County of Los Angeles **Department of Health Services**

OLIVE VIEW-UCLA MEDICAL CENTER
PHARMACY
POLICY & PROCEDURE

NUMBER: 1437
VERSION: 2

SUBJECT/TITLE: **625 - STERILE ROOM OPERATING PROCEDURES AND ENVIRONMENTAL CONTROL**

POLICY: The Pharmacy Department will prepare sterile preparations utilizing aseptic technique and quality control. The licensed pharmacist assigned to perform verification of sterile compounds is responsible for the adherence to these procedures.

PURPOSE: Provide standard operating procedures to prevent the contamination of sterile compounded preparations.

DEPARTMENTS: **PHARMACY/ ENVIRONMENTAL SERVICES/ FACILITES**

DEFINITIONS:

- **Ante-Area:** ISO Class 7 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling and other high particulate generating activities are performed that is adjacent to the area
- **Buffer Area or Cleanroom:** This is an ISO Class 7 or better area. The primary engineering control (PEC) is located in this area. Activities occurring in this area include the preparation and staging of components and supplies used when compounding CSPs.
- **Compounding:** Altering a dosage form, delivery system or dose of drug; combining components; preparing drug from chemicals or bulk ingredients. Compounding does NOT include reconstitution of drugs or attached delivery systems (e.g. Mini Bag Plus®).
- **Controlled room temperature:** 20°C-25°C (68°-77°F) or cooler
- **Controlled cold temperature:** 2°C-8°C (35°-46°F)
- **Controlled freezer temperature:** -25°C to -10°C (-13° to 14°F) or at range otherwise specified by the pharmaceutical manufacturer(s) for that product.
- **Critical Site:** Location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports) or openings (e.g. opened ampules, needle hubs) exposed and at risk of direct contact with air, moisture, or touch contamination.
- **CSP:** Compounded sterile preparation.
- **Direct Compounding Area (DCA):** Critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA filtered air, also known as first air.

- **IPA:** Isopropyl Alcohol
- **Personal protective equipment (PPE):** Clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, coveralls and gloves.
- **Primary Engineering Control (PEC):** Device that provides an ISO Class 5 or better environment for the exposure of critical sites when compounding CSPs. Examples include laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs) and compounding aseptic containment isolators (CACIs).

PROCEDURE:

A. Review of policy and procedure (P&P)

a. P&P will be reviewed on an annual basis by the pharmacist-in-charge (PIC).
b. Date and Signature reflecting annual review of P&P by the PIC will be documented.
c. Date and signature accompanying any revisions to the P&P approved by the PIC will be documented.
d. Any change in process will be communicated to staff by email and/or at staff meeting

B. Compounding Facility and Equipment Standards

a. Garbing and Handwashing (Refer to Table 1)

i. Access to the areas designated for sterile compounding is limited to those individuals who are properly attired.
ii. Prior to entering the ante-room, personnel must remove all personal outer garments, cosmetics and all wrist, hand, finger or other visible jewelry, piercings, headphones, earbuds, or personal electronic devices.
iii. Personnel with certain skin or respiratory conditions may be excluded from working in the ISO Class 5 and 7 areas until their conditions are remedied. (Conditions listed in Table I).
iv. Garbing shall be performed in an ante-area in the following order proceeding from those activities considered the dirtiest to those considered the cleanest.
1. Don shoe covers
a. Double shoe covers are required when entering hazardous drug buffer room.
b. Double shoe covers will be discarded immediately upon exiting the hazardous drug buffer room.

2. Don head cover
3. Don face mask (and beard cover if applicable).
4. Hands and forearms must be washed to the elbows for **at least 30 seconds** with soap and water and then dried
    a. Use hospital approved soap
    b. Be attentive to nail beds and space under the nails and between the fingers.
    c. Use rotary motion with friction.
    d. Dry hands with an approved towel
5. Apply a non-shedding coverall gown after hand washing.
    a. A chemo gown is required in addition to the coverall when compounding hazardous drugs.
6. Immediately prior to donning sterile gloves, compounding personnel disinfect hands with a persistently active alcohol-based product and allow hands to dry.
7. Compounding personnel don sterile, powder free gloves and ensure gloves fit tight without excess glove material at fingertips. Personnel must routinely disinfect gloves with sterile 70% Isopropyl Alcohol (IPA) before entering or re-entering the Primary Engineering Control (PEC) and after contact with non-sterile objects.
    a. Do not touch face, eyes, or over-garments with gloved hands.
    b. Routinely inspect gloves for holes, punctures and tears and replace immediately if such are detected.
8. Personnel must repeat garbing procedures after exposure to direct contact contamination (i.e. splash from sink).
9. Personal Protective Equipment (PPE) used in ante-room and buffer rooms may not be worn in the main pharmacy.
10. Shoe covers, hair and facial hair covers, face masks, head covering, gloves, and coveralls may not be reused and must be replaced with new ones.

