3. Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils. Tap water is not allowed.
4. Temperature will be monitored once daily for all drug components stored for nonsterile compounding.

L. Cleaning and Sanitizing
   a. Documentation shall include a record of the identity of the person completing the cleaning and sanitizing as well as the product name of the cleaning and sanitizing agents.
   b. Frequency is determined per USP 795.

M. Drug Recalls: See Policy: SVMC DRUG RECALL POLICY

N. Personnel Training and Evaluation

1. The elements of knowledge and competency include the following:
   i. Hand hygiene
   ii. Garbing
   iii. Cleaning and sanitizing
   iv. Handling and transporting components of CNSPs
   v. Documentation of the compounding process
2. The pharmacy will maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform assigned responsibilities relating to compounding. Additional topics will address the following:
   i. Quality assurance and quality control procedures
   ii. Container closure and equipment selection
   iii. Component selection and handling
   iv. USP 795 (2023)
3. All pharmacy personnel performing nonsterile compounding will complete an initial assessment and be re-evaluated at least every 12 months.
4. If a member of compounding personnel fails any aspect of training or demonstrated competency, he or she shall not be involved in compounding until after successfully passing reevaluations in the deficient area(s).
5. Pharmacy leadership will notify and educate staff of any changes in process via email, meetings or written material.

O. Compounding Quality Assurance

1. Pharmacy leadership will verify, monitor, and review the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel.
2. Pharmacy will comply with USP General Chapter 1163 (Quality Assurance in Pharmaceutical Compounding).
3. Authorized pharmacy personnel shall perform quantitative testing as deemed appropriate by the pharmacist in charge (PIC).

i. Potency testing
ii. Sterility testing

4. Any quality reports generated will be retained by the pharmacy and collated with the compounding record and master formula.
5. When a sample yields a significant variance from labeled strength, the pharmacist in charge shall be notified. Likewise appropriate follow up, corrective action and process improvement shall commence as deemed necessary based on the findings.

REFERENCES:

- California Pharmacy Lawbook Online-California Code of Regulations (2023), Division 17, Title 16, Section 1735-1735.14.
- USP. USP <795> Pharmaceutical compounding—Nonsterile preparations. Second supplement to USP 40–NF 35. December 29, 2022; 675–83.

CROSS REFERENCES:

- Drug Recall Procedure Policy

Table 3. Water Activity of Common Compounded Nonsterile Dosage Forms[a]

Nonaqueous Dosage Forms: a_w < 0.6			Aqueous Dosage Forms: a_w ≥ 0.6		
Dosage Form	**Description**	**a_w**	**Dosage Form**	**Description**	**a_w**
Animal treat	Animal treat (oil flavor)	0.507	Animal treat	Animal treat with 15%–18% aqueous flavor	0.716
Capsule (oil filled)	Olive oil encapsulated	0.468	Cream	Cream vehicle (oil in water emulsion, petrolatum free)	0.968
Capsule (powder filled)	Powder base encapsulated	0.435	Cream	Emollient cream (petrolatum and mineral oil)	0.984
Gel (glycol based)	Propylene glycol, ethoxy diglycol, hydroxypropyl cellulose gel	0.056	Cream	Cream (oil in water emulsion with natural oils)	0.989
Lollipop (sorbitol based)	Sorbitol-based lollipop	0.460	Foam	Foaming surfactant solution	0.983
Ointment	Hydrophilic petrolatum	0.396	Gel (water based)	Alcohol-free aqueous gel	0.990
Ointment	Polyethylene and mineral oil gel base	0.459	Gel (water based)	Hydroxypropyl methylcellulose (HPMC) gel	1.000

Nonaqueous Dosage Forms: a_w < 0.6			Aqueous Dosage Forms: a_w ≥ 0.6		
Dosage Form	**Description**	**a_w**	**Dosage Form**	**Description**	**a_w**
Oral solution (glycol based)	20% Polyethylene glycol and 80% propylene glycol	0.009	Lotion	Lotion (oil in water emulsion)	0.986
Oral solution (oil based)	Medium chain triglycerides oil	0.338	Nasal spray	Nasal spray	0.991
Oral suspension (fixed oil)	Fixed oil with thickener	0.403	Oral solution (water based)	Low-sucrose syrup vehicle	0.906
Powder for inhalation	Encapsulated powder for inhalation	0.402	Oral solution (water based)	90% Water and 10% glycerin	0.958
Stick	Lip balm	0.181	Oral suspension (water based)	Oral suspension base	0.992
Suppository	Polyethylene glycol base	0.374	Rinse	Polymer gel with 30% water	0.960
Suppository	Fatty acid base	0.385	Shampoo	Shampoo	0.976
Tablet (compressed)	Compressed tablet	0.465	Simple syrup	Simple syrup	0.831
Tablet (triturate)	Tablet triturate (lactose and/or sucrose)	0.427	–	–	–
Troche or lozenge (gelatin based)	Gelatin troche or lozenge with NMT 3% aqueous flavor	0.332	–	–	–
Troche or lozenge (glycol based)	Polyethylene glycol troche or lozenge with NMT 3% aqueous flavor	0.571	–	–	–

Table 1. Minimum Frequency for Cleaning and Sanitizing in Nonsterile Compounding Area(s)—Surfaces

Site	Minimum Frequency
Work surfaces	• At the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected • Between compounding CNSPs with different components
Floors	• Daily on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected
Walls	• When visibly soiled, after spills, and when surface contamination (e.g., from splashes) is known or suspected
Ceilings	• When visibly soiled and when surface contamination (e.g., from splashes) is known or suspected
Storage shelving	• Every 3 months, after spills, and when surface contamination (e.g., from splashes) is known or suspected

SUBJECT:	SECTION:
PATIENT BED PLACEMENT	***Emergency Department***

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To assure that patients are accurately placed in the correct treatment area, thus enhancing patient safety and patient throughput.

DEFINITIONS:

1. ESI – Emergency Severity Index

POLICY:

A. All patients will be placed in treatment areas according to this policy.

B. If, because of staffing, surge in census, etc., this policy cannot be followed, it is the responsibility of the Charge Nurse and the attending ED Physician to make reasonable changes.

C. If there is any circumstance that necessitates temporary changes to this policy, the Charge Nurse has the authority to make this change and then notify the department Manager or Director as to the change being made and why.

AFFECTED PERSONNEL/AREAS: *EMERGENCY DEPARTMENT NURSING AND MEDICAL STAFF*

PROCEDURE:

A. Patient arrives and is greeted, assessed, and assigned an ESI Triage Level.

B. Based on the ESI Triage Level, the patient will be assigned to the following ED treatment areas:

1. Level I, Level II and Level III (24 hours/day, 7 days/week)
    a. Main ED
2. Level III (When RN assigned)
    a. Rapid Medical Exam (RME)
3. Level IV and Level V
    a. Rapid Medical Exam (RME)
    b. Main ED

REFERENCES:

- Gilboy, N. et.al. (2020) Implementation Handbook 2020 Edition ESI Emergency Severity Index, Emergency Nurses Association.

SUBJECT: **PATIENT ELOPEMENT**	SECTION: **Page 1 of 1**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To provide a means of documenting the presence or lack thereof of a patient in the Emergency Department.

POLICY:

Any patient that has departed the Emergency Department after evaluation by a physician, nurse practitioner (NP) or physician assistant (PA), without notifying staff, after presenting for treatment with a medical complaint, is deemed as an elopement.

AFFECTED PERSONNEL/AREAS: *EMERGENCY DEPARTMENT DIRECTOR/EMERGENCY DEPARTMENT STAFF*

PROCEDURE:

The following shall be documented on the patient's chart:

1. Time the patient presented to triage or arrived by ambulance.
2. Time seen by the physician, NP or PA, if applicable.
3. Time the patient left the department, if observed.
4. Time noticed missing, if not observed.
5. If the patient was not placed in a room and was waiting in lobby:
    a. Documentation of **three attempts** to locate patient in the Emergency Department and the area immediately outside of the front lobby doors
    b. **Five-minute intervals**
6. Time the attending physician was notified of elopement.

REFERENCE:

- The Joint Commission (2020). Hospital accreditation standards. Joint Commission Resources. Oak Brook,IL.

SUBJECT: **PATIENT TRIAGE (ESI AND COMPREHENSIVE)**	SECTION: ***Emergency Department*** **Page 1 of 3**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To sort patients by acuity and place in the appropriate treatment area.

DEFINITIONS:

1. ESI – Emergency Severity Index. The Emergency Severity Index (ESI) is a tool for use in emergency department (ED) triage. The ESI triage algorithm yields rapid, reproducible, and clinically relevant stratification of patients into five groups, from level 1 (most urgent) to level 5 (least urgent). The ESI provides a method for categorizing ED patients by both acuity and resource needs.

2. Comprehensive Triage – The detailed assessment of one or more body areas depending on the patient's presenting complaint as well as the estimated time to see a Medical Provider.

POLICY:

A. Upon arrival to the Emergency Department, all patients (walk in and those arriving by ambulance) are to be assessed by a Registered Nurse that is trained and has shown competency in the use of the ESI 5-level triage system.

AFFECTED PERSONNEL/AREAS: *EMERGENCY DEPARTMENT NURSING STAFF, EMERGENCY DEPARTMENT MEDICAL PROVIDERS, AND EMERGENCY DEPARTMENT PATIENT ACCESS.*

PROCEDURE:

A. Upon arrival at the Emergency Department, all patients will be immediately seen by a Registered Nurse (RN).

B. The RN will elicit the appropriate information to assign an ESI Triage Level of I through V.

   1. Level I – Patients requiring immediate live saving interventions

   2. Level II – Patients that are:

      a. High Risk

      b. Confused, lethargic, or disoriented

      c. In severe pain or distress

   3. Level III – Patients who do not meet criteria to be a Level I or Level II and will require 2+ resources

   4. Level IV - Patients who do not meet criteria to be a Level I or Level II and will require 1 resource.

5. Level V - Patients who do not meet criteria to be a Level I or Level II and will require no resources.

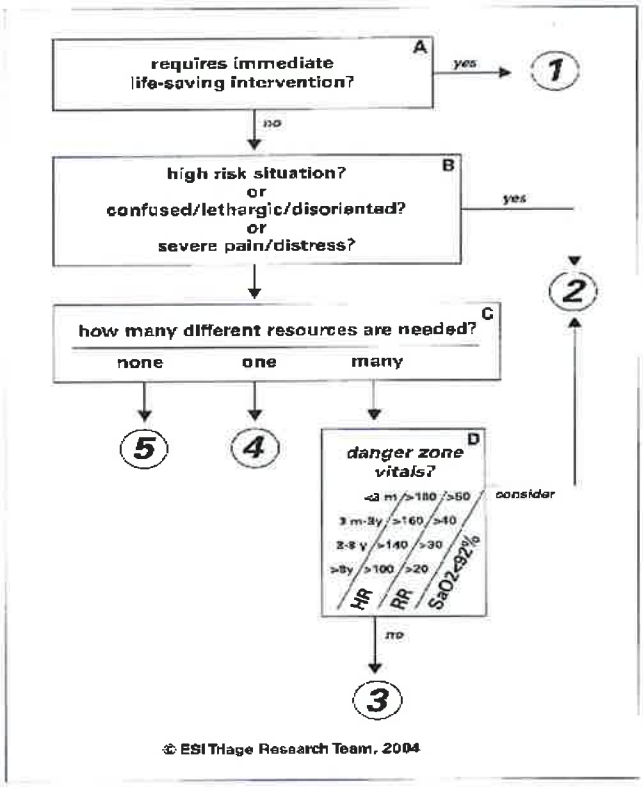
C. The RN will document findings within the Electronic Medical Record (EMR).

