

SUBJECT: STERILE COMPOUNDING - STAFF COMPETENCY	REFERENCE #1004
	PAGE: 1 OF: 3
DEPARTMENT: PHARMACY	EFFECTIVE:
APPROVED BY:	REVISED:

POLICY:

- This Pharmacy Department shall demonstrate, assess, maintain and improve staff competence on an ongoing basis.
- Competence assessment of staff is based on the following:
 - Populations served
 - The specific competencies required by the Pharmacy (safety, equipment, infection control)
 - The specific competencies that need to be assessed and reassessed on an ongoing basis, based on techniques, procedures, technology, equipment and skills needed to perform specified job responsibilities.
- Compounding personnel will receive didactic instruction in the theory and practice of compounded sterile preparations before assuming compounding responsibilities. A written test and media-fill tests for the appropriate risk level of CSPs must be passed before assuming compounding responsibilities.
- Competence assessment for compounding personnel include:
 - Hand hygiene
 - Attire in the clean room/area; donning said attire
 - Traffic flow in the buffer/clean room/area and DCA
 - Cleaning and disinfection of the ante-area, clean room and laminar airflow workbenches, CAIs, etc.
 - Working in the required conditions for aseptic processing
 - Aseptic manipulations of sterile products
 - Achieving and maintaining ISO Class 5 PEC devices
 - Safety procedures

SUBJECT: CSP MICROBIAL CONTAMINATION RISK LEVELS	REFERENCE #1009
DEPARTMENT: PHARMACY	PAGE: 1 OF: 3
APPROVED BY:	EFFECTIVE: REVISED:

POLICY:

- The Pharmacy Director who oversees compounding activities is responsible for determining the risk levels of CSPs prepared in the facility.
- Risk levels will be assigned according to USP <797> guidelines, applicable literature and the Pharmacy Director’s professional judgment and experience.
- Risk level of CSPs are based on probability of contaminating a CSP with:
 - Microbial contamination
 - Physical contamination
 - Chemical contamination
- The following is an overview of the three (3) risk levels, low, medium and high.
 - Low-Risk Level CSPs:
 - When the following conditions are met, CSPs are at a low risk of contamination:
 - ◆ Only sterile ingredients, components, supplies and equipment are used
 - ◆ Aseptic manipulations are performed in ISO Class 5 environment or better (i.e., laminar airflow workbench, barrier isolation)
 - ◆ Closed or sealed, sterile packaging systems are used
 - ◆ In the absence of sterility testing, storage timeframes must be followed. CSPs are stored appropriately and are exposed to:
 - Controlled room temperature for 48 hours or less before administration
 - No longer than 14 days at a cold temperature before administration
 - No longer than 45 days in a solid frozen state between -25 degrees C and -10 degrees C before administration

SUBJECT: CHEMOTHERAPY HANDLING	REFERENCE #1013
DEPARTMENT: PHARMACY	PAGE: 1 OF: 5
APPROVED BY:	EFFECTIVE:
	REVISED:

POLICY:

- All prospective employees must be informed that they may be required to work with antineoplastics. Note that this and the recommendations that follow apply to temporary staff as well as permanent staff. Supervisory staff shall review the procedures with their personnel. The toxic nature of antineoplastics shall be described to personnel in balanced terms. The rationale for each antineoplastic procedure or change in procedure shall be given. It should be noted that the procedures are felt to provide adequate safety, but that 100% protection cannot be guaranteed. All personnel must be informed that the procedures governing the handling of antineoplastics in the institution must be followed, and that adherence to these procedures will be monitored, and that noncompliance may result in disciplinary action.
- Under the US Environmental Protection Agency/Resource Conservation and Recovery Act (USEPA/RCRA), hazardous waste is a specific category of wastes that must be managed following a strict set of regulatory requirements. Of the large list of hazardous wastes, several were identified specifically as antineoplastic drugs; however, a number of drug formulations exhibit hazardous waste characteristics. Any drugs, including chemotherapy drugs utilized in this facility, meeting the criteria for hazardous drugs or with hazardous waste characteristics, will be managed according to the Occupational Safety and Health Administration (OSHA) standards, the Hazard Communication Standard, the Occupational Exposure to Hazardous Chemicals in Laboratories Standard and OSHA's Controlling Occupational Exposure to Hazardous Drugs guidelines.
 - Only those drugs determined to be hazardous agents will require management according to the federal hazardous chemicals standards listed above.
 - All other chemotherapy agents not identified as hazardous agents will be handled and disposed of as "simple" (i.e., not hazardous as identified by USEPA/RCRA standards) chemotherapy agents.
- Proper and timely medical treatment for acute antineoplastic exposures must be provided.

PROCEDURE:

- Only Pharmacy Department personnel specially trained and certified in chemotherapy handling will prepare or handle these drugs outside of the manufacturer's packaging.
 - Training shall occur before personnel prepare or handle hazardous drugs.
 - Training shall be ongoing.

SUBJECT: ATTIRE IN THE BUFFER AREA (CLEAN ROOM)	REFERENCE #1035
DEPARTMENT: PHARMACY	PAGE: 1 OF: 3
APPROVED BY:	EFFECTIVE: REVISED:

PURPOSE:

Attire in the buffer area or segregated compounding area provides a barrier between personnel and the ingredients and devices used when performing sterile compounding procedures.

POLICY:

- All personnel entering the clean room/buffer area shall be in clean room attire.
- Clean room attire consists of (to be put on in this order):
 - Non-shedding shoe covers:
 - Shoe covers are removed and disposed of when leaving the clean room.
 - Non-shedding head and facial covers:
 - The head cover/facial cover should confine the hair.
 - Head covers/facial covers are removed and disposed of when leaving the clean room.
 - Face mask/eyeshields
 - Used when working with hazardous drugs and other irritants
 - Non-shedding knee-length gowns/coveralls
 - Gowns/coveralls shall fit snugly at the wrist, shall be closed in the front, and are enclosed at the neck

Note: Gown is put on after the initial hand scrub in the ante-area.
 - Gloves:
 - Gloves shall be sterile and powder-free.
 - When compounding procedures are performed over a long period of time and when non-sterile surfaces are touched, compounding personnel will periodically disinfect gloves with 70% isopropyl alcohol.