Chewing gum, candy, food and drink are prohibited in the ISO Classified areas.

C. Environment and Equipment

a. Access to the buffer area is restricted to qualified personnel with specific responsibilities or assigned tasks in the compounding areas.

b. Calibration and Certification (Refer to Table 2)

i. Proper care and maintenance (i.e. certification and calibration)

of facilities and equipment will be performed in accordance with manufacturer's specifications, as required.

ii. Certification and testing of primary and secondary engineering controls will be performed by an outsourcing entity no less than every 6 months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area.

iii. Certification will be completed by a qualified technician familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities.

c. Viable Sampling (Refer to Tables 2 and 5)

i. Outsourced entity will perform viable air sampling at least once every 6 months.

ii. Olive View staff will perform surface sampling quarterly.
    1. Use contact plates to sample at conclusion of compounding
    2. Submit to OVMC microbiology to test for growth.
        a. Pharmacy Surface Samples Department of Pathology Procedure/Policy Manual 1-9A.
    3. Sampling locations will be recorded on microbiology report.

iii. Sampling sites include locations within each ISO Class environment, and include areas at greatest risk of contamination.
    1. Results will be trended over time for analysis.

iv. Colony forming units (CFU) will be identified to the genus level
    1. Highly pathogenic micro-organisms such as Gram negative Rods (GNR) and coagulase + staph, molds and yeast must be immediately remedied, regardless of CFU count.

v. Exceeded environmental action levels will result in immediate investigation of cleaning and compounding operations and facility management.

vi. Additional actions will be taken based on test results.

d. Pressures and Temperature (Refer to Tables 2 and 6)

i. Doors to the ISO Classified areas must be kept closed at all times except for entry and exit.

ii. The sterile compounding area is to be well-lit and include a temperature of typically 20°C (68°F) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

iii. A pressure gauge will be used to monitor pressure differentials
    1. Non-hazardous compounding requires a positive pressure differential of 0.02 to 0.05 inch water column relative to all adjacent spaces.
    2. Hazardous compounding requires a negative pressure between 0.01 to 0.03 inch water column relative to all adjacent spaces.
    3. USP<797> requires the pressure between the ante-room and general pharmacy not be less than 0.02 inch water column.

iv. Pressure and temperature readings will be documented daily by assigned pharmacy personnel. (Attachment 2)
    1. Readings outside of required range will initiate immediate notification to facilities for corrective action.

D. Supplies and Equipment

- **a.** Supplies stored in the ante-room and buffer rooms are limited to those that are used frequently and routinely. Efforts will be made to minimize the quantities of these items.
- **b.** Cardboard boxes are not allowed in the ante-room and buffer-room.
- **c.** All supplies will be decontaminated with sterile 70% IPA prior to placing in the buffer area. Supplies will be removed from shipping cartons prior to decontamination with sterile 70% IPA.
- **d.** Carts dedicated to the buffer room must be cleaned with a sporicidal disinfectant and disinfected with sterile 70% isopropyl alcohol prior to introduction into the buffer room.
    i. Carts dedicated to the buffer room may not be removed from the area, unless they undergo a repeat cleaning as described above prior to re-entry into the buffer room.
- **e.** When stocking medication and supplies, pharmacy technicians are required to assess stock for any outdates or soon to expire supplies and medication.
- **f.** At least monthly, an assigned pharmacy technician will inspect the stock of all ISO Classified rooms for outdates or soon to expire supplies and medication and remove them as necessary.

