

SUBJECT: CHEMOTHERAPY HANDLING	REFERENCE #1007
DEPARTMENT: PHARMACY	PAGE: 1 OF: 4
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.
- The organization will develop a list of drugs, including antineoplastic (chemotherapy) drugs, that are categorized as hazardous or having hazardous characteristics. Management of these drugs will follow the USEPA/RCRA standards for hazardous agents.

SUBJECT: CSP MICROBIAL CONTAMINATION RISK LEVELS	REFERENCE #1008
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DEPARTMENT: PHARMACY	EFFECTIVE:
APPROVED BY:	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:
 - 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); the clean room is maintained at ISO Class 8
 - ◆ 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

SUBJECT: LAMINAR AIRFLOW HOOD MAINTENANCE	REFERENCE #1024
DEPARTMENT: PHARMACY	PAGE: 1 OF: 1
APPROVED BY:	EFFECTIVE: REVISED:

POLICY:

The laminar airflow hood (LAFW) utilizing a HEPA filter will be used for all intravenous admixture activities within the Pharmacy Department.

PROCEDURE:

- The laminar airflow hood shall be turned on continuously except for filter changes and other required maintenance.
- Pre-filters will be changed monthly or more frequently if necessary due to working conditions. A log will be maintained documenting when the filters are changed.
- The laminar airflow hood shall be cleaned every shift and PRN with disinfectant solution. All surfaces should be cleaned adequately. Non-shedding cloths used to clean hood surfaces shall be discarded after use.
- The laminar airflow hood shall have routine contract maintenance performed every six (6) months, or when the LAFW is relocated, to assure proper function of HEPA filters. Documentation of such maintenance will be maintained in the Pharmacy Department.
- Air sampling will be performed in areas most prone to contamination during compounding activities.
- Air quality sampling will be completed:
 - Once a month, at a minimum, for sterile compounding areas used for low- and medium-risk preparations
 - Weekly, at a minimum, for sterile compounding areas used for high-risk preparations
- The laminar airflow hood shall be certified annually by an independent contractor.
 - The independent contractor will certify that the LAFW or barrier isolator is functioning correctly and meets the air quality requirement of ISO Class 5.

SUBJECT: AIR QUALITY CHECKS	REFERENCE #1028
DEPARTMENT: PHARMACY	PAGE: 1 OF: 2
APPROVED BY:	EFFECTIVE: REVISED:

POLICY:

- Air quality testing will be completed for LAFWs, barrier isolators, clean room and anteroom on a scheduled basis.
- Air quality checks for LAFWs and barrier isolators:
 - Monthly for compounding areas used for low-risk and medium-risk preparations
 - Weekly for compounding areas used for high-risk preparations
- Air quality checks for clean room and anteroom (particulate air sampling):
 - Test every six (6) months by a qualified operator to ensure a clean ISO Class 8 is met
- Air quality check records will be maintained by the Pharmacy Director.
- Air quality checks may be performed using electric air samplers or by exposing agar plates to the environment.
- Air sampling shall be performed at locations compounding personnel deem most prone to contamination during compounding procedures.
- If using an electric air sampler, follow manufacturer’s instructions.
- Agar Plates:
 - Remove covers of agar plates.
 - Place agar plates in designated areas.
 - Expose the agar plates to the environment for one (1) hour or more.
 - Collect the agar plates after exposure time has been completed.
 - Cover the agar plates and incubate at the temperature and time period specified by the manufacturer of the agar plates (usually 30 to 35 degrees C for at least 48 hours).