

## **07-02-0001—STANDARDS FOR COMPOUNDING AND DISPENSING STERILE PRODUCTS**

The purpose of this regulation is to provide standards in the conduct, practices, and operations of a pharmacy preparing and dispensing products requiring sterility, such as injectables, ophthalmics, and inhalants.

Except for those products where stability prohibits advanced compounding, all products dispensed by the pharmacy shall be in a form ready for administration, except in health care facilities where medications may be provided as demanded by policies and procedures.

Pharmacies and pharmacists dispensing sterile products shall comply with all applicable federal, state, and local law and regulation concerning pharmacy and also these additional rules:

- I. Guidelines for preparation of sterile products will be based on the distinction of sterile products as either low risk or high risk products.
  - A. Low risk sterile products are those products which meet the following characteristics:
    - a. The finished product is compounded with commercially available, sterile equipment (e.g. syringes, vials, needles.)
    - b. Preparation involves basic aseptic manipulations promptly executed (completion of product occurs without interruption.)
    - c. Closed system transfers are used in which the container closure system remains essentially intact throughout the process, compromised only by penetration of a needle or other device used to withdraw the product. (Ampuls will be considered closed systems.)
    - d. Individual products prepared upon receipt of a patient prescription order.
    - e. Quantities of 48 hours or less and expiration times of 72 hours or less.
  - B. High risk sterile products are those products which meet any of the following characteristics:
    - a. Compounding involves preparation over a prolonged period of time; or
    - b. Products used are non-sterile; or
    - c. Batch preparation of large quantities are performed in anticipation of prescription orders; or
    - d. Epidurals and intrathecal prepared using non sterile products; or
    - e. Preparation of parenteral nutrition solutions with expiration dates greater than 48 hours; or
    - f. quantities of more than 48 hours and/or expiration times of more than 72 hours, antibiotics and injectables with preservatives (ie: benzyl alcohol, methylparabens) would be exempted and considered as low risk steril products.

**C. Pharmacies and pharmacists preparing low risk sterile products shall adhere to all of this regulation except section X, which applies when high risk sterile products are prepared.**

**II. Pharmacist Requirements:**

**Any pharmacist in charge who performs or supervises the preparation or sterilization of sterile medications shall:**

- A. Have available written policies and procedures for all steps in the compounding of sterile preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, aseptic technique, quality assurance, expiration dating, and other procedures as needed.**
- B. Certify that all participating pharmacists and pharmacy technicians have completed a Board approved training and testing program in sterile product preparation. Documentation of training and testing shall be available for review, by February 30, 2002.**
- C. Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians to assure adherence to aseptic procedures.**

**III. Pharmacy Technician Requirements**

**Pharmacy Technicians participating in the preparation of sterile products shall have completed a Board approved pharmacist supervised training and testing program in sterile product preparation. Documentation of training and testing shall be available.**

**IV. Work Area and Equipment:**

**Any pharmacy dispensing sterile parenteral solutions shall meet or exceed the following requirements:**

- A. A separate controlled limited access area (also called a buffer area or buffer room) for compounding sterile solutions, which shall be of adequate space for compounding, labeling, dispensing, and sterile preparation of the medication. This area shall have controlled temperature and humidity. Cleanliness of the area is of critical importance. Drugs and other materials, taken into the limited access area, shall be removed from cardboard and other particle generating materials before being taken into the area.**
- B. The controlled limited access area shall have a certified and inspected class 100 environment. Such an environment exists inside a certified laminar airflow hood (clean room, biological safety cabinet or other barrier isolator meeting class 100 requirements) used for the preparation of all sterile products. The Class 100 environment device or area is to be inspected and certified yearly. Barrier isolator workstations are closed systems and are not as sensitive to their external environment as laminar airflow equipment.**

It is recommended to place them in a limited access area with cleaning and sanitizing in the surrounding area on a routine basis.

- C. Hazardous drugs shall be prepared within a certified Class 11 Type A (exhaust may be discharged to the outdoors) or Class 11 Type B (exhaust may be discharged to the outdoors) laminar flow biological safety cabinet. The Class 11, Type B can be obtained with a bag in--bag out filter to protect the personnel servicing the cabinet and facilitate disposal. When preparing cytotoxic agents, gowns and gloves shall be worn. All new construction, and those undergoing renovation requiring the moving of existing hoods used in the preparation of cytotoxic drugs, shall exhaust the hood to the outdoors, unless the Board of Pharmacy grants an exception. The cabinet of choice is a Class 11, Type B. For the purpose of this regulation, hazardous drugs shall be defined as agents that exhibit characteristics of genotoxicity, carcinogenicity, teratogenicity, or evidence of serious organ or other toxicity at low doses.
- D. The area shall be designed to avoid excessive traffic and airflow disturbances.
- E. The area shall be ventilated in a manner not interfering with laminar flow hood conditions.
- F. Daily procedures must be established for cleaning the compounding area.

