POLICY

To establish a quality assurance program to monitor and assure that aseptic techniques are validated and the correct ingredients and amounts are added to compounded sterile products (CSPs).

PROCEDURE

1 Work surface and air quality testing of the direct compounding environment will be conducted monthly. The workbench will be tested for microbial contamination using the EnviroTest kit by sampling three areas of the workbench (left, right and middle). For air quality testing, the IV Pharmacy Technician will place agar plates on the work area in the laminar airflow workbench for 30 (thirty) minutes while the workbench is in operation and sent to the laboratory for culture. If the results are positive, the workbench is cleaned and another test is done. If the second test result is positive, the workbench is shut down and Facilities Management and the vendor that certifies the hood are called to resolve the problem. The workbench remains out of operation until the problem is remedied. The vendor that certifies the workbench will semi-annually test the workbench or whenever the workbench is relocated to assure that it meets the air quality requirement of ISO Class 5. If not, the workbench is shut down and remains out of operation until the problem is remedied by Facilities Management and the vendor. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and reporting to the Infection Prevention Committee.

2 Semi-annual air quality testing of the buffer area. At the same time the workbenches are certified, the buffer area is tested at a minimum every 6 (six) months, as part of the commissioning and certification of new facilities and equipment, in response to identified problems with end products or staff technique, in response to issues with CSPs, observed compounding personnel work practices, or patient-related infections (where CSP is being considered as a potential source of the infection) for viable and nonviable environmental sampling utilizing an outsource vendor; CEPA. Viable air sampling shall be done by volumetric air sampling procedure, which tests a sufficient volume of air (400-1,000 liters) at each location. When the environmental monitoring action levels are exceeded, Pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to our policies and procedures and immediate reporting to the Infection Prevention Committee. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations. All certification records shall be

maintained and reviewed by supervising personnel or other designated employees with the intent to reduce the viable and nonviable burden. All viable air sampling results shall be reported biannually to the Infection Prevention Committee.

3 Visual confirmation by a qualified sterile compounding pharmacist that compounding personnel are properly donning and wearing appropriate items and types of protective garments as well as hand hygiene is performed.

4 Review of all orders and packages of ingredients by the IV Pharmacist to assure the correct identity and amounts of ingredients were compounded.

5 Visual inspection of CSPs by the IV Pharmacist to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, the final volume and the accuracy and thoroughness of labeling.

6 All Pharmacists and Pharmacy Technicians that prepare CSPs will be tested initially prior to sterile compounding and annually using the "GroMed Personal Aseptic Technique Test" kit.

Procedure:

- Sanitize work area using standard procedures.
- Follow the department's aseptic technique procedure.
- Select the "GroMed Personal Aseptic Technique Test" kit (product# GM7020). This will include the following:
    - 3 mL Syringe 1
    - 18G x 1½" sterile needles 10
    - GroMed Media 1 x 20mL
    - TSB Growth Media bag 1 x 100mL
    - IV foil seal 1
    - Label with include following information:
        - Date
        - Name of employee performing test
        - Initials
        - Media Lot#
    - Sterile 70% Isopropyl Alcohol (IPA)
- Place all items in the kit into the Barrier Isolator and/or Biological Safety Cabinet.
- Remove the syringe and needle from their outer wrapper.
- Attached the needle to the syringe.

- Swab the Media vial and bag with IPA. Follow the same procedure as you would to prepare an IVPB.
- Withdraw 2mL of GroMed media from the vial and inject it into the TSB Growth Media bag.
- Repeat procedure (above) 9 more times, using a total of 10 different needles but the same syringe and receiving bag of TSB. At the end of these transfers there will be approximately 120mL in the bag.
- Seal the port on the growth media bag and label.
- Turn in the growth media bag to your supervisor.
- The pharmacy supervisor will inspect the bag for particulates, corings, and fibers. These particles should not be recorded as microbial growth.
- The supervisor will store the media bag in an incubator at a temperature of 30 to 35 degrees Celsius for 14 days and will visually check the bag daily (Monday - Friday) for turbidity.
- Turbidity will indicate that there is a positive growth from a microorganism and the employee has failed the test. The employee will have to be retrained and retested until he/she has passed the test.
- A clear bag will indicate that the test is negative and the employee has passed the test.
- All results will be recorded on an "Employee Aseptic Technique Log" and maintained on file for 3 years.

7 All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure before initially being allowed to compound CSPs and annually (see P&P 5.05.6).

8 Any discrepancies will be reported in the monthly Pharmacy Supervisors' meeting and reported as needed to the Infection Control Committee.

9 A sterile compounded sample will be tested for sterility every month and documented. If the sample tests positive, the individual who prepared the contaminated sample will be re-trained by taking the written sterile compounding test as well as the Personal Aseptic Technique Test (PATT) while being observed for cleaning of the ISO 5 PEC and aseptic technique by a qualified sterile compounding pharmacist until the individual passes. Sterile compounded samples will be from different eligible personnel each month.

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10 A sterile compounded sample will be sent to an outside laboratory for quantitative (potency; active ingredient strength $\pm$ 10% of the labeled amount) analysis yearly. If the sample exceed the potency parameters, the individual who prepared the sample will be re-trained by taking the written sterile compounding test as well as provide a second compounded sample while being observed for accuracy by a qualified sterile compounding pharmacist and the sample tested for quantitative analysis by an outside laboratory until the quantitative parameters are met.

11 All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document.

12. The validation process on aseptic technique and aseptic area practices will be revalidated whenever:
    a. The quality assurance program yields an unacceptable result,
    b. There is a change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. The change includes, but is not limited to, when the PEC is moved, repaired, or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when the improper aseptic techniques are observed.
    c. The validation and revalidation process will be documented.

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