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

VALLEYCARE
OLIVE VIEW-UCLA MEDICAL CENTER/HEALTH CENTERS
POLICY & PROCEDURE

NUMBER: 1604
VERSION: 2

SUBJECT/TITLE: **ANTINEOPLASTIC ADMIXTURE SERVICE**

POLICY: The pharmacy is responsible for preparing and dispensing all parenteral antineoplastic medications. Procedures are developed to minimize potential hazards with these types of medications to health care providers and patients.

PURPOSE: To ensure the safe storage, handling and preparation of antineoplastic medications for administration along with the proper disposal procedures and minimize potential hazards with these type medications to health care providers and patients.

DEPARTMENTS: All

DEFINITIONS: BSC – Biological Safety Cabinet (Antineoplastic preparation hood)

PROCEDURE:

A. **Employee Training and Orientation**

Pharmacists and Pharmacy Technician training/orientation will include the following:

1. Employees must initially receive training instruction on IV Room accepted sterile aseptic procedures. The preparation of antineoplastic admixtures is limited to authorized employees, who successfully pass antineoplastic training and demonstrate competency.
   Such pharmacy technician training is to be documented on employee orientation/training checklist.

2. A list of all pharmacists and technicians who are authorized to prepare antineoplastic admixture solutions shall be kept on file and updated annually.

3. Basic Antineoplastic area training:
   a) Antineoplastic Admixture Service- Policy 550
   b) Chemo Hood Malfunction (BSC) - Policy 551
   c) Hazard Communication & MSDS - Policy 806
   d) Antineoplastic Waste Container-Disposal Procedures
   e) ASHP videotape “Safe Handling of Cytotoxic Drugs”
   f) Chemo Spill Kit Training
   g) Emergency Treatment – Eye Wash Training

4. Employees are to be familiar with and be able to recognize sources of exposure and materials that come in contact with hazardous drugs (including work surfaces, equipment, personal protective equipment (PPE), intravenous IV bags, patient labels).

B. Who May Prepare Antineoplastic Admixtures

1. A pharmacist or pharmacy technician who has successfully passed area training/orientation, and approved by the employee's immediate pharmacy supervisor.

2. Pharmacy technicians working under the immediate supervision of a pharmacist.

C. Annual Medical Examinations

1. Employee Health Service (EHS) will offer to provide LA County pharmacists and pharmacy technicians a chemo physical medical examination. This initial physical will be offered to new employee's, and then afterwards on an annual basis. Employee medical records are on file at EHS

2. Employee Health Service may advise the Pharmacy to exempt employees from admixing parenteral antineoplastic:
   a. Pregnant females or those actively seeking pregnancy.
   b. Breast feeding females
   c. Personnel with high risk evidenced by the diagnosis of cancer in two immediate family members.
   d. Employees with a legitimate medical statement from a physician may be exempt from preparing parenteral antineoplastics.

   Employee's excused from preparing chemotherapy will be assigned to other areas according to departmental needs.

D. Guidelines for Handling Cytotoxic Agents

3. **Environmental Protection**

Class II Biological Safety Cabinet (BSC)

a. Antineoplastic drug admixtures will be prepared in a vertical laminar airflow containment hood (a NSF Class II biological

safety cabinet without air recirculation).

b. Qualified personnel certify the biological safety cabinet **semi-annually** or anytime the cabinet is moved.

c. Documentation of such certification shall be maintained on a special sticker on the hood itself or in a special binder.

d. The exhaust fan or **blower** is to be kept "**ON**" at all times, except when the hood is being mechanically repaired or moved. If the blower is turned off, the hood is to be "decontaminated" before reuse.

e. The BSC is to be "disinfected" with a sterile 70% isopropyl alcohol wipe prior to start of shift and at end of shift, and documented on the Hood Cleaning Form.

f. The BSC shall be cleaned in the afternoon with a pharmacy approved bleach based disinfectant (observe manufacturer's dwell time), followed by a residue cleaning with a sterile 70% alcohol wipe, as well as whenever spills occur, or when the cabinet requires moving, service or certification.

g. A sterile absorbent drape or sterile chemo spill mat shall be placed on the work surface during preparation or reconstitution procedures. This mat shall be discarded once contaminated with a chemotherapy spill or at the end of the work day (whichever comes first.

h. Drug preparation must be performed only with the hood glass partition view screen at the manufacturer's recommended access-opening height, which is **(8) eight inches**.