D. The RN will, or have someone, escort the patient to the appropriate treatment area or direct them to a waiting area as appropriate.

E. If the patient is a level I or level II, the patient is not to be directed to a waiting area. The RN should confer with the Charge Nurse to find immediate placement for these patients.

F. The following flow chart is for reference:

Appendix B.
ESI Triage Algorithm, v.4



All Level I, II, and III patients are to receive a comprehensive assessment by a Registered Nurse. This assessment is to be based on presenting complaint and affected body system.

REFERENCES:

- Gilboy, N, et. al. (2020). Implementation Handbook 2020 Edition ESI, *Emergency Severity Index V4.;* Emergency Nurses Association.

SUBJECT:	SECTION:
SIGN-OUT PROTOCOL FOR BLOOD COMPONENTS	**Page 1 of 2**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

At the time a unit is issued, Blood Bank Standards require a final check of transfusion service records, the patient's identification, and each unit of blood or component.

POLICY:

- All units of blood and blood components must be signed out by a clinical lab scientist (CLS) and another clinical care representative. The CLS and clinical care representative must be on staff at Sierra View Medical Center (SVMC).

PROCEDURE:

- The clinical care representative must present a copy of the blood bank transfusion request containing complete patient identification when coming to pick up blood or blood components.

- After successful crossmatch of the unit, the clinical lab scientist will utilize printed unit "luggage tags" and attach them to the appropriate unit. At the time of issue, the CLS will examine the unit for appearance and expiration date and indicate the acceptability by documenting on the transfusion issue card. The transfusion luggage tag with the patient's name, medical record number, the donor unit number, the patient and donor unit ABO/Rh, and the expiration date of the unit will be compared with the identical information contained on the transfusion issue card, by both the CLS and the clinical care representative. All information must agree before the unit can be signed out for transfusion. ANY DISCREPANCIES MUST BE RESOLVED BEFORE ISSUE.

- After determining that the above information is in agreement and the identity of the recipient and donor are confirmed, the clinical care representative will sign the blood bank transfusion issue card (both copies).

- The clinical care representative will now be able to take the unit along with the transfusion issue card back to the nursing unit for transfusion.

- A clinical care representative will be allowed to sign-out more than one unit at a time for transfusion on the same patient, but will not be allowed to sign-out units on different patients simultaneously.

- Units of blood issued to surgery will be placed in resealable plastic bags with the patient name, date of birth, and Blood Bank number boldly written on the resealable plastic bag.

AFFECTED AREAS/PERSONNEL: *ALL CLINICAL EMPLOYEES*

REFERENCES:

- American Association of Blood Banks, "Standards for Blood Banks and Transfusion Services", 33rd Edition, 5.22 through 5.25.

- The Joint Commission (2023). Laboratory accreditation standards. QSA.05.10.01. Joint Commission Resources. Oak Brook, IL.

SUBJECT: **STERILE HAZARDOUS DRUG HANDLING**	SECTION: **Page 1 of 20**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To provide practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection. In addition, to provide for the safe receipt, storage, compounding, dispensing, administration, and disposal of sterile hazardous products and preparations at Sierra View Medical Center (SVMC).

DEFINITIONS:

A. Hazardous Drugs- Medications that in small quantities can produce severe adverse physiological effects. This category can be further subdivided into antineoplastic, non-antineoplastic, reproductive risk only.

B. USP 797- Refers to a chapter from the United States Pharmacopeia publication. The USP is a nationally recognized authority that established quality standards for the preparation of sterile intravenous products.

C. USP 800- Refers to a chapter from the United States Pharmacopeia (USP) publication. The USP is a nationally recognized authority that established quality standards for the preparation of sterile hazardous products.

D. Class II Type A2 Biological Safety Cabinet (BSC)- A ventilated cabinet often used for preparation of hazardous drugs. A partial barrier system that rely on the movement of air to provide personnel, environmental, and product protection.

E. ISO Class 5- A reference to a space of air that contains no more than 3,520 particles per cubic that are 0.5 microns or larger.

F. PPE- Personnel Protective Equipment includes chemotherapy rated gloves, gowns, eye, face, head, shoe, sleeve coverings that are intended to prevent exposure to hazardous drugs.

G. Category 1 Compounded Sterile Preparation (CSP)- Category 1 is a risk-based approach defined in USP 797 that establishes a specific BUD for products, personnel qualifications, environmental monitoring. It assigns a BUD of 12 hours at room temperature and 24 hours refrigerated.

H. Category 2 Compounded Sterile Preparation (CSP)- Category 2 is a risk-based approach defined in USP 797 that establishes a typically longer BUD. It assigns a BUD of 4 days at room temperature and 10 days under refrigeration.

I. BUD- Beyond Use Date is either the date or hour after which a CSP must not be used or administration must not begin. The BUD is determined from the date and time that preparation of the CSP is initiated.

J. CSTD- Stands for Closed System Transfer Device "a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of the hazardous drug or vapor concentrations outside the system."

POLICY:

It is the policy of SVMC that all injectable hazardous medications will be prepared in the Cancer Treatment Center in a negative pressure CACI/BSC by properly trained personnel who will practice safe established preparation techniques and proper handling procedures as outlined in USP 797, USP 800, and California State Board of Pharmacy regulations.

AFFECTED PERSONNEL/AREAS: *PHARMACY, CANCER TREATMENT CENTER, NURSING*

A. PERSONNEL PREPARATION:

1. All activities not requiring a sterile environment (e.g., checking labels, doing calculations) should be completed before accessing the CACI/BSC.

2. Hand washing is a critical component to ensuring IV admixtures are aseptically prepared as well as reducing chemotherapy trace contamination of both product and personnel.

   a. Wash hands before and after cleaning hood or preparing chemotherapy products.

   b. Wash hands for 30 seconds using chlorhexidine (digital timer provided). Wash up to elbows when possible.

   c. Utilize bactericidal soap.

   d. Pay particular attention to under fingernails and between fingers. Use nail picks to remove debris from underneath fingernails.

   e. No jewelry (rings, watches, etc.) may be worn during compounding.

   f. No nail polish, artificial nails, or cosmetics may be worn during compounding.

   g. After washing, use a lint-free (non-shedding) cloth or paper towel to dry hands.

   h. Prior to donning first pair of sterile HD-certified gloves, after washing hands as above, apply Sterillium© and allow contact time of at least 3 minutes.

3. Utilize gowns that are certified for use in the preparation of hazardous drugs. This will help protect both you as well as others from trace chemo contamination. Gowning will help protect you from any gross chemotherapy spills that could occur. Wearing protective garments (gown and gloves) is required when preparing, compounding, handling, cleaning, and disposing chemotherapy.

   a. After washing hands and applying Sterillium, don first (interior) set of sterile HD gloves.

   b. Sanitize outside the gloves with 70% isopropyl alcohol. Allow alcohol to dry.

c. Don protective chemotherapy-approved gown.

d. First set of gloves should be tucked under/inside the cuff of the gown.

e. Don second set of chemotherapy-approved sterile gloves (double gloves are recommended for hazardous drugs as permeability varies with material, thickness, and exposure duration).

f. Extend outer glove over the cuff of gown.

g. Sanitize outer HD glove with 70% isopropyl alcohol, and allow alcohol to dry.

h. Change gloves if they become contaminated, torn, or punctured.

i. Change outer gloves whenever you must exit and re-enter the BSC by opening the face of the BSC for cleaning or decontamination.

j. Gowns are not to be worn outside of the buffer area.

k. TWO sets of booties must be worn while compounding.

B. CHEMOTHERAPY PREPARATION TECHNIQUE:

1. Nothing should interrupt the flow of air between the HEPA filter and the sterile starting components. To maintain sterility, nothing should be placed above the work surface. Starting components should be placed at least six inches from the sides and front edge of the hood without blocking air vents. Hands should also be positioned to assure that airflow in the critical area of the HEPA filter and the sterile starting components is not blocked.

2. BSCs must run continuously 24 hours a day and must be inspected and certified by qualified personnel every six months.

3. Nothing should be stored on top of the BSC.

4. Clean the drug preparation area, left to right and top to bottom, with an approved sterile water, 70% isopropyl alcohol, and Peridox© (with a dwell time of at least 3 minutes). This will be done at the beginning and the end of the shift, when there is a spill or as needed.

5. Keep the area free of solutions, additives, and equipment that are not required to prepare the product.

6. All products necessary for preparing the admixture or batch should be gathered and sanitized with sterile 70% alcohol and readied for placement in the CACI or BSC. Obtain the basic parenteral solutions, additive drugs, syringes, needles, swabs, labels,

Chemo-transport bag, etc.

7. When using a BSC, place the medication label nearby for reference. You may also affix the label onto the final container to prevent errors. Then, place the sanitized starting components and supplies on top of the clean disposable mat inside the PEC.

8. If an infusion container (IV bag) will be utilized, attach the IV tubing and completely prime the tubing in the hood, making sure it is free of all air bubbles.

9. Prime tubing with fluid from container PRIOR to adding chemotherapy agent whenever possible.

10. Clean diaphragms and injection ports with sterile 70% alcohol swab prior to needle puncture.

11. The safe handling of hazardous drug solutions in vials or ampoules requires the use of a syringe that is no more than three-fourths full when filled with the solution. This minimizes the risk of the plunger separating from the syringe barrel.

12. Ensure that the syringe is the appropriate volume and needle is the appropriate gauge and length.

13. Use CSTD (ONGUARD system or other approved CSTD depending on market availability and as approved by PIC (Designated person) for all compounding in the CACI/BSC.

14. When reconstituting, the syringe should remain in the CSTD, and the contents should be swirled carefully until dissolved.

15. With the vial inverted, the proper amount of drug solution should be withdrawn in small aliquots (e.g., 1/4th to 1/5th of total volume in each aliquot) while equal volumes of air are exchanged for solution. The exact volume needed must be measured while the syringe is in the CTSD and any excess drug should remain in the vial.

    - If the preparation is to be administered in a syringe then it may be capped and labeled at this point in the procedure. If the final dosage form is an IV bag, then continue with the following procedure.

16. When transferring drug to the IV bag, attach the CSTD to the IV bag containing the base solution. Avoid puncturing the sides of the port or bag.

17. Attach the syringe with the drug to the CSTD on the IV bag and slowly inject.

18. After the drug solution is inserted into the IV bag; the IV port, container set, and gloves

should be decontaminated with sterile alcohol 70%.

19. The injection port of the final product should then be covered with a protective shield and chemotherapy seal.

20. The final preparation should then be placed into the pass-through chamber, inner airlock door closed, and the clean inner gloves should be used for labeling and placement into the chemotherapy transport bag.

21. When using a negative pressure BSC, all items must be wiped down with 70% sterile alcohol prior to being placed inside. They must be at least 6 inches in the hood and placed such that that turbulent airflow does not exist.

C. INSPECTION OF FINAL PRODUCT:

After completion of preparation, the pharmacist will notify the Cancer Treatment Center (CTC) nursing staff. One of the licensed registered chemo-certified nurses and the pharmacist will verify that the final product is free from visible particulate matter, turbidity, or discoloration. At this point, the final preparation is ready for administration to the patient. It will be sealed in a chemotherapy transport bag and taken by the nurse.

D. LIST OF HAZARDOUS DRUGS

1. A list of hazardous drugs that are handled at Sierra View Medical Center will be maintained by the pharmacy (PIC) and reviewed against the NIOSH list for changes annually.

E. RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS

1. The pharmacist-in-charge will be responsible for developing and implementing appropriate procedures and overseeing entity compliance with USP 800.

   a. Program integrity will be assured through the following:

      - Testing of product, environment, and personnel.
      - Correcting actionable results when necessary.
      - Hand-hygiene and use of PPE shall be employed at each phase of hazardous drug (HD) handling, e.g., receipt, transport, compounding, administration, spill, and disposal.

F. FACILITIES AND ENGINEERING CONTROLS

1. Designated areas for handling HDs

   a. Segregated Compounding Area (Main Pharmacy) and Suite B

      - A sign designating "hazard" must be displayed.
      - Access to HD preparation area must be restricted to authorized personnel.
      - Located away from breakrooms or areas for patients and visitors

   b. Receipt and Unpacking of HDs located at Cancer Treatment Center

      - A pharmacist will receive the HDs from the wholesaler.
      - A properly-garbed pharmacist will unpack the HD shipments in the compounding area.

   c. Storage at Cancer Treatment Center

      - HDs will be stored in the HD room, behind a locked door.
      - HDs will be stored as per manufacturer's recommendations and monitored as per SVMC policy MEDICATION PROCUREMENT, STORAGE, DISTRIBUTION AND CONTROL.

   d. Hand washing shall occur after handling and PPE has been doffed.

   e. Designated Administration Areas

      - Cancer Treatment Center
      - Clinical Decision Unit, Operating Room- Bladder Instillation

G. RECEIPT

1. Antineoplastic HDs must not be unpacked (removal from shipping containers) from their external shipping containers in positive-pressure areas.

   a. If the shipping container appears damaged:

      - Seal the container without opening and contact the supplier.

- If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous".
- If the supplier declines return, dispose of as hazardous waste.

b. If a damaged shipping container must be opened:

- Seal the container in a plastic or an impervious container.
- Transport it to a negative-pressure CACI/BSC and place on a plastic-backed preparation mat.
- Open the package and remove undamaged items.
- Wipe the outside of the undamaged items with a disposable wipe.
- Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous."
- If the supplier declines return, dispose of as hazardous waste.
- Deactivate, decontaminate, and clean the CACI/BSC and discard the mat and cleaning disposables as hazardous waste.
- Hand washing shall occur after handling and PPE has been doffed.

H. STORAGE

1. HDs must not be stored on the floor.
2. HDs must be stored on secured shelves with raised front lips.
3. Antineoplastic HDs must be stored separately from non-HDs in a manner that prevents contamination and exposure.
4. Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator.
5. After stocking, hand washing shall be completed.

I. COMPOUNDING

1. One licensed registered chemotherapy nurse will double check, and initial, the pharmacist's calculations prior to compounding.
2. Hand washing is a critical component to ensuring IV admixtures are aseptically prepared as well as reducing chemotherapy trace contamination of both product and personnel.

a. Wash hands before and after cleaning the PEC or preparing chemotherapy products.

b. Wash hands for 30 seconds with timer. Wash to elbows when possible.

c. Utilize bactericidal soap.

d. Pay particular attention to under the fingernails and between fingers. Use a nail pick for debris under fingernails.

e. No jewelry (rings, watches, etc.) may be worn during compounding.

f. No nail polish, artificial nails, or cosmetics may be worn during compounding.

g. After washing, use a lint-free (non-shedding) cloth or paper towel to dry hands.

h. Apply sterillium to bare hands prior to donning first pair of HD gloves.

3. Gowning will help protect both you as well as others from trace chemo contamination. Gowning and gloving is required when preparing, compounding, handling, cleaning and disposing of HDs.

a. After washing hands, don first (interior) set of HD gloves.

b. Sanitize HD gloves with 70% isopropyl alcohol.

c. Don protective chemotherapy-approved gown.

d. First set of gloves should be tucked under/inside the cuff of the gown.

e. Don second set of chemotherapy approved gloves (double gloves are recommended for hazardous drugs as permeability varies with material, thickness, and exposure duration).

f. Extend outer glove over the cuff of gown.

g. Sanitize and or soak outer glove with 70% isopropyl alcohol and allow product to dry.

h. Change gloves if they become contaminated, torn, or punctured.

i. Change outer gloves whenever you must exit and re-enter the PEC.

j. Gowns are not to be worn outside of preparation/buffer area.

4. Head, Hair, and Shoe Covers

   a. A second pair of shoe covers must be worn when entering the compounding area and compounding HDs. It also must be removed before leaving that area.

   b. Head covers/bouffants will be worn while compounding HDs.

5. Doffing of PPE after HD compounding

   a. Remove outer pair of HD gloves and place in HD waste container in buffer area.
   b. Remove outer pair of booties and place in yellow HD waste container in buffer area.
   c. While in the HD buffer area, remove the HD gown and place in yellow HD waste container.
   d. Remove inner pair of HD gloves while in buffer area.
   e. Exit HD buffer room, enter the clean side of anteroom, and go to the sink.
   f. Remove bouffant/mask and place in yellow HD waste container found under the sink.
   g. Wash hands as stated above.
   h. Remove inner booties and step across LOD.
   i. Use Sterillium gel.

6. Eye and Face Protection

   a. Must be worn when there is a risk of splash or spills outside of CACI/BSC, i.e., cleaning a spill, or working above eye level.

   b. Goggles must be used, not eye glasses.

   c. Goggles plus face shield provide full protection.

7. Respiratory Protection

   a. Shall be worn when unpacking HDs that are NOT contained in plastic bags.

   b. A N95 surgical respirator provides barriers to splashes, droplets, and sprays but not to vapors or gases.

   c. A full face-piece, chemical cartridge-type respirator should be worn when risk of exposure to vapor or:

      - Attending HD spills larger than what can be contained with a spill kit.

      - Deactivating, decontaminating, and cleaning underneath work surfaces.

- Known or suspected airborne exposure to powders or vapors.

8. Engineering Controls

   a. Primary Engineering Control (PEC) – A CACI/BSC will be used for all phases of compounding that provides an ISO Class 5 or better air quality.

   b. Supplemental Control - A closed system transfer device will be used in compounding and administering HDs.

9. CACI/BSC

   a. Must operate continuously 24 hours a day and 7 days a week.

   - Will be recertified every 6 months.
   - If there is any loss of power or if repair or moving occurs:
     - All activities in CACI/BSC must be suspended.
   - Upon return of power
     - Decontamination, cleaning, and disinfection must occur and the BSC must be given the manufacturer specified time to recover before compounding resumes.
   - A sink must be available for hand washing.
   - An eyewash station must be readily available.
   - Water sources and drains must be located at least 1 meter away from CACI/BSC.
   - CACI/HD hood must be externally vented.
   - Must provide an ISO Class 5 or better environment.

10. STERILE COMPOUNDING

   - All sterile NON-HD compounding must follow USP 797 standards.
   - LABELING
     - HDs shall be labeled "Caution Chemotherapy-Dispose of properly" or "hazardous- dispose of properly" and "Compounded by Pharmacy".

- All product labels shall include:
  - Name of pharmacy
  - Name of medication, strength, and volume
  - IV admixed medications shall include the solution used.
  - Instructions for storage, handling, and administration or rate of infusion
  - Beyond use date
  - Date of compounding
  - Lot number or pharmacy reference number

All compounded HDs will undergo visual inspection for particulate matter, turbidity, and evidence of contamination. Products with suspected adulterants will be discarded into the yellow HD waste container after the patient information has been removed and destroyed.

11. SVMC Policy IV PREPARATION AND DISPENSING shall be applied. HD guidelines from USP 800 shall supersede non-HD procedures where conflict exists.

12. Hand washing and donning PPE shall occur before compounding. Hand washing shall occur after doffing PPE.

A. TRANSPORT OF HDs

1. LABELING

   a. HDs must be clearly labeled as per USP 797 at all times during transport and include labels of "Chemotherapy-dispose of properly" or "Hazardous drugs-dispose of properly".

2. PACKAGING

   a. A designated HD transport tote will be labeled "Hazardous Drugs" and will be used solely for HDs.

   b. The transport tote will be cleaned before and after transport of HDs by properly garbed pharmacy technicians.

   c. Hand washing shall occur after PPE has been doffed.

B. ADMINISTERING

1. Sterile intravenous HDs will be administered via needleless closed system transfer device.

2. PPE used when administering HDs will be disposed of in a chemotherapy waste receptacle.

3. Hand washing shall occur after proper PPE has been doffed.

C. DISPOSAL

1. All personnel who perform custodial waste removal and cleaning activities will be trained to prevent and protect themselves from accidental exposure and contamination of the environment.

2. Hand washing shall occur after proper PPE has been doffed.

D. DISPENSING OF FINAL DOSAGE FORMS

1. Any oral dosage form HDs that do not require any further manipulation other than counting or repackaging of the final dosage form must not be placed into an automated counting machine.

E. DEACTIVATING, DECONTAMINATION, CLEANING, AND DISINFECTING

1. All personnel who perform deactivation, decontamination, cleaning, and disinfection in HD handling areas will be:

   a. Trained annually

   b. All personnel performing these activities will wear impervious personnel protective equipment, double gloves (chemo-grade), and eye protection if splashing is likely.

2. CACI/BSC MAINTENANCE

   a. Do not use a spray bottle. Lint free wipes shall be used.

   b. Disposal meets FDA regulations.

   c. All cleaning activities will be documented.

3. Deactivation

a. Shall occur daily, after a spill, or as deemed warranted.

b. A process whereby the HD compound is rendered inert. SVMC will use Peridox©.

4. Decontamination

a. Performed prior to any compounding, in between compounding different HDs, at the end of a shift, when a spill occurs, before and after certification, voluntary interruption, and if ventilation tool is moved.

- Removal of HD residue
  - Sterile Alcohol 70%

5. Cleaning

a. Shall occur prior to any compounding, in between compounding different HDs, at the beginning and end of a shift, when a spill occurs, before and after certification, voluntary interruption, at least every 30 minutes when compounding involving human staff is occurring, and if ventilation tool is moved.

- Removal of organic and inorganic material

SVMC will use Peridox© with a contact time of 3 minutes when agent is visibly wet.

6. Disinfecting

a. A process of inhibiting or destroying microorganisms. This shall be performed prior to any compounding, in between compounding different HDs, at the end of a shift, when a spill occurs, before and after certification, voluntary interruption, and if ventilation tool is moved. SVMC will use Peridox© with a contact time of at least 3 minutes.

b. Must occur after surfaces are cleaned using sterile 70% alcohol

c. SVMC Policy: STERILE PRODUCTS: STERILE PRODUCT QUALITY ASSURANCE shall be applied and followed.

7. Spill Control

a. Pharmacy personnel involved in handling HDs will receive annual training in the use of personnel protective equipment and respirator.

b. Spills must be contained and cleaned immediately by qualified personnel with appropriate PPE.

c. Signs must be used to restrict access to spill.

d. Spill kits must be available at all times while HDs are being handled.

e. All used spill kit items must be disposed of as hazardous waste.

f. Spill kits are located in CTC HD Pharmacy and Main Pharmacy.

g. Face pieces must be used if capacity of kit is exceeded or if vapors are known or suspected.

h. Material Safety Data Sheets are accessible 24 hours a day via the SVMC intranet.

i. When a spill occurs, protect the patients or employees who had cytotoxic drugs spilled on them.

a. If skin is exposed, wash the affected areas with copious amounts of non-medicated soap and water for 20 minutes.

b. If mucous membranes are exposed (i.e. eyes), rinse with copious amounts of clean water for at least 15 minutes.