**V. Storage:**

All Pharmacies preparing and dispensing sterile products must provide:

- A. Adequate controlled room temperature storage space for all raw materials.
- B. Adequate storage space for all equipment. All drugs and supplies shall be stocked on shelving above the floor.
- C. Adequate refrigerator storage space for compounded solutions, with routinely documented temperatures. Temperature ranges required are 36-46F or 2-8C.
- D. Adequate freezer storage space if finished products are to be frozen (e.g. reconstituted antibiotics.) There shall be a procedure to routinely document temperatures.

**VI. Labeling:**

In addition to regular labeling requirements, the label shall include:

- A. Parenteral products shall have the rate of infusion when applicable.
- A. Expiration date (Policies and Procedures shall address label change procedures as required by physician orders.)
- C. Storage requirements or special conditions.
- D. Name of ingredients and amounts contained in each dispensing unit.
- E. All products dispensed to outpatients, and removed from the site of preparation for administration different than the site of preparation, shall have label information as required by state law.

**VII. Shipping:**

- A. Policies and procedures shall assure product stability during

delivery.

- B. Pharmacy must assure ability to deliver products within an appropriate time frame.

**VIII. Home Patient Care Services:**

The pharmacist in charge of the pharmacy dispensing sterile parenteral solutions shall provide the following or assure that they are provided prior to providing medications.

- A. The pharmacist must assure that the patient is properly trained if self-administering.
- B. In situations where a pharmacy or pharmacist employs a nurse to administer medications, the pharmacist in charge must:
  - 1. Employ a Registered Nurse.
  - 2. Assure that proper records are maintained in compliance with laws and regulations.
  - 3. Make these records available to inspectors from appropriate agencies.
- C. 24-hour service shall be assured by the pharmacy.
- D. Pharmacists shall recommend and monitor clinical laboratory data as requested.
- E. Side effects and potential drug interactions should be documented and reported to the physician.
- F. Patient histories and therapy plans should be maintained.

**IX. Destruction of Cytotoxic Drugs:**

Any pharmacy providing cytotoxic drugs shall establish procedures assuring the return and proper destruction of any unused radioactive or cytotoxic drugs or other hazardous material (destruction containers for needles).

In every instance, the pharmacist in charge shall monitor the delivery, storage, and administration records of medications dispensed from his/her pharmacy.

- X. When preparing high risk sterile products, the above procedures, in addition to the following, shall be met:
  - A. Compound all medications in a separate controlled limited access area with a positive air flow room inspected and certified as meeting class 10,000 requirements (class 10,000 as defined by Federal Standard 209E). It is recommended that all pharmacies have an anteroom designed to be separate from the buffer room. The anteroom should be available for the decontamination of supplies and equipment, and donning of protective apparel. A sink should be available in the anteroom area so that personnel can scrub prior to entering the buffer room..
  - B. Use total aseptic techniques, including gowning, mask, and hair net. Scrubs may be worn instead of gowning if not worn or covered outside of the controlled limited access area.
  - C. Provide a system for tracking each compounded product including:
    - 1. Personnel involved in each stage of compounding;

2. Raw materials used including quantities, manufacturer, lot number, and expiration date;
  3. Labeling.
  4. Compounding records shall be kept for 2 years.
- D. Establishment of procedures for sterilization of all products prepared with any non-sterile ingredients by filtration with 0.22 micron or other means appropriate for the product components.
  - E. Establishment of procedures for monitoring microbial growth. All sterile products compounded using non-sterile ingredients and prepared in large batch quantities in which no patient specific prescription exists shall have end product sterility testing required. Any positive sterility test results shall prompt an investigation of aseptic technique, environmental control, and other sterility assurance controls to identify and correct problems as much as possible.
  - F. Establishment of procedures for yearly testing the techniques of pharmacists using simulated aseptic procedures and documentation thereof

Any construction requirements as required by this regulation (ie: separate controlled limited access area and certification of class 10,000) must be complied with by January, 2004)  
Adopted: 6/85 (Amended 8/2001)