

Subject:		Issued By:	
STERILE ADMIXTURE & INJECTABLE DRUG COMPOUNDING		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2007	September 1, 2007	April 14, 2008	June 1, 2008

Reference: Original IDS Sterile Admixture and Pharmaceutical Compounding Policy & Procedure dated 4-12-2006 and the 2008 version of the United States Pharmacopeial (USP) Convention Chapter 797 entitled "Pharmaceutical Compounding—Sterile Preparations." This Policy & Procedure was updated as of 5-1-2007, 9-1-2007 and 1-1-2008.

NOTIFY CA BOARD OF PHARMACY WHENEVER THIS POLICY CHANGES!

Whenever this policy is updated or changed, the California Board of Pharmacy must be notified and made aware of the specific changes being made. For information on how to contact the California Board of Pharmacy, please see the last page of this document.

PURPOSE

To ensure that proper aseptic techniques are used when creating sterile admixtures and that all drug compounding conforms to USP Chapter 797 Guidelines. *For more information about USP Chapter 797 click on the following hyperlinks:* <http://www.usp.org/USPNF/pf/generalChapter797.html> and <http://www.usp.org/pdf/EN/USPNF/generalChapter797.pdf>.

POLICY

1. **LAMINAR FLOW HOOD:** The IDS Pharmacy only will perform sterile admixture or drug compounding in an International Organization for Standardization (ISO) Class 5 air quality environment under a Class II Vertical Laminar Flow Biological Safety Cabinet (BSC);
2. **ASEPTIC TECHNIQUE:** Sterile admixture and drug compounding always will be performed using aseptic techniques. Sterile gloves, and sterile 70% isopropyl alcohol to disinfect, will always be used when preparing medications. For more information on aseptic techniques, click here: <http://www.globalrph.com/aseptic.htm>;
3. **ANNUAL OR SEMI-ANNUAL ASEPTIC TECHNIQUE VALIDATION:** Aseptic techniques must be validated annually for persons compounding in a low-to-medium risk environment and semi-annually for persons compounding in a high-risk environment. HRA's IDS Pharmacy Staff also must pass the following upon being hired and annually thereafter;
 - a. A Media Fill Test;
 - b. A Sterile Glove Fingertip Sampling;
 - c. A Written Test, and;

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- d. An Assessment of:
- Hand hygiene and garbing practices;
 - Aseptic technique related practices;
 - Cleaning and disinfection procedures (if this applies to the Staff Member in question);

4. **ADMIXTURES & COMPOUNDING MUST BE VERIFIED BY A LICENSED PHARMACIST:** All compounded medication must be checked and initialed by a licensed pharmacist prior to dispensing. The pharmacist should always verify all of the following:

- a. Treatment assignment;
- b. Dose calculations;
- c. Ingredients; and
- d. Labeling.

After every Compounded Sterile Preparation (CSP), the container contents must be inspected for the presence of particulate matter, evidence of incompatibility, and other defects.

The used additive containers – and, for those additives for which the entire container was not expended, the syringes used to measure the additive – should be quarantined with the final products until the final product check is completed;

5. **DETERMINING BEYOND-USE DATES (BUD) OR EXPIRATION DATES:** For CSPs, expiration dates noted on prescription labels will be determined by the manufacturer or by the Sponsor. If stability data or expiration dates are not noted in the protocol or package insert, HRA's IDS Pharmacy Staff will contact the manufacturer and/or the Principal Investigator (PI) to obtain an expiration date. This correspondence shall be noted in the protocol-specific binder;

6. **QUALITY ASSURANCE AND ENVIRONMENTAL QUALITY AND CONTROL:** The following are undertaken for Quality Assurance and Environmental Quality and Control:

- a. Upon hiring and annually thereafter, HRA's IDS Pharmacy Staff must pass certain criteria (see Annual Aseptic Technique Validation in Policy #3 above). If



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any of these criteria are not met, HRA's IDS Pharmacy Staff must repeat the test(s). A qualified evaluator will report and evaluate results;

- b. Every six months, the Biological Safety Cabinet (BSC) and IV "clean room" shall be inspected and recertified for air quality. Additional filters may need to be added if air quality does not meet specifications;
- c. Surface sampling of the BSC shall be performed monthly. If a qualified evaluator finds any growth on the sample(s), HRA's IDS Pharmacy Staff will perform another surface sample test;
- d. If possible, in order to ensure containment in operations preparing large volumes of hazardous drugs, air and surface sampling also will be performed every six months to verify containment. If any measurable contamination is found, practitioners shall make the decision to identify, document, and contain the cause of contamination.

PROCEDURES

1. **REPORT ALL ILLNESSES:** Any and all illnesses that may potentially compromise the sterility of the aseptic field must be reported to the Pharmacist-in-Charge. Await further instructions before proceeding;
2. **VENTILATE HOOD FOR 30+ MINUTES:** The hood ventilation must be turned on for at least 30 minutes prior to use. A second option would be to leave the hood ventilation on 24/7;
3. **HAND HYGIENE AND GARBING-RELATED PRACTICES:** The following hygiene and garbing practices must always be followed:
 - a. Wear clean and appropriate attire;
 - b. No cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) may be worn upon entry into ante-areas;
 - c. No food or drinks may be brought into or stored in the ante-areas or buffer areas;