8. Spills should be cleaned up immediately by the person responsible. An Environmental Services Supervisor is available during business hours. Call the Supervisor to assist if the spill is complicated (i.e., >50ml or >12 inches in diameter, or difficult to contain, for example liquid mercury spills) or the area is difficult to clean. The supervisor may also be called as an information resource on cleaning spills.

9. A written procedure for spill management is included in each spill kit. Components of a spill kit include, but may not be limited to, the following:

a. 2 pairs of disposable HD gloves

b. Low permeability gown and shoe covers

c. Goggles or face shield

d. Respirator mask (unless included in face shield)

a. Plastic backed absorbent sheets or spill pads (sufficient to absorb a spill of up to 1000mL)

e. Disposable towels or swabs for absorbing and cleaning liquid spills

f. At least 2 sealable plastic waste bags "Cytotoxic Waste"

g. Disposable scoop for collecting glass fragments

h. Puncture-resistant container for glass fragments, clearly labeled as cytotoxic waste container

i. Cleaning solution for cleaning and decontamination of area

j. Instructions on the management of a cytotoxic chemotherapy spill

k. Warning signs to alert other staff to the hazard and isolate the area of the spill

F. General clean-up procedure:

1. Assess the size and scope of the spill.

2. Spills that cannot be contained by two spill kits may require outside assistance and supervisor should be alerted.

3. Post signs to limit access to spill area.

4. Obtain spill kit.

5. Don PPE, including inner and outer gloves and mask.

6. Once fully garbed, contain spill using spill kit.

7. Carefully remove any broken glass fragments and place them in a puncture-resistant container.

8. Absorb liquids with spill pads.

9. Absorb powder with damp disposable pads or soft toweling.

10. Spill cleanup should proceed progressively from areas of lesser to greater contamination.

11. Completely remove and place all contaminated material in the disposal bags.

12. Rinse the area with water and then clean with detergent, sodium hypochlorite solution/wipes and neutralizer.

13. Rinse the area several times and place all materials used for containment and cleanup in disposal bags. Seal bags and place them in the appropriate final container for disposal as

hazardous waste.

14. Carefully remove all PPE using the inner gloves. Place all disposable PPE into disposal bags. Seal bags and place them into the appropriate final container.

15. Remove inner gloves; contain in a small, sealable bag; and then place into the appropriate final container for disposal as hazardous waste.

16. Wash hands thoroughly with soap and water.

17. Once a spill has been initially cleaned, have the area re-cleaned by housekeeping, janitorial staff, or environmental services.

G. After the spill has been cleaned up and the people who came in contact with the cytotoxic drugs have washed the involved skin areas for 20 minutes, consider the following:

1. If the spill is on a patient, notify the physician.

2. If the spill is on an employee:

   a. Call Employee Health Services during business hours or the emergency room for further instructions. The Employee Health nurse or emergency room physician will assess for injury related to the exposure with particular attention to the skin, eyes, and mucous membranes. If a baseline CBC has not been drawn, a CBC with differential will be done.

   b. A CBC with differential and follow-up exam will be done by the Employee Health Service nurse at the time of the expected nadir (the lowest point of circulating blood counts (e.g., WBCs and RBCs) of the drug.

3. Complete an incident report if a spill occurs anywhere or if a spill occurs on a patient or employee.

H. DOCUMENTATION AND STANDARD OPERATING PROCEDURES

1. Must be reviewed by the pharmacist-in-charge every 12 months.

2. Any changes to policy or records must be communicated and documented to all personnel handling HDs.

I. MEDICAL SURVELLIANCE

1. Pharmacy personnel involved in routine handling of HDs will be enrolled into SVMC's medical surveillance program which is administered through employee health.

2. All employees with potential exposure to cytotoxic drugs will be informed by their

department of the potential risks and the need to follow the procedures related to handling of chemotherapy. Training in the policies will be provided as appropriate for the department involved.

3. Employees will be informed by their department of the potential reproductive hazards and if they so request, staff members who are pregnant or breast-feeding, will be transferred to comparable duties that do not involve handling cytotoxic drugs.

4. ACTIONS IN RESPONSE TO EXPOSURE-RELATED HEALTH CHANGES

   a. Post-exposure examination tailored to type of exposure.

   b. Compare performance of controls with recommended standards.

   c. Conduct environmental wiping samples.

   d. Verify that all engineering controls are operating properly.

   e. Verify and document that employee complied with existing policies.

   f. Develop and document a plan of action that will prevent future exposure.

   g. Ensure a confidential two-way communication between employee and employee health regarding notification of a change in health condition.

   h. Provide and document a follow-up medical survey to demonstrate actions that are effective.

   i. Ensure that any exposed employee receive notification of any adverse health effect.

   j. Provide ongoing medical surveillance of all employees that handle HDs to ensure plan implemented is effective.

J. TRAINING

1. Personnel will be trained annually

   a. According to OSHA standards 1910.120 Hazardous Waste Operations Emergency Response

   b. USP 797

   c. USP 800

   d. California State Law. CCR 1735, CCR 1751.

e. Sierra View Medical Center Policy and Procedures related to USP 797 and 800.

f. Chemo Check Workbook ™

g. Environmental Services, Nursing, and Pharmacy shall read and sign "Hazardous Drug Risk" form that acknowledges risk of HDs to employees.

K. QUALITY ASSURANCE PROGRAM

1. Quality Indicators found in SVMC policy COMPOUNDED STERILE PREPARATION:QUALITY ASSURANCE PROGRAM that shall be followed include:

a. Personnel Performance

b. Equipment and Facilities

c. Product and Environment

- At a minimum of every 6 months, or as needed to verify containment, the following shall be done upon the interior of PEC, pass-thru chambers, surfaces in staging or work areas near PEC, areas adjacent to PEC, areas immediately outside buffer area, patient administration areas:
  - Environmental Wipe Sampling for Trace Chemo:
- In the event of a positive result, the pharmacist-in-charge shall:
  - Identify, document, and contain the cause of contamination
  - Reevaluate the workplace practices
  - Re-train personnel
  - Perform deactivation, decontamination, cleaning, and improving engineering controls
  - Repeat wipe-sampling to validate decontamination complete
- End Product Sampling
  - Sterility
  - Potency

L. HAZARD COMMUNICATION PROGRAM

1. Standards of handling HDs shall be implemented and evaluated thru annual employee

competencies.

2. All containers of HDs shall be labeled with the identity of the material and appropriate hazard warning.

3. Material Data Sheets are available for all employees 24 hours a day via the SVMC intranet.

4. Personnel shall receive training on exposure prior to handling HDs or when there are hazard changes.

5. Personnel of reproductive capability shall confirm in writing that they understand the risk of handling HDs.

M. CONTAINMENT REQUIREMENTS

1. For dosage forms (tablets or capsules, solid intact medications) that are administered to patients without modification shall be handled as per assessment of risk.

2. The selected containment strategy (handling precautions) will be communicated to staff via Electronic Medical Record and auxiliary stickers or pharmacy labels.

3. The facility risk assessment shall be reevaluated annually.

N. In the event of a drug recall, the procedure found in SVMC policy DRUG RECALL PROCEDURE shall be followed.

O. The pharmacy maintains written policies and procedures for compounding and understands any material failure to follow the pharmacy's policies and procedures shall constitute a basis for disciplinary action by the Board of Pharmacy.

P. All medications used for compounding sterile products, both hazardous and nonhazardous, will be procured from a registered wholesaler or from an FDA registered manufacturer.

Q. Documentation Retention

1. All records of compounding and materials used to compound sterile preparations shall be maintained in a readily retrievable form for three (3) years from the date the record was last in effect.

U. Whenever a change in a policy or procedure occurs, the pharmacist-in-charge will notify the staff via a meeting or email. Staff shall sign off on changes acknowledging changes and intent to comply. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action by the Board of Pharmacy.

V. All policies related to sterile HD IV compounding will be reviewed annually by the pharmacist-in-charge, and recordation of the annual review shall be present on each policy and be readily retrievable upon request by the Board of Pharmacy.

1. The pharmacy will maintain records of the acquisition, storage, and destruction of any components used in compounding.

R. A pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist will be responsible for reviewing any tasks completed in the temporary absence, i.e., restroom break, etc.

REFERENCES:

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- "ASHP Guidelines on Handling Hazardous Drugs." *American Journal of Health-System Pharmacy* 63, no. 12 (June 15, 2006): 1172–1191. doi:10.2146/ajhp050529. Accessed: November 6, 2018.
- Occupational Safety and Health Administration (OSHA) Guidelines for Controlling Occupational Exposure to Hazardous Drugs Accessed 6/24/20.https://www.osha.gov/SLTC/hazardousdrugs/index.html.
- 2023 Lawbook for Pharmacy. Business and Professions Code 4000. https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf Accessed 3/2/2022.

CROSS REFERENCES:

- MEDICATION PROCUREMENT, STORAGE, DISTRIBUTION AND CONTROL
- IV PREPARATION AND DISPENSING
- COMPOUNDED STERILE PREPARATION: QUALITY ASSURANCE PROGRAM
- DRUG RECALL PROCEDURE
- STERILE PRODUCTS: STERILE PRODUCT QUALITY ASSURANCE

SUBJECT: **STERILE PRODUCTS:EDUCATION AND COMPETENCY**	SECTION: **Page 1 of 6**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To provide the necessary training and education of pharmacy personnel to promote preparation of pharmacy-prepared sterile products.

DEFINITIONS:

Validation: Documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

USP 797- United States Pharmacopeia (USP) is a quality organization that publishes acceptable standards for sterile preparations and "797" refers to the chapter that deals with sterile product quality benchmarking.

Category 1 CSP- A compounded sterile preparation (CSP) assigned a beyond use date (BUD) of 12 hours or less at controlled room temperature or 24 hours or less refrigerated. All sterile products compounded in the hospital pharmacy will not exceed a BUD of 12 hours as they are prepared in a segregated compounding area.

Category 2 CSP- A CSP 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 standards found in USP 797.

POLICY:

It is the policy of Sierra View Medical Center (SVMC) that the Pharmacist in Charge shall ensure that all personnel engaging in preparation and handling of sterile products will have training and demonstrated competence in the safe handling and compounding of sterile drug preparations. All sterile products will be prepared according to USP 797 standards by appropriately trained pharmacy personnel.

AFFECTED PERSONNEL/AREAS: *PHARMACY*

PROCEDURE:

A. Initial and annual education shall include at the minimum:

1. USP 797 and 800: Pharmacy personnel preparing or dispensing sterile products will receive didactic and experiential training. Personnel shall read core competencies assigned by the PIC and take a test based on the contents. A passing score will be 90%.

2. Calculations and terminology: A written test on calculations and terminology will be required annually and maintained in personnel files. A passing score is 90%.

3. Education of core skills shall include a review of:

   a. Contamination of critical area/ environmental monitoring

b. Proper use or movement of PEC, equipment, and supplies

c. Compounding and documentation

d. Quality assurance procedures as outlined in COMPOUNDED STERILE PREPARATION:QUALITY ASSURANCE PROGRAM

e. Non-pharmacy and pharmacy personnel cleaning

f. Process validation

g. Aseptic technique

h. Proper hand hygiene, gowning, gloving and garbing technique

i. General conduct

j. Decontamination (where applicable), cleaning, disinfecting, and maintaining of the PEC, equipment, and controlled area.

k. Principles of High Efficiency Particulate Air (HEPA) filtered air

B. Initial and bi-annual (every 6 months) competencies shall include at the minimum:

1. Garbing and Hand Hygiene

i. Initial evaluation will be done immediately following initial hand hygiene and garbing procedure, each individual shall complete a gloved fingertip and thumb (GFT) sampling procedure (zero CFUs both hands) at least three times before being initially allowed to compound sterile drugs.

ii. Sampling must occur after garbing but before applying sterile 70% IPA to gloves.

