

POLICY AND PROCEDURE MANUAL PHARMACY SERVICES

CODE: 5.05.6 DATE: 3/12/97 REVISED: 4/19/22

SECTION: INTRAVENOUS ADMIXTURE PROGRAM

APPROVED: Thinh Tran, Pharm.D.

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SUBJECT: TRAINING/COMPETENCY OF PERSONNEL -

PREPARATION OF PARENTERALS

POLICY

The Pharmacy ensures proper training/competency of its professional and subordinate (technician) staff in the preparation of parenterals. The area supervisor maintains records of this training for three years.

PROCEDURE

The area supervisor provides guidelines for the safe and sterile preparation of parenterals by the staff as follows:

- 1. The concept of the preparation of piggybacks/large volume I.V. solutions in a barrier isolator/laminar flow hood is delineated (see Policy 5.04.0). Training in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures. Training and competence will include:
 - a. Didactic training
 - b. Passing written competence assessments
 - c. Personal Aseptic Technique Testing (PATT) see P&P 5.04.2
 - d. Undergoing skill assessment using observational audit tools, and media-fill testing.
 - i. Gloved Fingertip Testing
 - a) Sterile contact agar plates with neutralizing agents are used for sampling.
 - b) Initial testing occurs after garbing and subsequent testing after completing the media-fill preparation.
 - c) The evaluator collects a gloved fingertip and thumb sample from both hands.
 - d) Gloves are not disinfected with sterile 70% sterile isopropyl alcohol immediately prior to sampling.
 - e) The agar plates are incubated for the appropriate period and at the appropriate temperature conducive to multiplication of microorganisms.
 - f) All employees successfully complete an initial competency evaluation and gloved fingertip/thumb sample (0 cfu) no less than three times prior to being allowed to compound CSPs for human use.
 - g) The CFU action levels for gloved hands are documented, followed, and based on the total number of CFU on both gloves and not per hand.
 - h) When gloved fingertip sample results exceed action levels, the Department conducts a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices.

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- i) Gloved fingertip re-evaluation occurs at least annually for staff making CSPs.
- 2. Staff must pass all evaluations prior to commencing or resuming compounding.
- 3. Documentation of training/competency is placed in the Employee's area personnel file for three years.
- 4. Training shall include but is not limited to support personnel (e.g. institutional environment services, housekeeping, maintenance staff, supervising pharmacist, and all others) whose jobs are related to the compounding process. Department staff exempt from training are the following because personnel will never directly supervise compounding personnel or compound sterile products.:
 - a. Administrative staff
 - i. Director of Pharmacy
 - ii. Pharmacy Supervisors
 - b. Clinical Pharmacists
 - c. Outpatient Pharmacy staff
 - d. Procurement staff
 - i. Procurement Assistant
 - ii. Pharmacy Helper
 - e. Pharmacy staff with medical conditions
 - f. A detailed list of personnel will be on file with the pharmacist-in-charge (PIC) or designee.

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