I. Description

Describes the infection control guidelines followed by Pharmacy for the compounding and distribution of patient medications.

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II. Rationale

Aseptic technique is critical to reduce the risk of infection associated with pharmaceutical products. Strict adherence to the guidelines in this policy can reduce the risk of product contamination and potential infection.

III. Policy

A. Personnel

1. Hand Hygiene
   a. Hand hygiene must be performed in accordance with the Infection Control Policy IC0024: Hand Hygiene and Use of Antiseptics for Hand Preparation.

2. Occupational Health
   a. HCP should be familiar with and follow policies outlined in the following Infection Control Policies: IC0021 Exposure Control Plan for Bloodborne Pathogens, IC0060 Tuberculosis Control Plan, and IC0031 Isolation Precautions.
   b. Personnel actively infected with communicable diseases must not handle IV fluids or other medications. Personnel should be evaluated by Occupational Health Service (OHS). In addition, HCP should adhere to guidelines established by the Occupational Health Service (OHS). See the Infection Control Policy 0040: Infection Control and Screening Program: Occupational Health Services.
c. Personnel with minor cold symptoms (no fever) may continue to prepare and handle IV admixture products. However, if products are being prepared within a horizontal flow hood, a surgical mask must be worn in addition to standard IV admixture clothing, as outlined in the Pharmacy Policy 0251: Compounded Sterile Preparations (CSPs).

d. Department of Pharmacy personnel who participate in IV fluid compounding are thoroughly trained as outlined in Pharmacy Policy 0251: Compounded Sterile Preparations (CSPs).

3. Personnel should avoid direct hand contact with medications. Counting trays, spatulas, and other appropriate, clean measuring or counting devices should be used.

4. If it is necessary for personnel to directly handle medication (e.g., tablets or capsules being prepackaged in the Unit Dose Strip-Packer), hand hygiene must be performed and a clean pair of examination gloves must be used to protect the person and the medications. Clean tweezers are used in lieu of gloves to fill dispensing “wheels” for controlled substances.

5. Food must not be consumed in the work areas of the Pharmacy. Drinks may be consumed in all areas except the Ante Room or Clean Room where compounding occurs.

6. Pharmacy employees who work in areas that provide patient care must comply with required annual LMS training in OSHA rules on exposure to bloodborne pathogens and tuberculosis.

7. Accidental exposures of personnel (e.g., blood on open wound, abraded skin, and mucous membrane) to blood and body fluids are reported to the Occupational Health Service (e.g., Needlestick Hotline at 984-974-4480). Employee incident reports are completed according to hospital policy.

8. Designated uniforms and personal clothing shall be clean.

B. Isolation/Precaution Guidelines

1. Standard Precautions are followed by all department personnel when in contact with blood or body fluids.

2. All department personnel having contact with a patient on isolation precautions will follow the Infection Control Policy IC 0031: Isolation Precautions Policy. Specific instructions are posted on the Isolation Precautions sign outside a patient room (e.g., gowns, mask, and gloves).

C. Recall of Contaminated Items

1. All products prepared or repackaged by Pharmacy personnel are assigned lot numbers. If lots are found to be contaminated, they will be retrieved according to established Pharmacy Policy 0108: Drug Recalls.

2. Manufacturer or government initiated recalls are also processed according to the Pharmacy Policy 0108: Drug Recalls.

D. Equipment

1. Inpatient medication storage bins in the Pharmacy Department are washed with soap and water by hand or replaced when visibly soiled.

2. Tablet counting trays are cleaned with 70% alcohol on a routine basis (e.g. daily) and when the tray is visibly contaminated.

3. No food, drinks or specimens may be stored in refrigerators, freezers, or other areas intended for the storage of pharmaceuticals, supplies, or equipment.

4. Code Blue drug trays that become contaminated with blood or body fluids during resuscitation of a patient are cleaned with an EPA-registered disinfectant (Metriguard, Sani-
Cloth) or a solution of 5.25% sodium hypochlorite (bleach) diluted 1:10 with water (bleach solutions expire 30 days after mixing). The primary bleach container should have a manufacturer’s expiration date and the secondary container should be labeled with the mixture details, hazard information and expiration date.

5. Pharmacy refrigerators (housed in the pharmacy [e.g. central inpatient or satellites]) and freezers are wired to sound alarms in the Hospital Maintenance Department. An alarm will activate if the temperature goes outside the proper range. Maintenance will notify Pharmacy of any alarms. Pharmacy personnel are responsible for the routine cleaning of refrigerators and when spills occur. Cleaning of the medication refrigerators (e.g. Pyxis refrigerators) on the patient care units is the responsibility of Nursing personnel.

