	-
Total nonoperating revenues (expenses)	(32,057)	-	309,444	277,387
Net income/(loss) before extraordinary item	(2,559,866)	(8,385,592)	-	(10,945,458)
Extraordinary income	3,242,579	17,420,043	-	20,662,622
Increase/(decrease) in net position	682,713	9,034,451	-	9,717,164
Net position, beginning of the year	-	-	-	-
Net position, end of year	$ 682,713	$ 9,034,451	$ -	$ 9,717,164

See accompanying notes to the financial statements

JWT & Associates, LLP

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Independent Auditors Report on Internal Control over Financial Reporting and on Compliance and Other Matters Based on an Audit of Financial Statements Performed in Accordance with Government Auditing Standards

The Board of Directors
Pajaro Valley Health Care District
Watsonville, California

We have audited, in accordance with the auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in Government Auditing Standards issued by the Comptroller General of the United States, the combined financial statements of the business-type activities of the Pajaro Valley Health Care District (the District) as of and for the year ended December 31, 2022, and the related notes to the combined financial statements, which collectively comprise the District's combined financial statements, and have issued our report thereon dated October 25, 2023.

Internal Control over Financial Reporting

In planning and performing our audit of the combined financial statements, we considered the District's internal control over financial reporting (internal control) as a basis for designing audit procedures that are appropriate in the circumstances for the purpose of expressing our opinion on the combined financial statements, but not for the purpose of expressing an opinion on the effectiveness of the District's internal control. Accordingly, we do not express an opinion on the effectiveness of the District's internal control.

A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis. A material weakness is a deficiency, or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's combined financial statements will not be prevented, or detected and corrected on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.

Our consideration of internal control was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies. Given those limitations, during our audit we did not identify any deficiencies in internal control that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified.

Compliance and Other Matters

As part of obtaining reasonable assurance about whether the District's combined financial statements are free from material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements, noncompliance with which could have a direct and material effect on the combined financial statement. However, providing an opinion on compliance with those provisions was not an objective of our audit, and accordingly, we do not express such an opinion. The results of our tests disclosed no instances of noncompliance or other matters that are required to be reported under Government Auditing Standards.

Purpose of this Report

The purpose of this report is solely to describe the scope of our testing of internal control and compliance and the results of that testing, and not to provide an opinion on the effectiveness of the District's internal control or on compliance. This report is an integral part of an audit performed in accordance with Government Auditing Standards in considering the District's internal control and compliance. Accordingly, this communication is not suitable for any other purpose.

JJW & Associates, LLP

Fresno, California
October 25, 2023