2. Aseptic manipulation confirming sterile technique shall also be performed every 6 months. This process evaluates practical skills of personnel's sterile technique by utilizing a culture from multiple aseptic procedures upon a sterile broth medium, i.e., media fill test.

i. Surface sampling immediately after aseptic manipulation

C. Recertification of competencies including GFT sampling, media fill, garbing and hand hygiene, aseptic technique shall be done every 6 months after initial competency.

- Subsequent GFT sampling will be done once, not thrice like during the initial evaluation. Failure is indicated if the samples exceed 3 CFUs total.
- A visual observation will be conducted and documented.
- All records will be maintained on file in the pharmacy for at least three years.

D. Personnel who fail written tests regarding hand hygiene, garbing, and aseptic technique; gloved fingertip sampling; or media-fill test;

1. Must undergo immediate requalification and pass with 90% before they can resume compounding.

E. Personnel who fail any visual observation of hand hygiene, garbing, and aseptic technique; gloved fingertip sampling; or media-fill test;

1. Must repeat and pass the evaluation in the deficient area(s) before they can resume compounding.

F. After a pause in compounding-related activities (including but not limited to compounding & quality assurance monitoring)- Personnel who have not compounded in 6 months must be requalified. If the pause exceeds 6 months, that person will be treated as a new employee.

G. Competencies can be completed in approximately 8 weeks of the due date.

H. Routine performance checks shall occur to ensure adherence to aseptic policies and procedures.

I. All policies and procedures pertaining to sterile compounding shall be reviewed by all staff annually or when there are changes to any of the policies. All staff shall sign off on education of these policies and acknowledge that any material failure to follow the policies and procedures shall constitute a basis for disciplinary action by SVMC and/or the Board of Pharmacy.

J. Personnel Cleansing and Garbing

1. Personnel experiencing rashes, sunburns, weeping sores, oozing tattoos, conjunctivitis, or active respiratory infections or other communicable diseases shall not compound sterile products until their conditions have resolved.

2. Compounding personnel shall not wear cosmetics, hand, wrist, or other visible jewelry, artificial nails, or extenders. Cover any jewelry that cannot be removed. Natural nails shall be kept neat and trimmed. Remove head phones, ear buds, cell phones, bandanas, coats, hats, jackets, scarves, sweaters, and vests while compounding.

3. In preparation for entering the ante room, personnel shall first don shoe covers, hair covers, and facial covers.

4. Hand Hygiene

   a. Remove debris from under fingernails, if present. Use a nail cleaner (pick) under warm water.
   b. Hands and forearms shall be washed vigorously with soap and water for at least 30 seconds.
   c. Dry hands and forearms up to the elbows with low-lint disposable towels.
   d. Immediately before donning sterile gloves, apply a suitable alcohol-based hand rub, Sterillium©. Allow a sufficient time and amount of product to keep hands wet for manufacturer specified application time, at least 3 minutes.
   e. Allow hands to dry thoroughly before donning sterile gloves.
   f. After donning sterile gloves, apply sterile alcohol 70% to outside of gloves and allow alcohol to dry.

5. Gowns

   a. For a Category 2 with a CACI/Hood: A clean non-shedding gown dedicated to use in the compounding area shall be donned next.

   b. For a Category 1: A sterile gown or low-lint gown with sterile sleeves shall be donned next.

   c. Visibly soiled gowns must be changed immediately. Gowns and garbing items must be segregated and stored before use in an enclosure to prevent contamination (away from sinks to avoid splashing).

   d. Sterile gowns may be reused within the same shift by the same person if they are maintained in a manner that prevents contamination. This privilege does not apply to hazardous drugs.

6. Garbing and de-garbing shall not occur in the ante-area at the same time.

7. After gowning, sterile gloves shall be donned. If sterile sleeves are used, then they are donned after sterile gloves.

8. Once inside the compounding area, hands will be disinfected with an alcohol-based hand scrub.

9. Gloves will be disinfected with 70% IPA prior to entering the glovebox and anytime hands are removed and placed back into the glovebox.

10. Gloves that are in contact with non-sterile surfaces will be disinfected with 70% isopropyl alcohol.

K. Doffing Procedure when Exiting Hazardous Drug Compounding Area

i. Remove outer pair of HD gloves and place in HD waste container.
ii. Remove outer pair of booties and place in yellow HD waste container.
iii. Remove the HD gown and place in yellow HD waste container.
iv. Remove inner pair of HD gloves and place in HD waste container.
v. Exit HD buffer room, enter clean side of anteroom, and go to the sink.
vi. Remove bouffant/mask and discard in yellow HD waste container under the sink.
vii. Wash hands as stated above.
viii. Remove booties and step across LOD.
ix. Use Sterillium© gel.

L. Conduct

1. Food, drinks, and cardboard will not be permitted in the SCA or cleanroom suites.

2. Actions such as talking and coughing should be directed OUT of the SEC.

3. Unnecessary motion in the SEC should be avoided to minimize turbulence of air flow.

4. Activities in the SEC should only be related to procedures for parenteral preparations.

M. On cleaning the SCA, pharmacy personnel will be trained on:

1. Using the appropriately-labeled cleaner and disinfectant for the types of surface to be cleaned (floor, wall, etc.)

2. Following garbing procedures when cleaning in the SCA.

3. Mopping floors with a pharmacy-specific mop used ONLY for floors. The mopping should start at the wall opposite the entry room door. Mop the floor with even strokes toward the operator. The applied agent (Ecolab- hospital grade germicidal) shall remain visibly wet for 10 minutes, i.e., dwell time.

4. Cleaning the sink and all contact surfaces.

5. Cleaning of walls top to bottom, ceilings left to right toward the operator.

6. Cleaning of shelves, bins, buffer area chair, exterior of trash bins.

7. Documenting all cleaning.

N. On cleaning the CAI/hood, pharmacy personnel will be trained as follows:

1. When properly garbed, the pharmacy technician will, at a minimum twice a day, when there is a spill, or prior to preparing a new sterile product:

a. Wipe down the entire CAI/Hood chamber with sterile water.

- Using long strokes left to right on the bottom and top surfaces and long strokes top to bottom progressing towards the operator on the vertical sides of the CAI/Hood.
- This process will be repeated with 70% sterile alcohol and Peridox ©.

b. This procedure will be used for the application of germicidal and sporicidal agents (Peridox ©, with a dwell time of at least 3 minutes) as well. The daily, weekly and monthly cleanings shall NOT overlap and will be performed separately.

O. Cleaning competencies will be assessed with a written test and a visual observation annually. Records will be kept for three years.

P. Record Keeping

Records of training and demonstrated competency shall be maintained for each individual for at least three years.

Q. Whenever a change in a policy or procedure occurs, the pharmacist-in-charge will notify the staff via a meeting or an email. Staff shall sign off to acknowledge the change(s) with the intent to comply. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action by the Board of Pharmacy.

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- USP 797. (n.d.). Retrieved July 14, 2023, from http://www.usp.org/compounding/general-chapter-797.
- USP 800. (n.d.). Retrieved July 14, 2023, from http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

CROSS REFERENCES:

COMPOUNDED STERILE PREPARATION: QUALITY ASSURANCE PROGRAM

SUBJECT: **STERILE PRODUCTS: STERILE PRODUCT QUALITY ASSURANCE**	SECTION: **Page 1 of 17**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To provide procedures to ensure that compounded sterile preparations (CSPs) prepared at Sierra View Medical Center (SVMC) are of high quality and sterility.

DEFINITIONS:

Biological Safety Cabinet (BSC), Class II – A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.

Beyond-use date (BUD) – 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.

Category 1 CSP – A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated

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

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 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.

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.

ISO Class 5 - An airborne-particulate standard that states there are no more than 3,520 particles of at least 0.5-microns in size per cubic meter.

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.

Primary engineering control (PEC) - A device or zone that provides an ISO Class 5 or better environment through the use on non-turbulent air, unidirectional HEPA-filtered first air for compounding sterile preparations.

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 include CAIs and CACIs.

Secondary Engineering Control (SEC) – The area where the PEC is placed (e.g., a cleanroom suite or an SCA).

Segregated Compounding Area (SCA) - Space designated for sterile-to-sterile compounding where a PEC is located within a demarcated area (of at least 3 foot perimeter). This area will be void of activities and materials extraneous to sterile compounding. This area shall not be in a location that has unsealed windows or doors that connect to outdoors, location with high traffic flow, or adjacent to food preparation areas or construction. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.

USP 797 - United States Pharmacopeia (USP) is a national quality agency that creates the sterile product quality standards. The "797" designation is the chapter that relates specifically to the sterile product environment.

POLICY STATEMENT:

It is the policy of SVMC that all compounded sterile preparations (CSPs) will adhere to USP 797 standards of practice. No CSP shall be compounded if it is known, or reasonably known, that the environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of CSPs.

PROCEDURE:

I. SVMC will administer aseptic manipulation competency evaluations to ensure a quality product.

A. The evaluation consists of the following:
   a. Visual observation
   b. Media-fill testing
   c. Gloved fingertip and thumb (GFT) sampling on both hands
   d. Surface sampling of the direct compounding area

B. Process validation is assured by using simulated production of the aseptic processes in use at SVMC, substituting growth media for medications to check sterility.

C. All staff responsible for CSPs must be trained in aseptic technique and demonstrate competency by direct observation and successful passing of a media-fill test.

D. Aseptic technique will be monitored and critiqued. Retraining will be considered if major technique violations are seen. Major violations may include:

1. Violations of gowning, gloving and hand-washing policy

2. Touching of critical sites

3. Failure to wipe stoppers

4. Failure to work within proper hood area

5. Blockage of "first air" to critical sites

6. Failure to clean hood properly and keep clean during compounding

E. Gloved fingertip sampling

Initial Competencies	Subsequent Competencies
Visual observation of hand hygiene and garbing (3 times)	Visual observation of hand hygiene and garbing (1 time)
GFS after visual observation of hand hygiene and garbing (3 times)	GFS after visual observation of hand hygiene and garbing (1 time)
Media-fill test	Media-fill test
GFS after the media-fill test	GFS after the media-fill test
Surface sample in the DCA after the media-fill test	Surface sample in the DCA after the media-fill test

Note: GFT sampling shall occur after production of CSPs but before sterilization with alcohol.

F. An actionable level is a CFU count (from both hands) greater than zero after garbing and greater than 3 CFUs after media-fill testing.

1. Employee will be retrained in hand-hygiene, garbing, glove and surface disinfection and conduct in compounding area. Sampling will be repeated and didactic testing repeated.

2. Actionable levels will result in removal from compounding duties and require retraining.

3. Repeated actionable levels will require complete retraining and removal from compounding until sampling meets minimum standards. Root cause for repeat positive sampling will be sought out by the pharmacist-in-charge.

II. The sterile-compounding areas will be cleaned as per USP 797 established standards. All cleaning materials must be non-shedding and dedicated to use in compounding areas and shall not be removed except for disposal.