The BSC work area is between the front and back grills. And at least (6) inches away from each sidewall.

i. The front and rear air grills should never be obstructed.

4. **Personal Protective Equipment (PPE)**

Gloves

a. Hands should be thoroughly washed before donning gloves and after removing them.

b. At minimum, single gloves shall be worn during handling of antineoplastic drug shipping cartons or vials

c. Sterile outer gloves shall be used when preparing hazardous drugs. Such gloves will be powder free, since the powder can contaminate the sterile processing area and absorb hazardous drug contaminants.

c. Gown and double glove attire:
The inner glove is to be worn under the gown cuff.
The outer glove is to worn over the cuff of the gown.

d. After compounding has been completed and the final preparation surface has been wiped down, the outer glove should be removed and contained INSIDE the BSC.

The inner glove is worn to affix labels and place the preparation into a sealable zip-lock plastic bag. This must be done within the BSC.

e. Gloves (at least the outer glove) must be changed whenever it is necessary to exit and re-enter the BSC.

f. Gloves must also be changed immediately if torn, punctured, or knowingly contaminated.

g. When removing the gloves, the outer chemotherapy contaminated glove fingers must only touch the outer surface of the glove, never the inner surface. If the inner glove becomes contaminated, then both pairs of gloves must be changed.

Both the inner and outer gloves should be considered contaminated, and glove surfaces must never touch the skin or any surface that may be touched by the unprotected skin of others.

h. All contaminated gloves are to be disposed of in appropriate chemo waste container

Gown

a. Employees must wear a protective disposable, lint free, low

permeability fabric, solid front gown with closed cuffs.

b. No skin on the preparer's arm or wrist is to be exposed when preparing a hazardous drug.

c. Both gloves and gowns worn as barrier protection during the compounding of antineoplastics must be removed and discarded in an appropriate waste container located in the negative pressure compounding area.

Personnel Safe Practices

a. Eating, drinking, smoking, chewing of gum, applying makeup, and the presence of foodstuffs or storage of food near the BSC is prohibited. Each of these items is sources of infection.

b. Material Safety Data Sheets (MSDS) are available for staff use

c. Eye wash stations are available for emergency staff use

d. Wash hands with soap and water immediately before using personal protective clothing (such as disposable gloves and gowns) and after removing them.

e. Use syringes and IV sets with Luer-Lok fittings for preparing hazardous drugs

f. Dispose drug-contaminated syringes and needles in chemotherapy sharps containers for disposal.

g. Clean up small spills of hazardous drugs immediately, using proper safety precautions and PPE.

h. Transport bags must never be placed inside the BSC (hood).

i. Socializing is not permitted in this area

C. **<u>Compounding Procedures</u>**

1 Employees are to practice aseptic technique when preparing parenteral antineoplastics.

2 Gather all needed supplies **BEFORE** beginning compounding

3 Syringes and intravenous sets with **Luer-lock fittings** are to be used for preparing and administering cytotoxic drugs solutions since they are less prone to separate than friction fittings.

4 Syringes must be large enough so that they need never be more than three-fourths full. Syringes containing parenteral antineoplastics are "capped" prior to dispensing.

5 Unless the manufacturer of the drug product recommends otherwise, reconstituting vials shall be completed using a vented needle/spike containing a hydrophobic filter (**chemo dispensing pin**). Research shows that such devices eliminate internal pressure or vacuum and effectively stopped the release of drug aerosols in the air during reconstitution.

6 Pharmacy will prime parenteral antineoplastics IV bag lines prior to dispensing to the nursing unit.

7 The external surfaces of prepared syringes and IV bags should be wiped clean of any drug contamination with an alcohol pad or gauze moistened with 70% isopropyl alcohol. **DO NOT** reuse same alcohol pad or gauze to clean more than one pharmacy prepared sterile solution.