E. At least monthly a pharmacist will inspect the stock of all ISO classified rooms for outdates or soon to expire supplies and medication and remove them as necessary**Cleaning Requirements**

- **a.** Pharmacy and EVS personnel must adhere to cleaning requirements in tables 2 and 3.
- **b.** Cleaning shall be done using a germicidal agent and sterile water
    i. At least monthly, a sporicidal agent will be used.
- **c.** Pharmacy personnel will receive initial training and undergo initial and annual competency evaluation.

d. Pharmacy personnel are responsible for cleaning and disinfecting the ISO Class 5 PEC, storage areas and work surfaces (work tables, workstations, carts and pass-throughs).
   i. All ISO 5 surfaces, work table surfaces and carts are to be cleaned and disinfected daily.
   ii. Disinfection using sterile 70% IPA must occur on all surfaces in the ISO Class 5 PEC frequently, including:
      1. At the beginning of each shift
      2. At least every 30 minutes or before each lot
      3. After each spill
      4. When surface contamination is known or suspected.
   iii. At least once monthly all areas above and storage shelving will be cleaned and disinfected using a sporicidal agent.
   iv. Whenever liquids are spilled, the surfaces of the PEC are first cleaned with sterile water to remove water-soluble residues, then disinfected with sterile 70% IPA and a non-linting sterile wipe.
   v. At the end of each chemo shift, each chemo technician must decontaminate the hazardous ISO Class 5 PEC, he or she used, using the 2 step preparation, then sterile water and finally with sterile 70% IPA.

e. Pharmacy and Environmental Services Personnel will adhere to manufacturer's dwell time recommendations.

f. Environmental Services personnel assigned to the sterile compounding areas will be trained as applicable to their duties.
   i. Only trained EVS personnel may perform cleaning of the ante-room and cleanrooms.
   ii. EVS personnel must adhere to the cleaning schedule and expectations in Tables 2 and 3.
   iii. All cleaning tools, such as wipers, sponges and mops are non-shedding and dedicated to use in the buffer areas or ante-area, and shall not be removed from these areas except for disposal.

g. Pharmacy and Environmental Services will document cleaning activities using pre-printed forms. (Attachment 3)

h. The IV pharmacist is responsible to ensure all trash is removed from the IV cleanroom and anteroom by Sodexo in the morning. The chemo pharmacist is responsible to ensure all trash is removed from the chemo cleanroom in the morning. The mid-shift pharmacist is responsible for ensuring all trash, pharmaceutical waste and hazardous drug waste is removed from the ISO classified areas and to ensure the Environmental Services Cleaning log is completed. Each designated pharmacist must notify Sodexo if trash and any other waste is not removed or only partially removed.

F. Compounding Requirements

a. Sterile Compounding in Primary Engineering Control (PEC)

i. Utilize proper techniques and precautions when using laminar airflow hoods.
ii. Ensure laminar air flow hoods run continuous for 30 minutes prior to preparing sterile products.
    1. Primary engineering controls (LAFW and BSC) will be operated continuously during compounding activity.
iii. Work manipulations inside the laminar flow hood will be performed at least six inches from the front grill inside the hood.
iv. Keep hands, sleeves, and arms downwind of product (vials, plastic bags) to prevent turbulence of air prior to contact with the product.
v. Sterile components are arranged in the workbench to allow uninterrupted laminar airflow over critical surfaces of needles, vials, ampules, etc.
vi. All procedures are performed in a manner to minimize the risk of touch contamination.
vii. Do not allow objects (especially sharp or pointed objects) or liquids to contact the HEPA filter.
viii. Pens and any type of paper are not allowed inside the laminar flow hood.
ix. Avoid excessive talking and do not cough or sneeze into the hood.
x. Supplies to be used in the PEC are accumulated and then decontaminated by wiping or spraying the outer surface with sterile 70% isopropyl alcohol or removing the outer wrap at the edge of the DCA as the item is introduced into the aseptic work area.
xi. All rubber stoppers of vials and IV solutions and the neck of ampules are sanitized with sterile 70% IPA and allowed to dry prior to introduction of a needle or spike for removal of product.
    1. Cover ampule neck with a sterile pad and break ampoule by snapping away from the body (for safety purposes)
xii. Do not touch any critical areas (top of vial, tip of syringe, plunger, and any part of needle) when attaching needles, adding diluent, or withdrawing/adding drugs.
xiii. Inspect final products for evidence of incompatibilities, presence of particulate matter, or other defects.
xiv. Dispose of used syringes, needles and other waste in the

appropriate waste container.
1. Waste containers that are 2/3 full are to be sealed and replaced.

xv. Ophthalmic preparations are considered CSPs and must be compounded as such.

b. The Pharmacy Department shall not compound a drug preparation:
i. Classified by the FDA as demonstrably difficult to compound.
ii. That has been withdrawn or removed from the market because such product has been found to be unsafe or not effective.
iii. That is a copy or essentially a copy of one or more commercially available drug products, unless it appears on the ASHP or FDA drug shortage list at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding.