A. Cleaning of the compounding areas must be documented on a cleaning log.

B. Minimum cleaning frequency

Site	Cleaning	Disinfecting	Sporicidal
PEC(s) and equipment inside the PEC(s)	Daily and when surface contamination is known or suspected	Daily and when surface contamination is known or suspected	Monthly for entities compounding Category 1 or 2 CSPs
Removable work tray of the PEC	Daily on days when compounding occurs Monthly on all surfaces and the area underneath the work tray	Daily on days when compounding occurs Monthly on all surfaces and the area underneath the work tray	Monthly on all surfaces and the area underneath the work tray
Pass-through chambers	Daily on days when compounding occurs	Daily on days when compounding occurs	Monthly for entities compounding Category 1 or 2 CSPs
Work surface(s) outside the PEC	Daily on days when compounding occurs	Daily on days when compounding occurs	
Floor(s)	Daily on days when compounding occurs	Daily on days when compounding occurs	
Wall(s), plastic curtain(s), door(s), and door frame(s)	Monthly	Monthly	Monthly
Ceiling(s)			
Storage shelving and bin(s)			
Equipment outside the PEC(s)			

C. Disinfection of a PEC will be executed with sterile water, sterile 70% isopropyl alcohol (cleaning and disinfecting), and sporicidal Peridox RTU © (agent must be applied and be visibly wet for 3 minutes)

D. Sterile 70% isopropyl alcohol must also be applied in the follow scenarios:
   a. At the beginning of each shift and at the end of each shift
   b. After a spill
   c. At least every 30 minutes if the compounding process takes 30 minutes or less
   d. Immediately after when compounding activities exceed 30 minutes, or
   e. When surface contamination is known or suspected

E. Daily mopping of the floor using a clean/non-shedding mop. Mop must be kept in the SCA or buffer area and only be used for cleaning the buffer area floor. Mopping will be done by trained personnel using approved cleaning agents and will mop in a direction from clean area to dirty area. To ensure proper contact time, the mopped floor must remain visibly wet for 10 minutes.

F. Competency records of housekeeping staff will be kept in pharmacy for a minimum of three years after employment.

G. Weekly cleaning

   1. Hoods must be disinfected using an approved disinfecting agent, Peridox© will be used (agent must be applied and be visibly wet for 3 minutes). Use of this agent will occur after the use of sterile water and sterile 70% alcohol.

H. Monthly cleaning

   A. In addition to above cleaning, all surfaces in ISO classified areas or segregated compounding area will be wiped with sterile water and then sterile 70% alcohol including the inside of storage bins, carts, wheels, outside of hood, and wire racks, shelves, walls and ceilings, stools, and all other items in segregated compounding area

   B. A sporicidal will be used on the entire room and outside AND inside the RABS or BSC. SVMC will use Peridox© (agent must be applied and be visibly wet for 3 minutes).

I. Fixed glove assembly will be changed at least every 6 months or:

   1. When there is a visible tear;

   2. When a positive culture is obtained from sampling;

   3. When there is suspected contamination of product

IV. Certification or recertification

A. **Classified areas and PEC(s) will be recertified every six months by an outside agency**. During certification, the agency will evaluate the following:

1. Airflow testing
2. HEPA filter integrity testing
3. Total particle count testing
    a. Failure to meet ISO standards will be immediately addressed PRIOR to the vendor testing the PEC or before leaving SVMC.
    2. Corrective actions may include the following:
        - Replacing HEPA filters
        - Re-measuring the airborne particle count
        - Searching for mechanical causes
4. Dynamic airflow smoke pattern test

B. In addition, classified areas will be recertified in the following circumstances:

1. Classified area was redesigned
2. Classified area was constructed
3. Any PEC was replaced or relocated
4. Configuration of the room was altered that could affect airflow or air quality

C. A corrective action plan will be implemented in response to any out-of-range results.

D. Decontamination and terminal cleaning of PEC and SEC will occur immediately AFTER recertification.

V. Viable Sampling

A. The Department of Pharmacy or an outside agency will conduct viable surface and air sampling at least every one and six months, respectively.

1. In addition, sampling must be performed in the following circumstances:

a. In conjunction with the certification of new facilities and equipment

b. After any servicing of facilities or equipment

c. In response to identified problems (e.g. positive growth in sterility tests of CSPs)

d. In response to identified trends (e.g. repeated positive GFT sampling results, failed media fill testing, or repeated observations of air or surface contamination

2. Surfaces include PEC surfaces, surfaces of all classified areas, and pass-through chambers connecting to classified areas.

B. An actionable level of colony-forming units (CFUs) upon viable surface sampling is:

1. Action Levels for Surface Sampling

ISO Class	Surface Sampling Action Levels (CFU/Plate)
5	>3
7	>5
8	>50

C. An actionable level of CFUs upon viable air sampling shall be:

1. Action Levels for Air Sampling

ISO Class	Air Sampling Action Levels (CFU/m^3)
5	>1
7	>10
8	>100

D. Any actionable level in the PEC will result in the following action(s):

1. Immediate cessation of activity in the PEC.
2. Immediate cleaning and disinfecting of PEC and SEC.
3. Resampling of affected area after cleaning and disinfecting is completed.
4. Evaluation of engineering controls.
5. Communication with Infection Control and expert infectious disease consultation.
6. Communication with Risk Department and investigation for any product potentially-contaminated.
7. Review of cleaning and compounding operations and facility management.
    a. If levels measured exceed above action levels, an investigation and corrective action must be taken to prevent future deviations.
    b. Corrective action plans may include a change in procedure, facility, or equipment.

E. Any actionable level outside the PEC will result in the following action(s):

1. Investigate the cause.
2. Implement corrective action.
3. Evaluate the trend if data is available.
4. Resample the failed area to confirm corrective action was successful.
5. Attempt to identify microorganisms recovered to the genus level.

F. If needed, the following technique will be used when collecting viable surface samples to monitor environmental sterility:

1. A surface sampling media device will have a raised convex surface. Samples will be collected as follows (See Appendix A for diagram):

a. RABS – Interchamber and Main Chamber
b. BSC – Main Chamber

2. Using a rolling motion, firmly press the media surface onto the surface to be sampled. Remove the media device and cover. Clean and disinfect the sampled area.

3. Invert the media plates to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the CFU reading.

4. Label the plates with the date, time, and location of the sample followed the staff member's initials. Send the media devices to the Laboratory Department for analysis.

   a. Incubate the media device(s) at 30 – 35 degrees Celsius for at least 48 hours. Examine for growth and record identified colonies, CFU per media device, sample type, sample location, and sample date.

   b. Incubate the media device(s) at 20 – 25 degrees Celsius for at least 5 additional days. Examine for growth and record identified, CFU per media device, sample type, sample location, and sample date.

5. At the end of the incubation period, the pharmacy director or his designee will retrieve results utilizing the electronic medical record (EMR) and document the results.

6. Any positive result will be included in the quarterly Sterile Products report presented to the Pharmacy, Therapeutics and Infection Prevention Committee.

G. If needed, the following technique will be used when collecting viable air samples to monitor environmental sterility:

1. An air sampling media device will be a fingertip testing contact plate. Samples will be collected in the same area that the outside agency had sampled.

2. Operate a calibrated impaction air sampler to collect 1000 Liters of air from each location sampled. Remove the media device and cover.

3. Invert the media plates to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the CFU reading.

4. Label the plates with the date, time, and location of the sample followed the staff member's initials. Send the media devices to the Laboratory Department for analysis.

a. Incubate the media device(s) at 30 – 35 degrees Celsius for at least 48 hours. Examine for growth and record identified colonies, CFU per media device, sample type, sample location, and sample date.

b. Incubate the media device(s) at 20 – 25 degrees Celsius for at least 5 additional days. Examine for growth and record identified, CFU per media device, sample type, sample location, and sample date.

5. At the end of the incubation period, the pharmacy director or his designee will retrieve results utilizing the electronic medical record (EMR) and document the results.

6. Any positive result will be included in the quarterly Sterile Products report presented to the Pharmacy, Therapeutics and Infection Prevention Committee.

VIII. Quality Assurance/ Quality Control Testing

IX. Random monitoring of sterile technique along with fingertip glove sampling or end product testing will occur at the end of production monthly as needed.

A. Different personnel should be sampled with a goal of each employee being monitored yearly.

XI. Sterility verification of an end product will occur monthly.

A. A random IV that had been made at least one day prior will be chosen.

B. In the event of a positive culture:

1. The physicians involved in that patient's care and infection control officer will be notified of possible exposure as well as organism(s) involved in order to evaluate the patient.

2. Organism will be identified and reported to Infection Control.

3. Technician who compounded IV will be retrained in hand hygiene, garbing, gloving, and surface disinfection. Fingertip and end product testing will be repeated under observation for technique. Technician will stop making sterile products until a negative test is obtained.

4. If repeat testing results in a positive response, the technician will be removed from compounding duties and completely retrained.

5. In addition to the above, if the product is a batched product where more than one dose of a preparation has been made:

- The lot number of the product will be identified
- Potential patients exposed to contaminated product will be identified using dispensing and administration records
- The physicians involved in that patient's care and infection control officer will be notified of possible exposure as well as organism(s) involved in order to evaluate the patient.

C. Risk, Infection Control and Chief Nursing Officer will be immediately informed.

XIII. Quantification testing shall be performed at a minimum of twice a year to ensure product integrity and to validate labeled strength.

A. A random CSP will be sent out to a qualified laboratory to test for potency, endotoxin, and sterility. Pharmacy will follow the process outlined by the contracted laboratory.

B. If the drug sample is identified as below any standards for integrity, potency, quality, or labeled strength:

a. The technician and pharmacist making/checking the product will be removed from sterile product processing and retrained

b. A complete analysis of the compounding process will occur.

c. An additional product will be sent out for validation.

C. All of the above steps will be performed and BUD dating will be confirmed by using standard reference materials and research.

XIV. Compounding Room Temperature and Lighting

A. The sterile compounding area shall have a well-lit working environment.

B. A room temperature of 68 degrees Fahrenheit and humidity below 60% is ideal for sterile compounding. The temperature and humidity will be recorded daily.
   i. In the event of a temperature excursion:
      1. Engineering will be contacted for temperature or humidity correction.
   ii. Pharmacist-in-Charge will be notified.
   iii. If temperature > 40 degrees Celsius for at least 4 hours, any CSP exposed to these conditions will be discarded.

XV. Pressure Differential

a. A minimum of 0.02-inch water column is required for positive pressure to separate each ISO classified area, except in segregated compounding areas.
b. Negative pressure will be negative 0.01 to negative 0.03 inches of water.
c. A pressure gauge or velocity meter will be used to monitor airflow between the following paired areas:
    a. Ante-area and buffer areas
    b. Ante area and outside the cleanroom suite
    c. RABS and the SCA.
d. The pressures will be documented and reviewed daily or by a continuous monitor.

XVI. In the event of a product recall, SVMC will follow the established policy of DRUG RECALL PROCEDURE

XVII. All records will be retained for a minimum of three years.

XVIII. Whenever a change in a policy or procedure occurs, the pharmacist in charge will notify the staff via a meeting or email. Staff shall sign off on changes, acknowledging changes and intent to comply. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action by the Board of Pharmacy.

EDUCATION:

SVMC Pharmacy Staff: All pharmacists and pharmacy technicians will receive education regarding the preparation of pharmacy-prepared IV admixtures.