6. Storage areas within the automated dispensing machines (i.e., Pyxis) will be the responsibility of the Pharmacy Department. The interior and shelving should be cleaned on a regular schedule, when dust/debris has accumulated, upon request, or after a spill of a medication. Pharmacy Techs should assess the Pyxis for dust or debris when stocking and clean as necessary. Cleaning of the top work surface is the responsibility of Nursing and EVS.

E. General Housekeeping

1. Countertops are wiped down with an EPA-registered disinfectant detergent (preferred) or 70% alcohol at least once during each shift and when visibly soiled or known to be contaminated by department personnel.

2. Floors are cleaned according to Infection Control Policy 0020: Environmental Services.

3. Floors should remain clear of boxes and clutter to allow for adequate cleaning of the floors.

F. Formulations

1. Sterile water for irrigation or commercially prepared distilled water is used for non-IV compounding procedures (e.g., oral suspension reconstitutions). Sterile pour (irrigation) solutions are single-use and any unused portion must be discarded immediately after use.

2. Refer to the Administrative Policy 0104: Medication Management: Use of Multi-Dose Vials/Pens of Parenteral Medications in Acute Care and Ambulatory Care Environments for multi-dose vial use outside the pharmacy.

3. Aseptic technique must be used when entering a medication vial. Vials should be handled with clean hands. Cleanse the rubber diaphragm of the medication vial with a sterile alcohol pad before accessing the vial. Use a new sterile syringe with a new needle or a new sterile vial adaptor for each access. If touch contamination occurs before penetrating a vial, repeat alcohol cleansing procedure and discard contaminated needle/syringe. If contamination occurs after vial is penetrated, discard the vial and needle/syringe.

G. Admixture Services

1. Refer to Pharmacy Policy 0251: Compounded Sterile Preparations (CSPs) for all related policy content.

H. Hazardous Products

1. The following products are prepared in the Class II Biological Safety Cabinet:
   a. Blood products
   b. Anti-neoplastic medications
   c. Parenteral investigational drugs
   d. Substances which pose a potential hazard to the operator of the equipment
2. Preparation and disposal of hazardous drugs (antineoplastic, biological, cytotoxic, and immunosuppressant drugs) will be made in accordance with the Environmental Health and Safety Policy 0024: Handling and Disposal of Hazardous Drugs.

3. After the manipulation of blood products the laminar flow work surface is cleaned with 70% isopropyl alcohol or an EPA registered disinfectant detergent.

4. Spills of blood products outside the laminar flow hood are contained and cleaned up by:
   a. Donning 2 pairs of gloves.
   b. Absorbing the product with gauze.
   c. Cleaning blood spills with a solution of 5.25% sodium hypochlorite diluted 1:10 with water (30 day expiration after dilution) or an EPA registered disinfectant detergent.
   d. Disposing of all waste materials in a trash receptacle and discarding with general hospital waste.

5. Needles are discarded in designated needle disposal containers and are not recapped before disposal. Needle disposal containers must conform to OSHA/NIOSH guidelines for sharps containers (refer to the Infection Control Policy 0021: Exposure Control Plan for Bloodborne Pathogens). Needle containers, when 2/3 full, are securely closed and discarded in the red trash bags.

6. Materials contaminated with potentially infectious agents (e.g., BCG vaccine) are discarded in red trash bags for incineration.

7. Bloody items with less than 20ml of blood per unit vessel (e.g., bloody gloves) do not need to be placed in the red trash bags. Items that contain >20ml of blood per unit vessel that cannot be poured down a toilet or flushable hopper must be discarded in the red trash bag.

8. Red bag refuse containers are removed at least once a day by Environmental Services to be destroyed by incineration according to hospital policy.

I. Quality Control

1. Sterile products manufactured or prepared by the Pharmacy Department in batch (i.e., not patient-specific) are assigned unique lot numbers.

2. Samples of selected products (i.e., parenteral products prepared by Special Formulations) are tested for sterility by the Hospital Epidemiology Department medical technologist. The lots undergoing testing are quarantined until a “no growth” report has been returned to the Pharmacy Department.

J. Special Formulations Services

1. Sterile products are prepared in accordance with the procedures outlined in Pharmacy Policy 0265: Extemporaneous Compounding.

2. The reuse of commercial containers and disposable supplies is prohibited.

K. Special Services

Medicinal leeches are occasionally ordered and dispensed for use in overcoming the problem of venous congestion. Personnel involved in the handling, use and disposal of leeches should follow the manufacturer’s instructions. Leeches which have been used on a patient should be disposed of by initially narcotizing them using 8% alcohol and then placing them in 70% alcohol for 5 minutes. Discard in the red bag waste for incineration.
L. Implementation
   The implementation and enforcement of this policy is the responsibility of the Director of Pharmacy.

IV. Reviewed/Approved by
   Hospital Infection Control Committee

V. Original Policy Date and Revisions