HIGH DESERT HEALTH SYSTEM

Department of Pharmacy POLICY AND PROCEDURE

POLICY NUMBER: 1371
VERSION: 3

SUBJECT: Quality Control and Competency Assessment: Garbing, Hand Hygiene, and Aseptic Technique

PURPOSE: Personnel preparing compounded sterile preparations (CSPs) are the most likely cause of CSP contamination. As a result, formal competency testing shall be in place to ensure personnel involved in aseptic preparations are well trained and qualified in proper garbing, hand hygiene, and aseptic technique.

POLICY:
All personnel involved in the preparation and handling of compounded sterile preparations (CSPs) must be trained and qualified. Competency in garbing, hand hygiene, and aseptic manipulation shall be demonstrated via a visual audit and sampling. Corrective actions shall be taken when personnel are found to be deficient.

PROCEDURE:

I. Written Test
   A. Personnel involved in preparing CSPs must complete a yearly written competency test. The written competency shall include, but is not limited to, policies and procedures related to sterile compounding and use of equipment, aseptic technique, calculations, and other material necessary to perform functions related to area of practice as determined by Pharmacy Chief.
   B. Personnel who fail written competency shall be re-evaluated and be immediately retested. Failure to pass the retest will result in re-training in sterile compounding operations before they can continue work related to sterile compounding.

II. Garbing and Hand Hygiene
   A. Competency in garbing and hand hygiene shall be established yearly. The evaluation shall include a visual audit and gloved fingertip/thumb testing. Gloved fingertip/thumb testing must be performed after media-fill preparation test.
      1. Prior to gloved fingertip/thumb testing, personnel shall complete garbing and hand hygiene and media fill testing per policy and procedures.
      2. Gloved fingertip/thumb testing shall be performed in the SteriShield as follows:
         a. Use the sterile gloves placed over the gauntlet gloves for the gloved fingertip test sample
         b. Do NOT disinfect gloves with sterile 70% isopropyl alcohol.

c. **Obtain two media contact plates, one for each hand, and visually inspect each plates for signs and contamination or dryness before use.**
    i. **Media shall be a nutrient agar containing neutralizing agents**
d. **Collect a gloved fingertip and thumb sample by lightly pressing each fingertip into the agar.**
    i. **Each lot of medium shall be accompanied by a certificate of analysis showing it has passed growth promotion tests. This certificate shall be retained in the pharmacy.**
e. **Re-cover the agar plates without further contact with agar and label with initials, right or left hand, date, and time. In addition, the manufacture, lot number, and expiration date of the plate used shall be recorded.**
f. **Immediately discard gloves after sampling.**
g. **Send the sample plates to lab for incubating.**
    i. **Plates shall be inverted and incubated at a temperature of 30-35 degrees C for 48-72 hours.**

B. Initial competency evaluation

1. **Initial competency shall be demonstrated via three successful visual audit and gloved fingertip/thumb testing samples.**
    a. **A successful visual audit is defined as zero deficiencies found.**
    b. **An initial successful gloved fingertip/thumb test is defined as zero colony-forming units found in testing samples.**

C. Ongoing competency evaluation

1. **Competency shall be demonstrated every 12 months following initial evaluation and shall include one visual audit and gloved fingertip/thumb test sample**
    a. **A successful visual audit is defined as zero deficiencies found in the audit.**
    b. **An ongoing successful gloved fingertip/thumb test is defined as no more than a total of three CFU's found on both gloves combined.**

III. Aseptic Technique

A. Competency in aseptic technique and related practices, such as proper use and cleaning of the primary engineering control (PEC), shall be evaluated yearly via a visual audit and media fill testing.

1. **Media fill testing shall be performed using the PATT2 Test using 1 GroMed ampules, 1 GroMed partially filled minibag, 1 GroMed 20 ml vial, 20 sterile 18G x 1" needles (or smaller size as appropriate) and one sterile 3, 5, or 6 ml disposable syringe.**
    a. **Certificate of analysis shall be obtained from the supplier of the growth medium and retained.**
2. **After personnel preparation, PEC sanitation, and introduction of materials into the PEC the media fill testing shall be completed in the SteriShield as follows using proper aseptic technique:**

a. **Draw up contents of ampule and inject into the GroMed vial, Shake to mix indicator dye.**
b. **Withdraw 1 ml of TSB from the GroMed vial and inject the TSB into the bag of sterile TSB. Change the needle.**
c. **Repeat (step b) 19 more times, using 19 different needles but the same syringe and receiving bag of TSB. The final transfer should empty the contents of the vial.**
d. **Immediately inspect the final container contents for particulates, corings, and fibers. These particles should not be recorded as microbial growth.**
e. **Label the final container with name, date, and time complete. In addition, the manufacture, lot number, and expiration date shall be documented.**
f. **Submit to lab for incubation at 20˚- 25˚C or 30˚- 35˚C for 14 days.**
    i. **The container shall be examined daily for turbidity. If turbidity is observed, growth from microorganisms is indicated and the test is positive. If the TSB is clear, the test is negative.**

3. **Competency evaluation**
    a. **An initial and ongoing evaluation shall include a visual audit on aseptic technique and media fill test sampling. This evaluation shall be conducted after successful completion of hand hygiene and garbing competency.**
        i. **A successful visual audit is defined as zero deficiencies found in aseptic technique.**
        ii. **A successful media fill test sample is defined as a negative test.**
        1. **Ongoing competency evaluation shall be completed every 12 months after successful initial competency evaluation completion.**

IV. Failure of Garbing, Hand Hygiene, and Aseptic Technique Competencies

A. Personnel who do not pass competency evaluations must undergo immediate requalification through additional training and pass three successive reevaluations in the deficient area before they can resume sterile compounding operations.

V. Documentation

A. Documentation of competency testing shall be retained in a readily retrievable form in the pharmacy department for at least three years beyond the period of employment for each individual.

Attachments:
Hand Hygiene and Garbing Checklist
Aseptic Technique Checklist

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