REFERENCES:

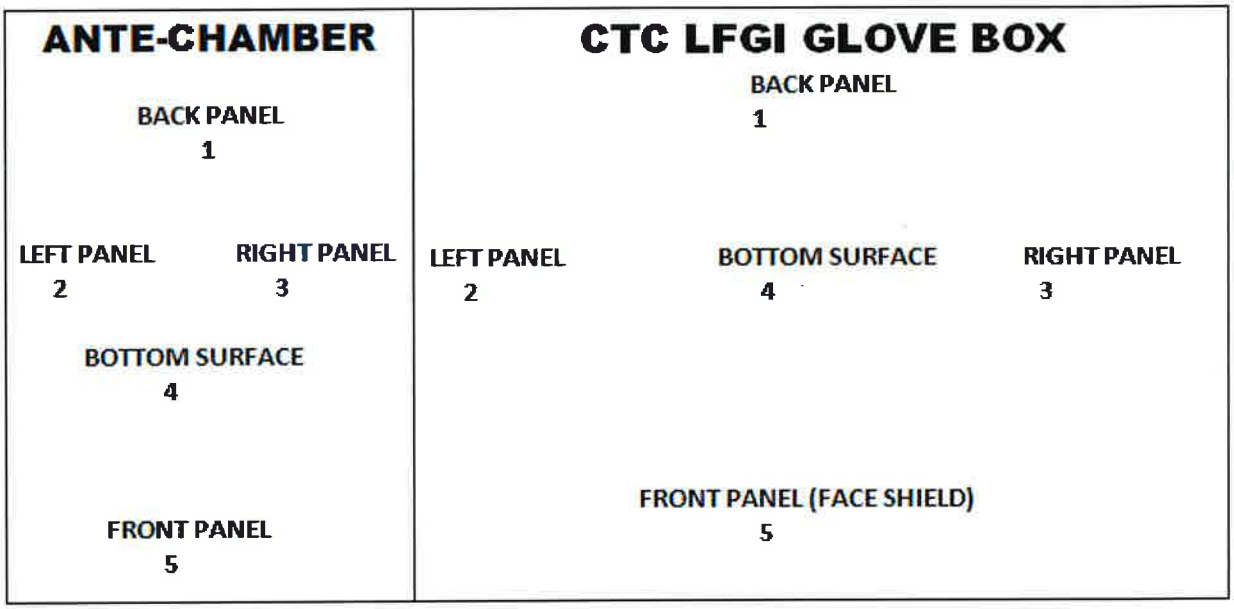
- The Joint Commission (2023). Hospital accreditation standards. Joint Commission Resources. Oak Brook, IL.
- Pharmacy Law: California Edition. (2023) San Clemente, California: Law Tech Publishing Group.
- USP 797.(n.d.). from http://www.usp.org/compounding/general-chapter-797.
- CCR 1751.4 Facility and Equipment Standards for Sterile Compounding. Retrieved November 24, 2021, from https://www.law.cornell.edu/regulations/california/16-CCR-Sec-1751-4.

CROSS REFERENCES:

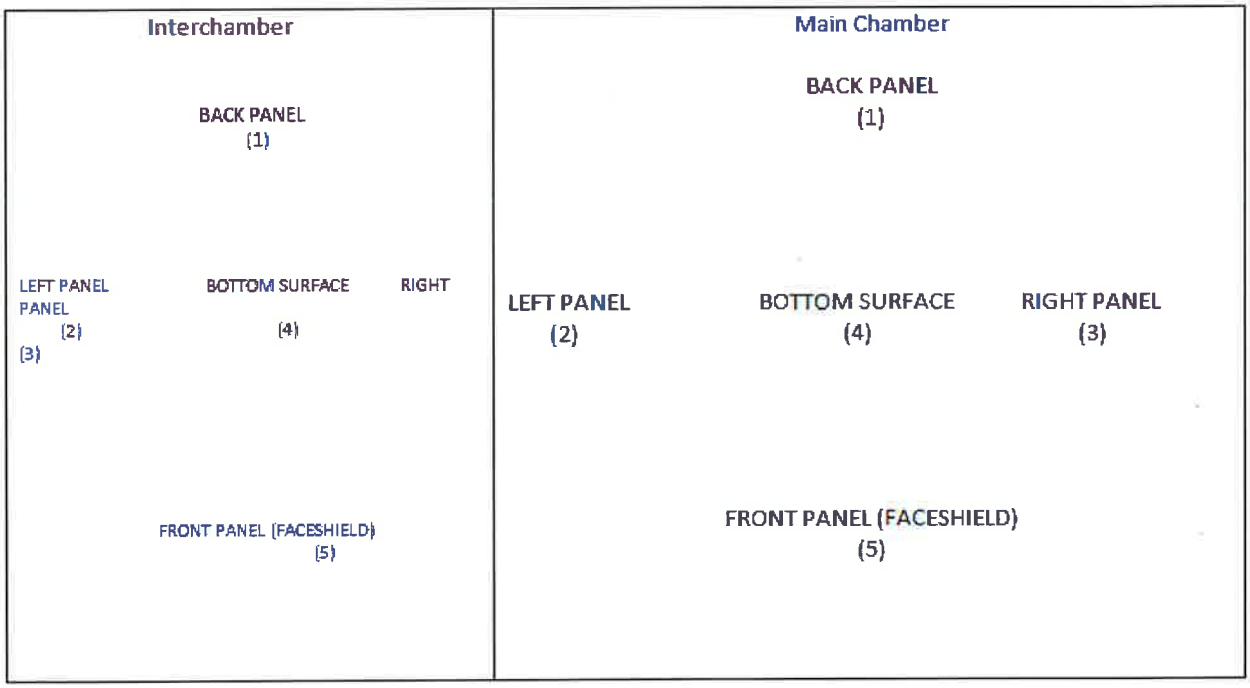
- DRUG RECALL PROCEDURE

APPENDIX A (See attachment)

Map of GERMFREE LAMINAR FLOW GLOVEBOX ISOLATOR - CTC



Map of NuAire COMPOUNDING ASEPTIC ISOLATOR – Main Pharmacy



SUITE "B" POSITIVE & NEGATIVE PRESSURE HOODS ENVIRONMENTAL SAMPLING MAP

NUAIRE HOOD

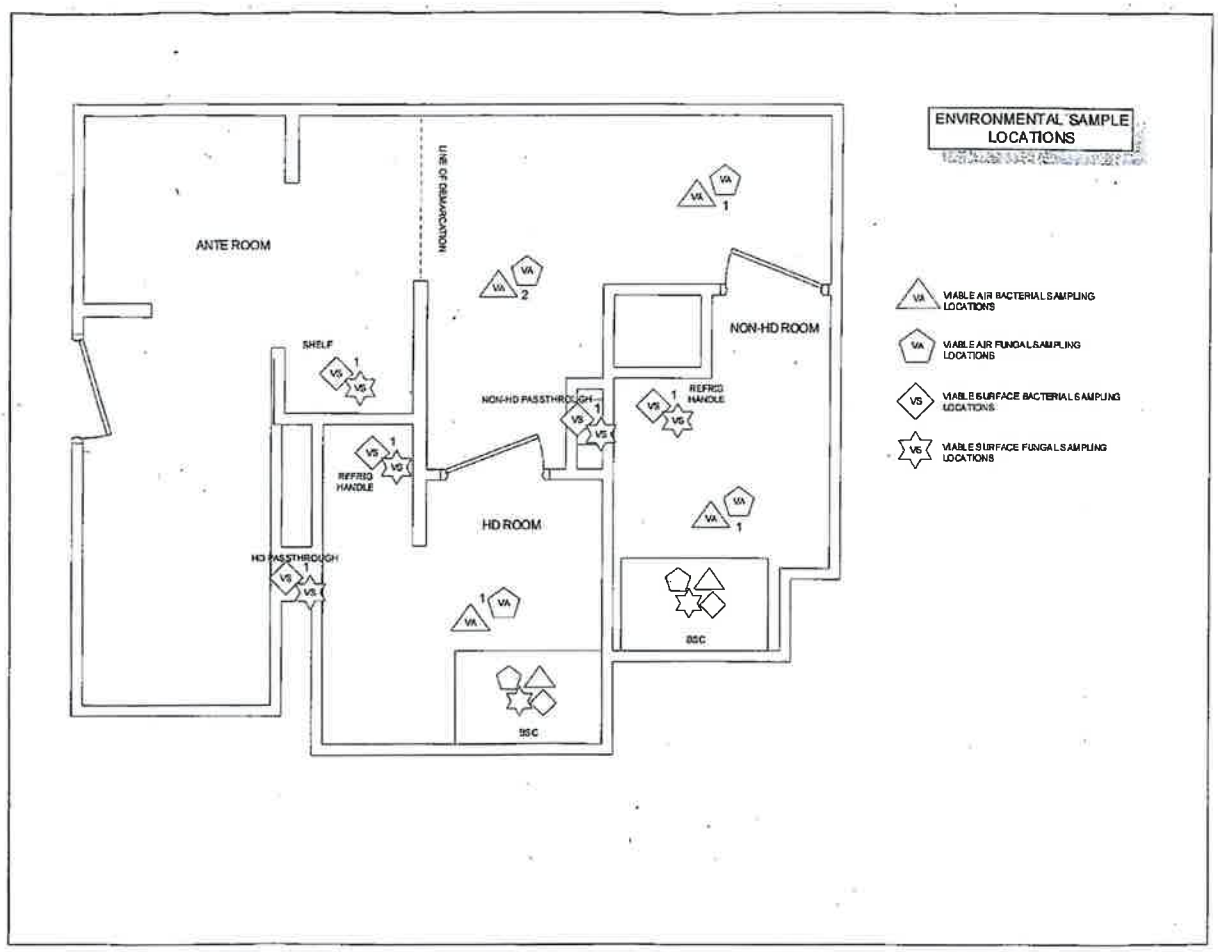
BACK PANEL
2

LEFT PANEL
1

BOTTOM PANEL
3

RIGHT PANEL
4

FRONT PANEL
5


ENVIRONMENTAL SAMPLE LOCATIONS
ANTE ROOM
LINE OF DEMARCATION
SHELF
NON-HD PASSTHROUGH
REFRIG HANDLE
HD ROOM
HD PASSTHROUGH
NON-HD ROOM
REFRIG HANDLE
BSC
BSC
VIABLE AIR BACTERIAL SAMPLING LOCATIONS
VIABLE AIR FUNGAL SAMPLING LOCATIONS
VIABLE SURFACE BACTERIAL SAMPLING LOCATIONS
VIABLE SURFACE FUNGAL SAMPLING LOCATIONS

SUBJECT:	SECTION:
VENOUS BLOOD COLLECTION	**Page 1 of 2**

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

PURPOSE:

To instruct personnel of the proper procedure for collecting a specimen via venipuncture.

SYNONYMS:

Venipuncture, phlebotomy, venous blood collection.

CONTAINER:

Syringe with 20-21 gauge needles for volumes to 10 ml. Vacutainer or similar system for multiple specimens or anticoagulants.

AFFECTED AREAS/PERSONNEL: *ALL CLINICAL EMPLOYEES*

PROCEDURE:

1. Verify the patient's identity using two identifiers.
2. Cleanse hands. Put on fresh pair of gloves.
    a. Apply tourniquet.
3. Select a suitable site for venipuncture. Prepare the site by scrubbing with 70% alcohol (isopropanol). Dry with sterile gauze.
4. Cleanly puncture the skin.
5. Apply gentle suction.
6. Release the tourniquet.
7. Remove the needle and fill the tubes without delay.
8. Gently invert the tubes 10 times to assure mixing of anticoagulants.
9. Aftercare:
    a. Apply pressure to the venipuncture site and elevate the arm until bleeding stops. If bleeding persists, apply a pressure dressing to the site.
10. Limitations:
    a. Venipuncture is technically difficult in obese patients, infants, children and patients with collapsed veins, such as those in shock. Hemolysis may occur as a result of excessive

suction during collection, violent mixing of specimen, or vigorous transfer of the specimen from syringe to tube.