8 After the surface has been decontaminated, the outer glove should be removed and contained inside the BSC. The inner glove is worn to affix labels and place the preparation into a zip-lock plastic bag. This must be done within the BSC.

9 A pharmacist will check all antineoplastic preparations for correctness, unusual discoloration, and correct labeling and verify by initialing the label.

10 Inner clean gloves must be worn when placing the zip-locked plastic bag containing the checked antineoplastic preparation inside a larger yellow Transport plastic bag, which is identified by the patients name, MRUN, and location and an Antineoplastic Warning Label. Refer to Transportation (delivery) section. The Transfer plastic bag is not to be touched with contaminated gloves.

11. **Documentation of Preparation**
    a) Pharmacy computerized Patient Medication Profile
    b) Pharmacy's Patient Antineoplastic Therapy Profile sheet
    c) Pharmacy's Chemo Service Communications Log Sheet

d) Chemo Workload Report

E. **Oral Chemotherapy Administration**

1. Oral Chemotherapy drugs (i.e., tablets or capsules) are not to be crushed or opened to administer at the Nursing station.

2. If the patient is unable to swallow or has a nasogastric tube, contact pharmacy for appropriate preparation.

F. **Hours of Operation**

1. The pharmacy provides service to the Special Treatment Clinic (STC) from 8:00 A.M to 4:30 P.M., Monday through Friday.

2. The pharmacy provides daily service to the inpatient wards. New patient chemotherapy orders should be sent to the Pharmacy as early as possible, preferably prior to 3:30pm. Orders written after 3:30 P.M. may not be filled on the same day except in an emergency.

3. On-going patient orders may be filled until 4:30 pm. if necessary in cases where lab tests are delayed.

G. **Physician Orders**

1. Orders for antineoplastic drugs must be authorized by oncology attending physicians or oncology fellows. Special exceptions are made by the P&T Committee for services outside Hematology/ Oncology (e.g. OB-GYN, urology, neurology, etc.)

2. Orders are written on a "Chemotherapy Physician's Order" form, which may be scanned to Pharmacy via Pyxis Connect System. Telephoned parenteral chemotherapy verbal orders to pharmacy are not permitted, except to clarify physician written order discrepancies (administration errors, dosage errors, etc.).

3. The pharmacist shall review the physician's order and the patient's profile prior to entry into the pharmacy computer. Any discrepancies are immediately investigated and reported to the physician and/or RN and resolved prior to preparation and dispensing. **Patient's height, weight, and BSA are to be entered into pharmacy's patient medication profile.**

4. All **"NEW"** patient orders, and/or any **CHANGES** in patient's height, weight, BSA or dosages, and/or any **new drug regimens**, will have their dosage calculations **DOUBLE CHECKED** by a second pharmacist.

5. Rounding- Off Dosages is permitted, however the pharmacist must first notify and receive approval from the physician.

6. All pharmacy preparations are to be visually checked for particulate matter, unusual discoloration, and are to be appropriately labeled prior to pharmacy dispensing to clinic/ward.

7. Outpatient STC Orders

a. On the prior day, STC will deliver all anticipated patient physician patient chemotherapy written orders to the Inpatient Pharmacy for the chemo pharmacist's review to ensure there is sufficient supply of antineoplastic injectable drug on hand to process on the following day.

b. At the clinic, the RN will verify name of patient and, physician's order, with the pharmacy prepared medication, prior to administration to the patient. Any discrepancies are immediately reported to the pharmacist prior to administration to the patient. Such discrepancies must be resolved before drug is administered to the patient.

H. <u>Labeling</u>

Antineoplastic admixture preparations shall bear a label clearly identifying the product as an antineoplastic, so that all health care providers will exercise appropriate caution in handling the drug.

