

(i) Nothing in this rule shall be interpreted to amend, alter, or modify the provisions of Alabama Code Section 34, Chapter 23 or supporting regulations.

**Author:** James S. Ward, Board Attorney

**Statutory Authority:** Code of Ala. 1975, §§34-23-92.

**History:** Filed November 6, 1987; Effective January 1, 1988.

**Amended:** July 6, 1993; Effective January 1, 1994. **Amended:** Filed August 6, 1993. **Amended:** Filed February 13, 1997; effective March 20, 1997. **Amended:** Filed September 20, 1999; effective October 25, 1999. **Amended:** Filed April 3, 2003; effective May 8, 2003. **Amended:** Filed September 22, 2009; effective October 27, 2009. **Amended:** Filed January 30, 2012; effective March 5, 2012. **Amended:** Filed April 14, 2015; effective May 19, 2015. **Amended:** Filed June 8, 2016; effective July 23, 2016. **Amended:** Filed August 23, 2019; effective October 7, 2019.

**680-X-2-.19      Parenteral Sterile Therapy.**

(1) Purpose: Whereas the Alabama State Board of Pharmacy is charged with the duty and responsibility to control the compounding and distribution of prescription drug products in the State of Alabama, and is further charged to protect the citizens from inferior drug products and inappropriate compounding procedures. This rule shall provide guidelines and regulations for the compounding and distributing of parenteral products in Alabama, and to assure the Alabama consumer of sterile parenteral products that are dispensed or prepared by qualified pharmacists using acceptable pharmaceutical techniques and equipment.

(2) Registration and Certification, Pharmacies: All pharmacies engaged in the compounding of products which should be sterile shall be registered with the Alabama State Board of Pharmacy biennially which shall expire on December 31 of even-numbered years and Alabama pharmacies shall receive a permit in accordance with Code of Ala. 1975, §34-23-30. Such pharmacies shall be certified, further, by the Alabama State Board of Pharmacy as a parenteral sterile compounding pharmacy.

(3) Registration and Certification, Pharmacists: All pharmacists, permitted and practicing in Alabama, engaged in compounding and dispensing of product which should be sterile, including cytotoxic agents, shall register each renewal cycle with the Board of Pharmacy in accordance with Code of Ala. 1975,

§§34-23-51, 34-23-52. After January 1, 1994, pharmacists who have not successfully completed a certifying course for sterile compounding approved by the Board, will not be registered as sterile compounding pharmacists until they have completed said certifying course. Programs submitted for certification shall be a minimum of eight (8) contact hours, including didactic and hands on experience. All programs certified by the Board shall require a written exam as a part of the training. Pharmacists performing high risk sterile compounding shall complete an additional four (4) hour board approved high risk program. All pharmacists approved by the Alabama State Board of Pharmacy as sterile compounding pharmacists must successfully complete two (2) continuing education hours approved by the Board including didactic and hands on training each renewal cycle.

(4) It shall be the responsibility of the supervising pharmacist to verify the parenteral certification of pharmacists involved in the preparation of parenteral products.

**Author:** Donna C. Yeatman, R.Ph., Executive Secretary

**Statutory Authority:** Code of Ala. 1975, §34-23-92.

**History:** Filed July 18, 1989. **Amended:** March 19, 1993.

**Amended:** Filed July 24, 2012; effective August 28, 2012.

**Amended:** Filed July 24, 2012; effective August 28, 2012.

**Amended:** Filed July 25, 2018; effective September 8, 2018.

**Amended:** Published December 31, 2020; effective February 14, 2021.

#### 680-X-2-.20 Nuclear Pharmacy.

(1) Purpose and Scope: It is unlawful to receive, possess, or transfer radioactive drugs, except in accordance with appropriate pharmacy statute(s) and rule(s). It is also unlawful for any person to provide radiopharmaceutical services unless he/she is a pharmacist or a person acting under the direct supervision of a pharmacy acting in accordance with appropriate pharmacy statute(s) and the State Board of Pharmacy rule(s) and rules of the State Board of Health relating to radiation control. No person may receive, acquire, possess, use, transfer or dispose of any radioactive materials except in accordance with the conditions of a radioactive materials license issued by the State Board of Health. The requirements of these nuclear pharmacy regulations are in addition to, and not in substitution for, other applicable provisions of regulations of the State Board of Pharmacy and the State Board of Health.