HIGH DESERT HEALTH SYSTEM

Department of Pharmacy POLICY AND PROCEDURE

POLICY NUMBER: 897
VERSION: 4

SUBJECT: Sterile Compounding Quality Control: Environmental Monitoring and End Product Testing

POLICY:

Monitoring and testing of the sterile compounding facilities, environment, and end-product samples shall be conducted on an on-going basis to ensure continuous quality.

PROCEDURE:

A. Primary Engineering Control (PEC) Certification
    1. Shall be done initially prior to use and every 6 months
    2. Shall include airflow testing, HEPA filter integrity testing, total particle counts, and smoke studies
B. Environmental Controls
    1. Segregated Compounding Area
        a. Temperature must be maintained at room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit)
            i. Medications requiring storage in controlled room temperature allow for excursions below 20 degrees to 15 degrees Celsius (68 to 59 degrees Fahrenheit)
        b. Humidity must be below 60% at all times
        c. Pressure in the Segregated Compounding Area containing the ChemoSHIELD must be negative and between 0.01 and 0.03 inches of water column and documented on a daily basis.
        d. Pressure in the Segregated Compounding Area containing the SteriSHIELD will be maintained at a positive pressure and documented on a daily basis.
        e. Inform facilities department immediately if temperature, humidity, or pressures are found to be out of range. Continue with compounding activities if it is determined it is safe to continue.
    2. Primary Engineering Controls
        a. Pressure of the ChemoShield must be monitored and recorded daily and maintained at the following pressures
            i. Pass Thru Chamber: Shall maintain a negative pressure of 0.30 to 0.33 inches of water column
            ii. Main Chamber: Shall maintain a negative pressure of 0.17 to 0.23 inches of water column
            iii. The main chamber shall be lower or less negative than the pass thru chamber

b. Pressure of the SteriShield must be monitored and recorded daily and maintained at the following pressures
  i. Pass Thru Chamber: Shall maintain a positive pressure of 0.10 to 0.15 inches of water column
  ii. Main Chamber: Shall maintain a positive pressure of 0.20 to 0.25 inches of water column
  iii. The main chamber pressure shall be higher than the pass through chamber
c. If pressures for PEC are out of range immediately suspend compounding activities and inform supervisor and facilities department for correction

C. Environmental monitoring

1. Air sampling of the PEC must be conducted during typical operating activities every six months.
  a. Nonviable airborne particulate sampling during typical activity
    i. To measure the performance of the PEC to ensure the ensure appropriate air quality and cleanliness and remains an ISO Class 5 or better environment
    ii. Corrective actions shall be implemented immediately and will include immediate cessation of compounding activities until a corrective action plan is implemented.
  b. Viable airborne particulate sampling during typical activity shall use a growth medium that supports bacteria and fungi and test at least 1 cubic meter or 1000 liter of air from each area sampled.
    i. To assess microbiological air quality in the PEC and ensure zero CFU's are found in the air
    ii. If a CFU count is identified, a re-evaluation of the adequacy of number of colony-forming units (cfu) on a settling plate personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location should be prompted. Highly pathogenic microorganism (i.e. gram-negative rods, coagulase positive staphylococcus, mold, and yeast) are potentially fatal and must be remedied through cleaning and disinfection. In addition, the genus must be identified.
    iii. An investigation into the source of contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices.
    iv. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.

2. Surface Sampling of the PEC for microbial contamination must be performed every six months at the conclusion of compounding activities but before the area is cleaned and disinfected.

   a. **The pass-thru chamber and work chamber must be sampled**
   b. **If more than 3 CFU/plate are found, all compounding activities must cease in the PEC, and an immediate investigation of the cause must be conducted and corrective action must be taken**

D. End-Product Testing

1. **Shall be done yearly**
2. **Shall be done using a commonly dispensed IVPB medication**
3. **Sterility and Potency testing shall be conducted**
   a. **Currently HDRHC Pharmacy utilizes Dynalabs for end product testing**
4. **Results shall be retained and documented in the sterility testing log**
   a. **Failed sterility test shall result in an investigation of aseptic technique and environmental controls and shall be corrected.**
   b. **Failed potency test shall be evaluated for cause and be corrected.**

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