NOTES: See individual test for specific collection requirements.

REFERENCE:

- Turgeon, Mary Louise, Linne and Ringstrud's Clinical Laboratory Science, 8th Edition, 2019.

Date and time of call_____ Patient Name_____

Patient Age and Date of Birth _____Transferring Facility_____

Caller Name and Position_____ Caller Ph#_____

Transferring Physician_____

SVMC Staff receiving call_____

Services being requested to support patient_____

Pt Accepted Y/N_____ If No, please give the reason the patient was not accepted, then fax this form to 559-791-3818 and leave copy in folder in Transfer Center Office (Do not complete remainder of form if patient is not accepted)

_____

_____

_____

If Patient is accepted, please provide the following information:

Diagnosis_____Level of Care:_____Intubated Y/N_____

Most Recent Vital Signs: Time taken _____HR _____BP_____ Resp rate_____

O2 Sat_____O2 Delivery Mechanism _____

COVID Test Date/results_____ Isolation?_____ GCS of: _____

Code Status_____ Advanced Directives in place Y/N_____

Family Decisions Maker/Proxy identified_____

Decision makers contact info_____

Initial when completed below:

_____Is the patient stable for transfer? Ground or Air?_____

_____ Acuity of Patient is appropriate for SVMC (Clinical and Specialty/Consult is available and can be provided by SVMC)

PATIENT'S LABEL

_____ Staffing on desired unit is available (Approved by Charge Nurse and/or Housing Nurse Supervisor)

_____Resident/Hospitalist/Intensivist is aware and in agreeance (ensure they see and read entire clinical picture from Medical Chart provided from transferring facility, and a Doc to Doc conversation has happened)

_____Accepting Physician _____

_____Specialty Consult needed, must be approved in same manner as Hospitalists and/or the Intensivists have done above

_____Accepting Specialty Physician_____

_____Orders are written and with Registration (Y/N)

_____Financial department has patient Demographics and insurance coverage information and given financial clearance M-F 8-5. (this step is bypassed for Emergent cases)

_____CM/SS Manager has been notified and provided a copy of the patient packet (this step is bypassed for Emergent cases)

_____Utilization Management Director has been notified (this step is bypassed for Emergent cases)

_____If after hours was AOC notified (Y/N)

_____Transfer Back Agreement signed by transferring facility and received

Bed Assigned: _____RN assigned to receive report/ext #_____

Date Bed Assigned_____ Date being transported to us_____ Time_____

Date and Time Patient was Received by SVMC_____

Notes: _____

Form Completed By:

Printed Name	Signature	Date & Time
_____	_____	_____
_____	_____	_____

PATIENT'S LABEL

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MINUTES OF A REGULAR MEETING OF THE BOARD OF DIRECTORS OF SIERRA VIEW LOCAL HEALTH CARE DISTRICT

The regular meeting of the Board of Directors of Sierra View Local Health Care District was held **September 26, 2023 at 5:00 P.M.** in the Sierra View Medical Center Board Room, 465 West Putnam Avenue, Porterville, California

Call to Order: Chairman REDDY called the meeting to order at 5:04 p.m.

Directors Present: **REDDY, LOMELI, MARTINEZ, PANDYA, KASHYAP**

Others Present: Blazar, Dan, Patient Experience Officer, Canales, Tracy, VP of Human Resources, Dickson, Doug, Chief Financial Officer, Dorwart, Stephanie, Altius, Franer, Julie, Admin Director of Revenue Cycle, Gomez, Cindy, Director of Compliance, Hefner, Donna, President/Chief Executive Officer, Hudson, Jeffery, VPPCS/CNO/DIO, Mandujano-Roberts, Silvia, Manager of Care Integration for Social Services and Case Management, Nelson, Michael, Darden Architects, Pryor-DeShazo, Kimberley, Director of Marketing, Reed-Krase, Alex, Legal Counsel, Sandhu, Harpreet, Chief of Staff, Wallace, Marcella, Director of Communications, Watts, Whitney, Executive Assistant and Clerk to Board of Directors, Wheaton, Ron, VP Professional Services and Physician Recruitment, Wilbur, Gary, Admin Director of General Services

I. Approval of Agenda:

Chairman REDDY motioned to approve the Agenda. The motion was moved by Director PANDYA, seconded by Vice Chairman LOMELI, and carried to approve the agenda. The vote of the Board is as follows:

REDDY	Yes
LOMELI	Yes
MARTINEZ	Yes
PANDYA	Yes
KASHYAP	Yes

II. Closed Session: Board adjourned Open Session and went into Closed Session at 5:04 p.m. to discuss the following items:

A. Pursuant to Evidence Code Section 1156 and 1157.7; Health and Safety Code Section 32106(b): Chief of Staff Report

B. Pursuant to Evidence Code Section 1156 and 1157.7:

1. Evaluation- Quality of Care/Peer Review/Credentials

2. Quality Division Update

D. Pursuant to Gov. Code Section 54962; Health and Safety Code Section 32106(b): Discussion Regarding Trade Secrets. Estimated Date of Disclosure – February 2025

Closed Session Items C, and E-H were deferred to the conclusion of Open Session as there was not time for discussion prior to Open Session.

III. Open Session: Chairman REDDY adjourned Closed Session at 5:35 p.m., reconvening in Open Session at 5:35 p.m.

Pursuant to Gov. Code Section 54957.1; Action(s) taken as a result of discussion(s) in Closed Session.

A. Chief of Staff Report provided by Chief of Staff Sandhu. Information only; no action taken.

B. Pursuant to Evidence Code Section 1156 and 1157.7:

1. Evaluation – the Quality of Care/Peer Review

Following review and discussion, it was moved by Director PANDYA, seconded by Vice Chair LOMELI, and carried to approve the Quality of Care/Peer Review as presented. The vote of the Board is as follows:

REDDY	Yes
LOMELI	Yes
MARTINEZ	Yes
PANDYA	Yes
KASHYAP	Yes

2. Quality Division Report

Following review and discussion, it was moved by Director PANDYA, seconded by Vice Chair LOMELI, and carried to approve the Quality Division Report as presented. The vote of the Board is as follows:

REDDY	Yes
LOMELI	Yes
MARTINEZ	Yes
PANDYA	Yes
KASHYAP	Yes

D. Discussion Regarding Trade Secret

Following review and discussion, it was moved by Director PANDYA, seconded by Vice Chair LOMELI, and carried to approve continued engagement with Altius Healthcare Consulting Group as presented. The vote of the Board is as follows:

REDDY	Yes
LOMELI	Yes
MARTINEZ	Yes
PANDYA	Yes
KASHYAP	Yes

IV. Public Comments

None.

V. Consent Agenda

The Medical Staff Policies/Procedures/Protocols/Plans and Hospital Policies/Procedures/Protocols/Plans were presented for approval (Consent Agenda attached to the file copy of these Minutes). It was moved by Director MARTINEZ, seconded by Vice Chair LOMELIL, and carried to approve the Consent Agenda as presented. The vote of the Board is as follows:

REDDY	Yes
LOMELI	Yes
MARTINEZ	Yes
PANDYA	Yes
KASHYAP	Yes

VI. Approval of Minutes:

Following review and discussion, it was moved by Director PANDYA and seconded by Vice Chair LOMELI to approve the August 22, 2023 Regular Board Meeting Minutes as presented. The motion carried and the vote of the Board is as follows:

REDDY	Yes
LOMELI	Yes
MARTINEZ	Yes
PANDYA	Yes
KASHYAP	Yes

VII. CEO Report

Donna Hefner, President/CEO provided a report of activities and happenings around Sierra View:

In the District:

- Our Emergency Department, Maternal Child Health Department and a collaboration of several departments have been participating in patient safety initiatives through the BETA Healthcare Group (BETA), one of the largest insurers of healthcare professional liability coverage in California.

- Join the Sierra View Foundation on October 14th, 2023 to Rock N Roll for a Cause!

- The annual Run for Life hosted by the Porterville Breakfast Rotary Club was an absolute HIT! 364 runners laced up their sneakers, hit the pavement, and made a significant impact in the fight against cancer.

- Our second Unitek Cohort kicked off their nursing journey at SVMC! Sierra View Medical Center's Nursing Education Pathway, Powered by Unitek College allows our employees to pursue their dreams of becoming registered nurses while continuing to serve our wonderful community.

VIII. Business Items

A. August 2023 Financials

Doug Dickson, CFO presented the Financials for August 2023. A copy of this presentation is attached to the file copy of these minutes.

Total Operating Revenue was $13, 452, 644. Supplemental Funds were $1,399,984. Total Operating Expenses were $14,233,613. Loss from operations of $780,969.

Following review and discussion, it was moved by Director PANDYA, seconded by Vice Chair LOMELI and carried to approve the August 2023 Financials as presented. The vote of the Board is as follows:

REDDY	Yes
LOMELI	Yes
MARTINEZ	Yes
PANDYA	Yes
KASHYAP	Yes

B. Capital Budget – Quarter 4

Doug Dickson, CFO presented the Capital Budget for Quarter 4. A copy of this presentation is attached to the file copy of these minutes.

Following review and discussion, it was moved by Director PANDYA, seconded by Vice Chair LOMELI and carried to approve the Capital Budget for Quarter 4 as presented. The vote of the Board is as follows:

REDDY	Yes
LOMELI	Yes
MARTINEZ	Yes
PANDYA	Yes
KASHYAP	Yes

IX. Closed Session: Board adjourned Open Session at 6:12 p.m. and went into Closed Session at 6:12 p.m. to discuss the following items:

C. Pursuant to Gov. Code Section 54956.9 (d) (2): Conference with Legal Counsel: significant exposure to litigation; privileged communication

E. Pursuant to Gov. Code Section 54962; Health and Safety Code Section 3206(b): Cal. Civ. Code§ 3426.1 (d): Discussion Regarding Trade Secrets (1 Item) Estimated Dated of Disclosure – January 2025

F. Conference with Sierra View Local Health Care District Real Property Negotiator to give instructions regarding price and sale terms pursuant to Cal. Gov. Code § 54956.8. Property: 633, 663, and 643 N. Westwood Street, Porterville, CA 93257. Sierra View Local Health Care District Hospital Negotiator: Ron Wheaton. Prospective Purchaser: Chris Mano negotiating on behalf of the Burton School District or any other interested parties.

G. Pursuant to Gov. Code Section 54962; Health and Safety Code Section 32106(b): Discussion Regarding Trade Secrets, Pertaining to Service and Strategic Planning

H. Pursuant to Gov. Code Section 54956.9(d)(2), Conference with Legal Counsel about recent work product (b)(1) and (b)(3)(F): significant exposure to litigation; privileged communication (1 Item)

X. Open Session: Board adjourned Closed Session at 7:40 p.m. and went into Open Session at 7:40 p.m. to discuss the following items:

C. Conference with Legal Counsel. Information only; no action taken.

E. Discussion Regarding Trade Secret. Information only; no action taken.

F. Conference with Legal Counsel Re: Real Property Negotiations. Information only; no action taken.

G. Discussion Regarding Trade Secret and Strategic Planning. Information only; no action taken.

H. Conference with Legal Counsel. Information only; no action taken.

XII. Announcements:

A. Regular Board of Directors Meeting – October 24, 2023 at 5:00 p.m.

The meeting was adjourned 7:40 p.m.

Respectfully submitted,

Areli Martinez
Secretary
SVLHCD Board of Directors

AM: ww