POLICY

To establish standard operating procedures to limit the risk of contamination of compounded sterile products.

PROCEDURE

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

2 All supplies in cartons are decontaminated in the anteroom area by removing them from shipping cartons and wiping or spraying with a disinfecting agent, such as sterile 70% isopropyl alcohol.

3 Supplies required frequently or otherwise needed close at hand (but not necessarily needed for scheduled operations of the shift) are decontaminated and stored on the shelving in the anteroom area.

4 Carts used to bring supplies from the storeroom cannot be rolled beyond the demarcation line and carts used in the sterile compounding area cannot be rolled outward beyond the demarcation line unless cleaned and sanitized before re-entry.

5 Supplies required for the scheduled operations of the shift are prepared and brought into the sterile compounding area. Supplies that are required for back-up or general support of operations may be stored on the designated shelving in the sterile compounding area; but, excessive accumulation of supplies should be avoided.

6 Objects that shed particles cannot be brought in the buffer area; these include pencils, cardboard cartons, paper towels, and cotton items. Only non-shedding paper-related products can be brought into the buffer area.

7 Traffic flow in and out of the buffer area must be minimized.

8 Personnel entering the sterile compounding area must remove all jewelry from hands and arms.

9 Personnel entering the sterile compounding area must first scrub hands and arms with soap, including attention to both the fingers and fingernails.

10 Personnel prior to entering the sterile compounding area should don designated attire; namely, shoe covers, hair covers, face mask, hand cleanse, and non-shedding coveralls in that order. Inside the sterile compounding area, compounding personnel will perform antiseptic hand cleansing using waterless alcohol surgical hand scrub prior to donning sterile powder-free gloves.

11 Under no circumstances is chewing gum, candy, or food items permitted in the sterile

compounding area.

12 At the beginning of each shift, before and after each batch, after liquids are spilled, and when surface contamination is known or suspected, the surfaces of the direct compounding environment are first cleaned with purified water to remove water soluble residues. Immediately thereafter, the same surfaces are sanitized with sterile 70% isopropyl alcohol for at least 30 seconds, or another effective antimicrobial agent approved by Infection control, using a lint-free wipe.

13 When LAFWs or barrier isolators are used to provide an ISO Class 5 air quality environment, their blowers must be operated continuously during compounding activity, including during dormant periods of less than 8 hours. When the blower is turned off and before other personnel enter to perform compounding activities, only one person can enter the contiguous buffer area for the purpose of turning on the blower (for at least 30 minutes) and for sanitizing the work surfaces. Sterile gloves will be donned over the isolator gloves before compounding.

14 Traffic in the area of the direct and contiguous compounding areas *(*DCCA) is minimized and controlled. The DCCA is shielded from all less clean air currents that are of higher velocity than the clean laminar airflow.

15 Supplies to be utilized in the DCCA for the planned procedures are accumulated and then decontaminated by wiping or spraying the outer surfaces with sterile 70% isopropyl alcohol or removing the outer wrap at the edge of the DCCA as the item is introduced into the aseptic work area.

16 Supplies are arranged such that a clear, uninterrupted path of HEPA-filtered air will bathe all critical sites at all times during the planned procedures. No objects may be placed behind an exposed critical site.

17 All supply items are arranged in the DCCA so as to reduce clutter and to provide maximum efficiency and order for the flow of work.

18 All procedures are performed in a manner designed to minimize the risk of touch contamination. Gloves are sanitized with adequate frequency with sterile 70% isopropyl alcohol or hospital approved sanitizer.

19 All rubber stoppers of vials, bags, and bottles and the neck of ampules are sanitized with sterile 70% isopropyl alcohol prior to the introduction of a needle or spike for the removal of a medication.

20 After the preparation of every admixture, the contents of the container are thoroughly

mixed and then inspected for the presence of particulate matter, evidence of

incompatibility, or other contaminants.

21 After procedures are completed, used syringes, bottles, vials, and other supplies are removed; a minimum of exit and re-entry into the DCCA is essential to minimize the risk of introducing contamination into the aseptic workspace.

22 A sample from a compounded sterile product will be taken once a month for sterility testing.

23. All products used for sterile compounding are FDA approved and meet USP requirements assuring integrity, potency, quality, and labeled strength of compounded drug products.

24. All compounded sterile products will have a beyond use date of no more than 12 hours from the time of preparation according to USP 797 or less according to the manufacturer's product information.

Reviewed: 11/18/16ll, 01/02/19bdk, 4/19/2022 TT
PIC Signature:_____ Date:_____