<u>On Syringes</u>

1. Patient name, MRUN, and location
2. Name of drug and strength
3. Drug volume
4. Preparation date
5. Expiration date (Beyond Use Date)
6. Auxiliary labeling as appropriate
7. Pharmacist initials

* These labeled syringes are then placed in a labeled zip-lock bag. <u>On IVPB's and LVP's and on Zip-lock bags containing prepared Syringes</u>

1. Patient's Name, MRUN, and location
2. Drug name and strength
3. Diluent and volume
4. Preparation date
5. Expiration Date (Date/Time)
6. Auxiliary labeling as appropriate (REFRIGERATE, PROTECT

FROM LIGHT, etc.)
7. Pharmacist initials
8. Antineoplastic Warning Label
9. All cytotoxic parenteral admixtures bags are labeled with the warning:

CAUTION
ANTINEOPLASTIC (CARCINOGENIC) DRUG

HANDLE WITH LATEX GLOVES
DISPOSE OF PROPERLY

**Prepared IVPB's and LVP's are then placed inside a larger sized zip-locked plastic bag with a Antineoplastic Warning Label

H. Storage

1. Parenteral antineoplastic drugs are stored separately from other drugs.

2. Access to these drugs is limited to pharmacists and pharmacy technicians who are authorized to stock or manufacture parenteral antineoplastics.

3. A list of antineoplastic medications is updated annually, and kept in the in the antineoplastic area.

I. Transportation (Delivery)

Cytotoxic admixtures are to be placed inside a large disposable "yellow" (Chemotherapy) zip-lock plastic Transport bag for delivery to nursing units. Transport bags must never be placed inside the BSC during the compounding process, which contaminates the outer surface of the bag.

a. INPATIENT: Affixed to the "yellow" chemotherapy bag, is a label identifying the patient's name, MRUN, and bed location, plus an Antineoplastic Warning Label.

b. SPECIAL TREATMENT CLINIC: STC personnel may utilize an "Igloo" container or "yellow" bag identified with by an Antineoplastic Warning label, to transport prepared parenteral antineoplastic.

c. Pneumatic tubes are not to be used to transport antineoplastic drugs.

d. All individuals transporting hazardous drugs must have safety training on chemo spill control.

J. Administration of chemotherapy

Chemotherapy may only be administered to inpatients and STC patients by a chemotherapy certified nurse, per Nursing protocol and standards. Parenteral chemotherapy medications are HIGH ALERT medications, which requires a double -check by (2) chemo certified RN's , verified by their (2) signatures on the Medication Administration Record (MAR). (Refer to Policy, "High Alert Medication")

K. <u>Antineoplastic Spills (ASHP Guidelines)</u>

Chemo Spill Kits
The Pharmacy stocks a "Chemo Spill Kit" which contains appropriate personal protective equipment (PPE) and supplies needed to clean up cytotoxic spills. Kits are stored in the pharmacy and nursing areas where antineoplastic drugs are prepared and administered.

The circumstances and handling of "substantial" spills should be documented. When reporting "substantial" spills the Exposure Report Form supplied in the kit shall be used.

1. **<u>If spill occurs inside the vertical hood:</u>**
   a) Spills occurring inside the BSC are to cleaned up immediately

   b) Put on the goggles from the chemotherapy spill kit

   c) Leave the blower, ON

   d) Lift glass shield only if spill cannot be totally contained through (8) inch front opening.

   e) Obtain a spill kit if the volume of the spill exceeds (30) mls or the contents of one drug vial or ampoule.

   f) Utility gloves (from spill kit) should be worn to remove broken glass.

   g) Place glass fragments in the (5) gallon chemo sharps container located inside the hood.

   h) Thoroughly clean and decontaminate the BSC

   i) Clean and decontaminate the drain spillage trough located under the class II BSC.

j) If the spill results in liquid being introduced onto the HEPA filter or if powdered aerosol contaminates the "clean side" of the HEPA filter, use of the BSC is to be suspended until the BSC has been decontaminated and the HEPA filter replaced.

2. **<u>If spill occurs outside the BSC hood:</u>**

a) Assess the size and scope of the spill. Call for trained help, if necessary. Safety Office (Day) – (818) 364-3405.
After hours, Notify the operator at x- 111

1. Spills that cannot be contained by two spill kits may require outside assistance.
2. Post signs to limit access to spill area.
3. Obtain spill kit and respirator

An appropriate NIOSH-approved respirator should be used for either powder or liquid spills where airborne powder or aerosol is or has been generated. CONTACT the Safety Officer (818) 364-3405. After hours, call the operator at ext. 111.

b) Put on the goggles from the spill kit.

c) Don personal protective equipment (PPE), including inner and outer gloves and respirator.

d) Once fully garbed, contain the spill using spill kit.

