

## SECTION .2800 - STERILE PHARMACEUTICALS

### 21 NCAC 46 .2801 SCOPE AND PURPOSE

The purpose of this Section is to provide standards for the preparation, labeling, and distribution of sterile products by licensed pharmacists, pursuant to an order or prescription. These standards are intended to apply to all sterile products, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office).

*History Note:* Authority G.S. 90-85.6;  
Eff. October 1, 1990;  
Amended Eff. April 1, 2003.

### 21 NCAC 46 .2802 DEFINITIONS

- (a) Anti-neoplastic. A pharmaceutical which causes the death of cancer or tumor cells.
- (b) Enteral. Within or by way of the intestine.
- (c) Parenteral. Sterile preparation of drugs for injection through one or more layers of the skin.
- (d) Sterile Pharmaceutical. A dosage form free from living microorganisms (aseptic).

*History Note:* Authority G.S. 90-85.6;  
Eff. October 1, 1990.

### 21 NCAC 46 .2803 REQ/PHARMACIES DISPENSING STERILE PHARMACEUTICALS

All locations holding a pharmacy permit where sterile pharmaceuticals are routinely compounded for dispensing must meet the following requirements:

- (1) The location shall have a designated area with entry restricted to designated personnel for preparing compounded sterile products. This area shall be structurally isolated from other areas, with restricted entry or access, and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility. It shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
- (2) The permit-holder preparing sterile products shall have the following equipment in addition to that required by Board Rule .1601 of this Chapter:
  - (a) Environmental control devices capable of maintaining at least Class 100 conditions in the work place where critical objects are exposed and critical activities are performed;
  - (b) Sink with hot and cold running water that is convenient to the compounding area for the purpose of hand scrubs prior to compounding;
  - (c) Disposal containers for used needles, syringes, etc., and if applicable cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients' homes;
  - (d) When cytotoxic drug products are prepared, environmental control devices also include biohazard cabinetry;
  - (e) Refrigerator-freezer with a thermometer;
  - (f) Temperature controlled delivery containers; and
  - (g) Infusion devices, if appropriate.
- (3) The permit-holder dispensing sterile pharmaceuticals shall maintain inventories of the following supplies: Disposable needles, syringes, and other supplies needed for aseptic admixture; disinfectant cleaning solution; handwashing agents with bactericidal action; disposable, lint-free towels or wipes; appropriate filters and filtration equipment; oncology drug spill kit; and disposable masks, caps, gowns, and gloves.
- (4) In addition to the requirements of Rule .1601(a)(3) of this Chapter, a permit-holder dispensing sterile pharmaceuticals shall have in its reference library the following reference materials: Handbook on

Injectable Drugs (ASHP); King's Guide to Parenteral Admixtures; American Hospital Formulary Service; and Procedure for Handling Cytotoxic Drugs (ASHP).

*History Note:* Authority G.S. 90-85.6;  
Eff. October 1, 1990;  
Amended Eff. April 1, 2003; September 1, 1995.

#### **21 NCAC 46 .2804 RESPONSIBILITIES OF PHARMACIST-MANAGER**

The pharmacist-manager of a permit-holder where sterile pharmaceuticals are prepared or dispensed must be knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. The pharmacist-manager shall be responsible for the development and continuing review of all policies and procedures, training manuals, and quality assurance programs. Additionally, the pharmacist-manager is responsible for assuring that there is a system for disposal of infectious waste within the pharmacy in a manner so as not to endanger the public health.

*History Note:* Authority G.S. 90-85.6;  
Eff. October 1, 1990;  
Amended Eff. April 1, 2003.

#### **21 NCAC 46 .2805 LABELING**

In addition to any other labeling requirements, containers of sterile pharmaceuticals dispensed to patients shall be labeled with instructions for storage to maintain sterility and, for anti-neoplastic drugs, appropriate warning labels.

*History Note:* Authority G.S. 90-85.6;  
Eff. October 1, 1990;  
Amended Eff. April 1, 2003.

#### **21 NCAC 46 .2806 RECORDS AND REPORTS**

The pharmacist-manager shall maintain access to and submit as appropriate such records and reports as are required to insure the patient's health, safety, and welfare. Such reports shall be readily available, maintained for three years, and subject to inspections by the Board or its agents.

*History Note:* Authority G.S. 90-85.6;  
Eff. October 1, 1990.

#### **21 NCAC 46 .2807 ANTI-NEOPLASTIC AGENTS**

The following additional requirements are necessary for those permit-holders who prepare anti-neoplastic drugs:

- (1) All anti-neoplastic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet, or similar appropriate preparation area. There must be strict adherence to the hood-cleaning procedures before preparing a product in the hood not classified as an anti-neoplastic agent.
- (2) Protective apparel shall be worn by personnel compounding anti-neoplastic drugs. This shall include disposable gloves and gowns with tight cuffs.
- (3) Appropriate safety and containment techniques for compounding anti-neoplastic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile parenteral products.
- (4) Disposal of anti-neoplastic waste shall comply with all applicable local, state, and federal requirements.

- (5) Written procedures for handling both major and minor spills of anti-neoplastic agents must be developed and must be included in the policy and procedural manual for the permit-holder.
- (6) Prepared doses of anti-neoplastic drugs must be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

*History Note:* Authority G.S. 90-85.6;  
Eff. October 1, 1990;  
Amended Eff. February 1, 2006.

## **21 NCAC 46 .2808 QUALITY ASSURANCE**

There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment and facilities. Appropriate samples of finished products shall be examined with such frequency as will assure that the pharmacy is capable of consistently preparing sterile products meeting specifications. Such examination shall include testing for microbial contamination. Quality assurance procedures shall include: recall procedures; storage and dating of products; maintenance of a log of the temperature of the refrigerator and/or freezer; routine maintenance and report of laminar flow hood certification; replacement on a regular basis of the pre-filters for the clean air source with documentation of the replacement dates; testing, with written documentation, of the end-product for microbial contamination; maintenance of written justification, or reference to published standards, for the chosen expiration date for compounded products; and regular quality assurance audits, including infection control and sterile technique audits.

*History Note:* Authority G.S. 90-85.6;  
Eff. October 1, 1990;  
Amended Eff. April 1, 2003.