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Sequence Number: 04-08-14
Notice ID(s): 2153
File Date: 4/7/14

Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission: Department of Health
Division: Tennessee Medical Laboratory Board
Mollie A. Gass
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Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact: ADA Coordinator
710 James Robertson Parkway,
Address: Andrew Johnson Building, 5th Floor, Nashville, Tennessee 37243
Phone: (615) 741-6350
Email: Tina.M.Harris2@tn.gov

Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	Metro Center
Address 2:	665 Mainstream Drive, Poplar Conference Room
City:	Nashville, Tennessee
Zip:	37228
Hearing Date:	07/18/2014
Hearing Time:	9:00 a.m. <input checked="" type="checkbox"/> CST/CDT <input type="checkbox"/> EST/EDT

Additional Hearing Information:

Revision Type (check all that apply):

Amendment
 New
 Repeal

Rule(s) (ALL chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
1200-06-03	General Rules Governing Medical Laboratories
Rule Number	Rule Title
	Table of Contents

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

Chapter 1200-06-03
General Rules Governing Medical Laboratories

Amendments

Chapter 1200-06-03 Table of Contents

- 1200-06-03-.01 Definitions
- 1200-06-03-.02 Licensing Procedures and Licensure Exemptions
- 1200-06-03-.03 Change in Location, Director, Owner, Supervisor or Testing in a Medical Laboratory
- 1200-06-03-.04 Inspections - Reports
- 1200-06-03-.05 Licensure Discipline, Civil Penalties, Assessment of Costs, and Subpoenas
- 1200-06-03-.06 Minimum Standards
- 1200-06-03-.07 Participation In Proficiency Testing
- 1200-06-03-.08 Patient Test Management
- 1200-06-03-.09 Quality Control
- 1200-06-03-.10 Performance Improvement Program
- 1200-06-03-.11 Facilities, Safety, Infectious and Hazardous Waste Disposal
- 1200-06-03-.12 Reportable Diseases
- 1200-06-03-.13 Personnel Policies
- 1200-06-03-.14 Personnel Requirements for a Medical Laboratory
- 1200-06-03-.15 Special Regulations for ASTC, Blood Donor Centers, and Plasmapheresis Centers
- 1200-06-03-.16 Alternate Site Testing
- 1200-06-03-.17 Waived Testing
- 1200-06-03-.18 Collection Stations
- 1200-06-03-.19 Preparatory Portions of Laboratory Tests
- 1200-06-03-.20 Advertising
- 1200-06-03-.21 Renewal of Laboratory License
- 1200-06-03-.22 Special Regulations Regarding Laboratories Licensed Under T.C.A. § 68-29-138

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, 68-29-105, 68-29-111, 68-29-113, 68-29-114, 68-29-115, and 68-29-138.

New Rule
1200-06-03-.22

1200-06-03-.22 Special Regulations Regarding Laboratories Licensed Under T.C.A. § 68-29-138.

- (1) Medical laboratories performing advanced esoteric applied toxicological, forensic, or biochemical analysis utilizing emerging technology shall be licensed.
 - (a) Licensing procedures set out in Rule 1200-06-03-.02 shall be met.
 - (b) Laboratories licensed under T.C.A. § 68-29-138(a) are subject to all provisions of the Medical Laboratory Act except for the provisions of the Medical Laboratory Act and rules promulgated under the Act that require persons who accept specimens for laboratory examination and perform analytical testing or report the results of a laboratory examination to be licensed as a technologist, technician, laboratory trainee, or special analyst.
 - 1. To be eligible for the licensed personnel exemption, a medical laboratory must obtain a license pursuant to T.C.A. § 68-29-138. This license shall be unique and in addition to other licenses for laboratories located in contiguous buildings on the same campus that do not fall within the exemption.
 - (c) The application for licensure under this exemption shall require a specific testing menu.

- (2) Laboratories licensed under this rule shall be subject to on-site surveys by the Department. The survey shall include inspection of the following: laboratories, tools therein, and educational requirements of personnel defined in T.C.A. § 68-29-138(c).
- (3) Only medical laboratories engaged in advanced esoteric applied toxicological, forensic, or biochemical laboratory analysis utilizing emerging technologies shall be given an exemption defined in subparagraph (1)(b).
 - (a) Definition: advanced esoteric applied toxicological, forensic, or biochemical laboratory analysis is narrowly focused analysis that takes place within independent laboratories.
 - (b) Emerging technologies include, but are not limited to, chromatographic and non-chromatographic techniques coupled with mass spectrometer based detector systems and molecular diagnostic techniques.
- (4) Personnel in laboratories licensed under T.C.A. § 68-29-138 shall not be required to complete the procedures for personnel licensure as provided in Rule 1200-06-01-.05. However, personnel who analyze or report laboratory results shall possess a baccalaureate or advanced degree in the appropriate sciences with at least sixteen (16) semester hours of chemistry and/or biological science courses.
 - (a) Licensed personnel shall be allowed to perform tasks for which they are appropriately licensed and trained in laboratories exempt from hiring licensed personnel.
 - (b) Determining the appropriate sciences for baccalaureate or advanced degree for unlicensed personnel shall be left to the medical director of the laboratory.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, 68-29-105, 68-29-111, 68-29-113, 68-29-114, 68-29-115, and 68-29-138.

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: 4/7/14

Signature: Mollie A. Gass

Name of Officer: Mollie A. Gass
Assistant General Counsel

Title of Officer: Department of Health

Subscribed and sworn to before me on: 4-7-14

Notary Public Signature: Supreme Meekhoff

My commission expires on: _____

MY COMMISSION EXPIRES
APRIL 19, 2017

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Filed with the Department of State on: 4/7/14

Tre Hargett
Tre Hargett
Secretary of State

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