1. G. Compounding Records The following records shall be maintained for at least 3 years.
a. Master Formula Document
i. Includes at least the following:
1. Active ingredients to be used
2. Inactive ingredients to be used
3. Equipment to be used
4. Maximum allowable beyond use date and rationale or reference source justifying its determination.
5. Specific and essential compounding steps used to prepare the drug.
6. Quality reviews required at each step in preparation of the drug.
7. Post-Compounding process or procedures required (i.e. seal the bag)
8. Instructions for storage and handling of the compounded drug preparation

ii. *For products not routinely compounded, documentation on prescription or compounding record is allowed.*

b. Compounding Log (Attachment 1)
i. Name and strength of compounded drug preparation (may use label)
ii. Date of compounding
iii. Identity of compounding pharmacy personnel
iv. Identity of pharmacist reviewing final preparation.

v. Quantity of each ingredient
vi. Manufacturer, expiration date and lot number of each component.
    1. Exemption: For preparations compounded in a single lot (one time use) for administration within 72 hours and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia.
vii. Pharmacy-assigned unique reference code
viii. BUD or BUD and time of final compounded preparation
ix. Final quantity or amount of drug preparation compounded for dispensing.
x. Documentation of quality reviews and required post-compounding process and procedures.

c. Records of acquisition, storage and destruction of all components used in compounding.
d. Records of maintenance and cleaning of facilities and equipment, including certifications and environmental sampling.
    i. Includes video of smoke studies of all ISO certified spaces.
e. All QA reports.
f. Training and Competencies

Records of training and demonstrated competence shall be retained for three years beyond the period of employment.

G. Packaging, Handling, and Transport

a. After CSPs are prepared, products will be stored in accordance to recommended storage condition. All special storage instructions (e.g. protect from light) will be followed.
    i. CSPs requiring refrigeration are maintained at refrigeration temperatures 2 -8 ^{o} C (35 – 46^{o} F) except for brief periods of product verification and delivery processes.
b. All personnel involved in delivering shall receive training before they are allowed to deliver any sterile product.
c. All patient HIPAA info will be covered during the transport of CSPs.
d. Unused or returned CSPs will be brought back to pharmacy. Only CSPs retrieved from proper storage condition and followed all other compounding regulatory requirements will be re-used. The rest will be discarded.
e. Temperature monitoring documentation requirements will be followed- See table 2; Actions will be taken for any out of range temperature variations, as required.
f. Tamper-proof seals are placed on IV product injection ports to ensure

product integrity.

g. Chemotherapy products are placed in two containers to provide spill protection.

h. Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous and requiring special disposal and handled accordingly.

H. Returned or Discontinued Large Volume Parenteral Solutions with Additives and Intravenous Piggyback Units

a. When an order is changed or discontinued, the pharmacy technician will remove from the nursing units and return these products to the Pharmacy for proper disposition.

b. Prepared intravenous products that are non-deteriorated and that have not yet expired may be recycled.

c. The intravenous product is to be discarded when the medication has exceeded the written beyond use date, or when the quality of the product is suspect by a pharmacist. This may be due to extended exposure to room temperature.

In reissuing an intravenous piggyback, the original date and time of preparation are to be visible or "clearly" rewritten onto the new label.

I. Labeling, Ingredient Verification, and Final Product Check

a. Labels of CSPs bear correct names and amounts of ingredients; the total volume; beyond-use date; the appropriate route of administration; the storage conditions; and other information that may be required for safe use, verified when reviewing physician order. Sterile products at this facility are labeled by the technician or pharmacist as follows:

i. Name of the compounding and dispensing pharmacy
ii. Patient name
iii. MRUN #
iv. Patient location
v. Drug(s) name and strength
vi. Diluent name and volume
vii. Total product volume (calculated by computer)
viii. Route of Administration.
ix. Instructions for storage and handling – protect from light, etc.)
x. Beyond-use date (Listed on label as "Do not administer after ____")
xi. The expiration time must be included when expiration occurs in less than 24 hours.
xii. Frequency or rate of administration
xiii. Date prepared/printed.

xiv. Auxiliary label or other specific info for the institution and cautionary instructions
xv. All hazardous CSPs shall bear a special label identifying it as hazardous and requiring special disposal.
xvi. Medications prepared in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug is considered hazardous.
xvii. Pharmacy Reference Number

b. Compounding personnel place drug vials, used for product preparation, preparation labels, and plunger extension indicating volume added, on the review cart for pharmacist verification, and final check.
i. For NICU/Pediatric, chemotherapy, narcotic and insulin products, the medication will not be injected into the primary solution until a pharmacist has performed a pre-check.