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

f) Absorb liquids with spill pads.

g) Absorb powder with damp disposable pads or soft toweling.

h) Spill clean-up should proceed progressively from areas of lesser to greater contamination.

i) Completely remove and place all contaminated material in the disposable chemo bag.

j) Rinse the area with water and then clean with detergent, sodium hypochlorite solution, and neutralizer.

k) Rinse the area several times and place all materials used for containment and clean up in disposable bags. Seal bags and place them in a large chemo waste container for disposal as hazardous waste.

l) Carefully remove all PPE using the inner glove. Place all disposable PPE into disposable bags. Seal bags and place them in the large chemo waste container.

m) Remove inner gloves; place in a small chemo yellow bag and into the large chemo waste container.

n) Wash hands thoroughly with soap and water.

o) Once a spill has been initially cleaned, have the area re-cleaned by housekeeping/environmental services.

L. <u>Disposal of Antineoplastic Drugs</u>

1. Contaminated swab gauze, disposable gloves, long-sleeve gowns, Plastic-backed absorbent liners and gauze pads are placed in special cytotoxic waste disposal bag clearly labeled for chemotherapy material.

2. In the course of preparation, all contaminated syringes, vials, needles, vented filters, damaged or broken antineoplastic drug vials, etc. are placed in special plastic **CHEMOTHERAPY WASTE RECEPTACLES** clearly marked with cytotoxic warning label. These receptacles should be closable, puncture-resistant, and shatter-proof. Needles are not to be clipped. This container is labeled "**For Incineration Only**"

3. Cytotoxic waste shall not be mixed with any other hospital waste.

4. Both the small chemotherapy waste containers and cytotoxic waste bag are placed in a larger chemotherapy waste bag or container that is clearly labeled.

5. All cytotoxic, and only cytotoxic, waste should be placed in such waste receptacles.

6. Environmental services shall pick up chemotherapy waste bags and properly dispose of them. This waste will be disposed of as hazardous waste by an appropriately licensed contractor in an Environmental Protection Agency (EPA) permitted hazardous waste incinerator of

EPA certified waste site.

7. Unused or non-punctured pharmacy prepared "sealed" patient parenteral antineoplastic preparations are to be returned to the pharmacy for proper disposition.

   a) Deposit unused, non-punctured returned prepared parenteral antineoplastic into a (5) gallon waste container (provided by Safety Office). Hazmat Specialist, Safety Officer or designee will pick up this container when full with the completed documentation form, for disposal in accordance to regulations.

N. **Infiltration Emergency Procedures**

1. Infiltration and extravagation shall be reported immediately to the physician.

O. **Extravasation Kits**

1. Extravasation kits are prepared and issued by the pharmacy.

2. A kit will be kept in an area accessible to the nurse administering the chemotherapy.

P. **Emergency Treatment** (OSHA recommended steps for immediate treatment of workers with direct skin or eye contact)

1. Call for help for help, if needed.
2. Immediately remove contaminated clothing.
3. Flood the affected eye with water or isotonic eyewash for at least (15) minutes.
4. Clean affected skin with soap and water; rinse thoroughly.
5. Obtain medical attention.
6. Document exposure in employee's medical record.

Q. **QUALITY ASSURANCE**

1. Pharmacists and pharmacy technicians who have passed orientation/training are permitted to prepare antineoplastics.

2. Each BSC hood will be certified bi-annually by a qualified technician (CEPA).

3. A designated pharmacist will attend STC staff meetings

Forms

1. Hood Cleaning Documentation Log Sheet
2. Antineoplastic Patient's Chemotherapy Profile Sheet (to be replaced by Chemotherapy Flow Sheet)
3. Chemo Service Communication Log

References: ASHP Guidelines on Handling Hazardous Drugs –2006; NIOSH-Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs In Healthcare Settings – 2004; Employee Health Service -2009	
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