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- d. Always be aware of the line of demarcation separating clean and dirty sides of the pharmacy and observe the required activities for both sides;
 - e. Don shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate;
 - f. Don beard cover, if necessary;
 - g. Don head cover assuring that all hair is covered;
 - h. Don face mask to cover bridge of nose down to include chin;
 - i. Perform hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds;
 - j. Dry hands and forearms using lint-free towel or hand dryer;
 - k. Select the appropriate sized gown and examine for any holes, tears, or other defects before donning;
 - l. Don gown and ensure full closure;
 - m. Disinfect hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allow hands to dry thoroughly before donning sterile gloves;
 - n. Don appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips;
 - o. Examine gloves ensuring that there are no defects, holes, or tears;
 - p. While engaging in sterile compounding activities, routinely disinfect gloves with sterile 70% IPA prior to working in the Direct Compounding Area (DCA) and after touching items or surfaces that may contaminate gloves;
 - q. Remove Personnel Protective Equipment (PPE) on the clean side of the ante-area;
 - r. Remove gloves and perform hand hygiene;
 - s. Remove gown and discard it, or hang it on a hook if it is to be reused within the same work day;
 - t. Remove and discard mask, head cover, and beard cover (if used);
 - u. Remove shoe covers or shoes one at a time, ensuring that the uncovered foot is placed on the dirty side of the line of demarcation and perform hand hygiene again. (Remove and discard shoe covers every time the compounding area is exited);
4. **ASEPTIC TECHNIQUE AND RELATED PRACTICES:** HRA's IDS Pharmacy Staff will be periodically evaluated to ensure that they adhere to the following techniques and practices:
- a. All hand hygiene and garbing practices described in Procedure #3 above;

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- b. Disinfect the ISO Class 5 device surfaces with an appropriate cleaning agent;
 - c. Disinfect components/vials with an appropriate cleaning agent prior to placing into ISO Class 5 work area;
 - d. Introduce only essential materials, in a proper arrangement, into the ISO Class 5 work area;
 - e. Do not interrupt, impede, or divert flow of first-air to critical sites;
 - f. Ensure that syringes, needles, and tubing remain in their individual packaging and are only opened in the ISO Class 5 work area;
 - g. Perform manipulations only in the appropriate Direct Compounding Area (DCA) of the ISO Class 5 device;
 - h. Do not expose critical sites to contact contamination or worse than ISO Class 5 air;
 - i. Disinfect stoppers, injection ports, and ampul necks by wiping with sterile 70% isopropyl alcohol (IPA) allowing sufficient time to dry;
 - j. Affix needles to syringes without contact contamination;
 - k. Puncture vial stoppers and spikes infusion ports without contact contamination;
 - l. Label preparation(s) correctly;
 - m. Disinfect sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations;
 - n. If applicable, clean, set up, and calibrate automated compounding device (e.g., "TPN compounder") according to manufacturer's instructions;
 - o. Dispose of sharps and waste according to institutional policy and recognized guidelines.
5. **CLEANING AND DISINFECTING PROCEDURES:** HRA's IDS Pharmacy Staff will strictly adhere to the following cleaning and disinfecting procedures:
- a. Prepare the correct concentration of disinfectant solution according to manufacturer's instructions;
 - b. Use appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.);
 - c. Document disinfectant solution preparation;
 - d. Follow garbing procedures when performing any cleaning activities;
 - e. At the beginning of each shift, clean all ISO Class 5 devices prior to compounding in the following order: top, back, sides, front, bottom, and outside hood;

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- f. Use a lint free wipe soaked with sterile 70% IPA, or other approved disinfectant solution, and allow to dry completely;
 - g. Remove all compounder components and clean all ISO Class 5 areas as stated above at the end of each shift;
 - h. Clean all counters and easily cleanable work surfaces;
 - i. Mop floors, using the mop labeled “floors”, starting at the wall opposite the room entry door. Mop floor surface in even strokes toward the operator. Move carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops;
 - j. In the ante-area, clean sink and all contact surfaces. Clean floor with a disinfectant solution or use a microfiber cleaning system;
6. **ONE ORDER AT A TIME:** Only one order shall be under the hood at any one time;
7. **CHEMOTHERAPY AGENTS IN ZIPLOC[®]-TYPE BAGS:** All chemotherapeutic agents are to be dispensed in a Ziploc[®]-type bag;
8. **LABELING:** The final product must be labeled with ALL of the following:
- a. Patient name;
 - b. Drug name;
 - c. Physician name;
 - d. Pharmacist initials;
 - e. Pharmacy name and address;
 - f. Concentration, amount or strength of drug;
 - g. Total volume;
 - h. Route of administration;
 - i. Prescription Number;
 - j. Directions for use;
 - k. Protocol number;
 - l. Expiration date;
 - m. Expiration time (IVs);
 - n. Storage requirements if refrigeration is needed;
 - o. Date prepared;
 - p. Cytotoxic label, and
9. **PRESSURE DIFFERENTIAL MONITORING:** A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented in a log at least during every work shift or by a continuous recording device.



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RESPONSIBILITY

All IDS Pharmacy Staff

CALIFORNIA BOARD OF PHARMACY CONTACT INFORMATION:

If there have been changes in this Policy & Procedure in the past year, an electronic copy of the new Policy & Procedure must be provided to the California Board of Pharmacy via e-mail and sent to: compoundingpharmacy@dca.ca.gov. Include the IDS Pharmacy's California injectable, sterile compounding license number (LSC and five-digit number) in the subject line of the e-mail to ensure proper identification and list or identify the changes to the Policy & Procedure in the e-mail.