c. The verifying pharmacist is responsible for checking all drugs, components and calculations for the sterile preparations. After the preparation of the admixtures, the contents of the containers are thoroughly mixed and then inspected for the presence of particulate matter, discoloration, evidence of incompatibility, or other defects. The verifying pharmacist is responsible to ensure all ingredients, and the final preparation are in compliance with pharmaceutical standards for integrity, potency, quality and strength.

d. At any step during the compounding process, if it was found that the preparation may not be sterile, does not have the correct amount of drug or diluents, mislabeled, or in any manner is compounded in non-conformance to pharmacy policies and procedures, it must be discarded and a new one made based on the judgment of the pharmacist or pharmacist-in-charge of the CSP Service or the pharmacy supervisor.

J. Intravenous Piggy Back (IVPB) Order Verification and Dispensing

a. A pharmacist will dispense IVPBs upon receipt of a physician order. An exceptional provision can be made for emergency orders, whereby the pharmacy will dispense the IVPB with the verbal order from the physician, and physician shall electronically co-sign the order within 24 hours.
b. Accessing the patient's computer profile, the pharmacist verifies each IVPB ordered for a patient. Patient allergies, dietary status and patient weight entered (weight entered as required). Pregnancy/ lactation information entered if applicable.
c. The pharmacist, or technician under the direct supervision of the IV pharmacist, will compound and label a 24-hour supply of the IVPB's.

K. Large Volume Parenteral Solutions (LVP) Computer Order Verification and Dispensing

a. General LVP Procedures
- i. The pharmacist verifies LVP orders as ordered by provider in the electronic health record.
- ii. The pharmacist will prepare a 24-hour supply of the LVP.
- iii. New orders are prepared and delivered in a timely manner.

b. Potassium Chloride (KCL)
- i. The ordering/storing of any concentrated KCL vials on any Ward/Clinic is **not permitted**, unless approved by P&T Committee for a specified procedure.

c. Sodium Chloride Solutions Above 0.9%
- i. Sodium Chloride 3% -500mls will be dispensed only upon receipt of a physician's order. Pharmacy will process as an LVP and appropriately label as per standard procedures.

d. Miscellaneous IV Solutions Categorized as Large Volume IV
- i. Multivitamin solutions (including "Banana bag") are labeled and prepared by the pharmacy service.
- ii. Additional intravenous product preparation is added per pharmacy management.

Policy Reviewed by PIC: _____

Last reviewed: _____

Last revised: _____

Table 1 - Garbing

General Garbing Requirements	
PPE	**Order of garbing in the anteroom**
Shoe covers	1
Head cover	2
Facial hair cover, if applicable	3 followed by washing of hand to elbows for 30 seconds with soap and water and drying
Non-shedding gown	4

Gloves	5 use antiseptic hand gel before donning sterile gloves
Hazardous Compounding Garbing Considerations	
PPE	**Specification / Information**
Double shoe covers	Don the 2nd pair upon entering the clean room. Remove upon leaving
Sterile chemo gloves	Chemo gloves must be ASTM standard 6978 or its successor. No powder
Disposable chemo gowns made of polypropylene or other laminate materials (should be glossy)	Must be changed every 2-3 hours or per manufacturer guidance. NEVER worn outside the HD handling area. Must be closed in the back, long-sleeve, closed cuffs that are knit or elastic. No seams or closures that HDs could pass through.
Face shield/goggles	Required when working outside a C-PEC (i.e.. for spill cleanup)
Prohibited items and individuals	
• Visible jewelry • Piercing with jewelry • Headphones • Earbuds • Personnel electronic devices • Cosmetics • Nail polish • Artificial nails • False eyelashes (eyelash extensions are permitted) • Food and drinks • Any objects that shed particles (cardboard boxes, paper towel)	
Excluded from ISO 7 and ISO 5 spaces until resolved	
• Exposed rashes • Sunburn • Weeping Sores • Conjunctivitis • Active respiratory infections • Communicable diseases	

