

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-25-.08 EQUIPMENT. AMENDED., AND NOTICE OF PUBLIC HEARING**

TO ALL INTERESTED PERSONS AND PARTIES:

Notice is hereby given that pursuant to the authority set forth below, the Georgia State Board of Pharmacy (hereinafter "Board") proposes amendments to the Georgia Board of Pharmacy Rules, Rule 480-25-.08 EQUIPMENT. AMENDED. (hereinafter "proposed amendments").

This notice, together with an exact copy of the proposed amendments and a synopsis of the proposed amendments, is being forwarded to all persons who have requested, in writing, that they be placed on an interested parties list. A copy of this notice, an exact copy of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments may be reviewed during normal business hours of 8:00 a.m. to 5:00 p.m. Monday through Friday, except official State holidays, at the Department of Community Health at 2 Peachtree Street NW, Atlanta, Georgia, 30303. These documents will also be available for review on the Georgia State Board of Pharmacy's web page at www.gbp.georgia.gov.

A public hearing is scheduled to begin at 11:00 AM on April 15, 2015 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, Georgia 30303 to provide the public an opportunity to comment upon and provide input into the proposed amendments. At the public hearing, anyone may present data, make a statement, comment or offer a viewpoint or argument whether orally or in writing. Lengthy statements or statements of a considerable technical or economic nature, as well as previously recorded messages, must be submitted for the official record. Oral statements should be concise and will be limited to 5 minutes per person. Additional comments should be presented in writing. Written comments are welcome. To ensure their consideration, written comments must be received prior to April 8, 2015. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, Atlanta, Georgia 30303 FAX: 678-717-6694. You may email your comments to tbattle@dch.ga.gov.

The proposed amendments will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 11:05 AM on 4/15/2015 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, Georgia 30303. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed amendments pursuant to authority contained in O.C.G.A. §§ 26-3-7, 26-3-17, 26-4-27, 26-4-28, 26-4-110, 26-4-130, 26-4-170, 26-4-172, 26-4-174, and 26-4-178.

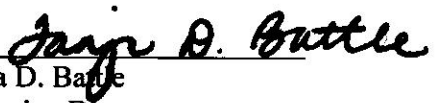
At its meeting on December 18, 2014, the Board voted that the formulation and adoption of these rule amendments do not impose excessive regulatory cost on any licensee, and any cost to comply with the proposed amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22.

At its meeting on 12/18/2014, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A§ 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these amendments will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

For further information, contact the Board office at 404-651-8000.

This notice is given in compliance with O.C.G.A. §50-13-4.

This 19th day of February, 2015.



Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: February 19, 2015

**SYNOPSIS OF GEORGIA STATE BOARD OF PHARMACY RULE
480-25-.08 EQUIPMENT. AMENDED.**

Purpose of Rule: The purpose of this rule is to add to the list of the equipment required for nuclear pharmacies.

Main Features: The main feature of this rule is to require both the articles and equipment required by the Board for all pharmacies in the State and also equipment specific to nuclear pharmacies.

**DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-25-.08 EQUIPMENT. AMENDED.**

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

480-25-.08 Equipment. Amended.

(1) In addition to other articles and equipment required by the Board for all pharmacies in the State, the nuclear pharmacy shall have:

- (a) dose calibrator;
- (b) vertical laminar flow hood;
- (c) single or multiple channel scintillation analyzer;
- (d) microscope and hemocytometer;
- (e) adequate glassware, utensils, and gloves;
- (f) calculator;
- (g) laboratory incubator;
- (h) water or oil bath;
- ~~(i) ultrasonic bath;~~
- (j)(i) aluminum ion test kit; and
- ~~(k)(j)~~ adequate apparatus and supplies for performing chromatography.

(2) Nuclear pharmacies shall also have equipment required for the safe handling and storage of radioactive materials, as required by the Department's Rules and Regulations for radioactive materials.

(3) Each nuclear pharmacy shall utilize unit dose transport containers, a/k/a lead pigs,

(a) Unit dose transport containers, a/k/a lead pigs, for radioactive doses shall include:

- 1. an effective tamper-evident seal;
- 2. an effective mechanism to avoid radioactive contamination; and
- 3. an effective system to prevent contamination of the transport container with blood, bodily fluids, or other biohazardous substances.

(b) No nuclear pharmacist or nuclear pharmacy shall re-use a unit dose transport container or lead pig that has been contaminated with blood, bodily fluids, or other hazardous substances.

(c) Any unit dose transport container or lead pig returned to a nuclear pharmacy with the tamper-evident seal broken and containing an exposed unit dose syringe shall be considered contaminated.

(d) Section 3 of this Rule shall not apply to:

- 1. an individual prescriber preparing radiopharmaceuticals for administration to his or her own patients;

2. transfer of radioactive material, not intended for use as a drug, to other legally authorized persons; and
3. the occasional transfer of bulk radiopharmaceuticals to other authorized entities or persons to meet shortages.

(e) Biohazardous prevention systems containing a barrier that if used properly eliminates or substantially reduces the potential for contamination of the unit dose transport container, or lead pig, would meet the requirements of these regulations. Improper use of such system resulting in ineffective sanitation of the unit dose transport container, or lead pig, would require that such containers be effectively sanitized prior to subsequent use or discarding of that container.

Authority: O.C.G.A. §§26-3-7, 26-3-17, 26-4-27, 26-4-28, 26-4-110, 26-4-130, 26-4-170, 26-4-172, 26-4-174, and 26-4-178