Table 2 –Frequency of Documentation, Testing and Certification

DAILY	Low & Medium risk	Responsible staff
All medication storage room in the pharmacy (20°C to 25°C)	X	Pharmacy
Refrigerator (twice daily for vaccines) (2°C to 8°C)	X	Pharmacy
Freezer (-25°C to °-15°C) or per specific recommendations	X	Pharmacy
Air Pressure differentials	X	Pharmacy
Cleaning with germicidal cleaners/sterile water and then disinfected with sterile isopropyl alcohol (IPA) Counters, cleanable surfaces and carts	X	Pharmacy

Disinfecting within the ISO 5 environment with germicidal cleaners/sterile water and then disinfected with sterile isopropyl alcohol before each shift, q30 mins., before/after each batch, after each spill and when surface contamination is known or suspected)	X	Pharmacy
Decontamination of the biological safety cabinet.	X	Pharmacy
Cleaning of Ante-room and buffer room floors.	X	EVS
Twice Monthly		
Cleaning with germicidal cleaners/sterile water and disinfected with suitable agent. Sporicidal agent is required to be used at least monthly Terminal Clean- Walls, ceilings, floors, windows, doors, door knobs, exterior of laminar flow hoods and refrigerators, sink, storage shelving, tables, and any other surface in the anteroom and cleanrooms with exception of ISO 5 hoods.	X	EVS
Biannual		
Viable surface sampling, all CFUs identify genus per USP 797	X	Pharmacy
Volumetric air sampling-Particle count. CFUs identify genus per USP 797	X	Outsourcer
Hood and Room Certification under dynamic conditions	X	Outsourcer
Sterility testing (end product testing)	X	Outsourced lab
Annual		
Media Fill/Finger gloved test for employees	X	Pharmacy
Competency testing	X	Pharmacy
Potency testing (end product testing)	X	Outsourced lab

Table 3. EVS Cleaning Expectations

Equipment/material use
Follow proper garbing procedure to maintain an aseptic environment
Do not perform cleaning activities in the IV admixture areas during aseptic operations
Use only non-shedding cleaning materials that are dedicated to the controlled areas.
Only approved cleaning equipment are used
Floor mops may be used in cleanrooms and anterooms BUT only in that order
Discard cleaning tools after each use, unless they are thoroughly rinsed and sanitized and stored in a clean environment between uses.
Cleaning materials must NOT be removed from these areas EXCEPT for disposal
Follow approved minimum contact time for all disinfectants.
When needed, perform additional cleaning after any unanticipated event that could increase the risk of contamination.
Document the use of a sporicidal disinfectant on the cleaning record.
Trash must be collected and removed with minimal disruption of operation

Do not clean/touch surface of IV hood	
Document cleaning activities on cleaning log.	
Frequency of cleaning	
Twice Daily	Empty Trash
Daily	Floors
Twice Monthly	Floor Scrubbing Terminal Clean

Table 5 - Required Testing

<table>
<tr><th>Environmental Testing</th><th>Instructions and Action Levels</th></tr>
<tr><td>Viable surface sampling – by Pharmacy under dynamic condition
• Quarterly
• Each hood</td><td rowspan="2">• Incubate surface sampling by OVMC microbiology protocol
• Air samples sent to outside lab per CEPA protocol
<table><tr><th>Location</th><th>Viable airborne</th><th>Viable surface</th></tr><tr><td>ISO 5 PEC</td><td>>1</td><td>>3</td></tr><tr><td>ISO 7 Buffer</td><td>>10</td><td>>5</td></tr><tr><td>ISO 8 Anteroom</td><td>>100</td><td>>25</td></tr></table></td></tr>
<tr><td>Viable air sampling by volumetric impaction (400-1,000) – by CEPA under dynamic condition
• Every 6 months
• IV room, chemo room, Ante room</td></tr>
<tr><td>Non-viable particle counts by outsourcer under dynamic condition
• Every 6 months
• IV Room, Chemo Room , Ante room</td><td>Outsourcer to certify</td></tr>
</table>

Table 6. Clean Room requirements

	Non-hazardous	Ante-Room to Main Pharmacy	Hazardous
ISO Class	ISO 7	ISO 7	ISO 7
Pressure differential relative to adjacent spaces	Positive pressure 0.02 to 0.05	≥0.02	Negative 0.01 to 0.03
Air changes per hour ACPH	30	Ante-Room 30	30
PEC			Each hood is Externally vented

References: California Pharmacy Law, California Code of Regulations <797> Pharmaceutical Compounding- Sterile Preparations, USP Convention	
Approved by: Michael Hedgecock (Unassigned), Nadrine Balady-Bouziane (Pharmacy Director)	Date: 01/26/2018
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