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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission: Department of Health
Division: Tennessee Medical Laboratory Board
Contact Person: Mollie Gass
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. 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
1200-06-03-22	Special Regulations Regarding Laboratories Licensed Under T.C.A. § 68-29-138

(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

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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.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Cheryl K. Arnott, CT	X				
Tereyo M. Cox, MT	X				
Mark A. Calarco, DO	X				
Kathleen Kenwright, MT		X			
Stephanie Dolsen, MT	X				
Patti J. Walton, MT	X				
Carla M. Davis, MD	X				
Jason S. Nolan, M.D.	X				
Jerry L. Miller, MD	X				
Royce E. Joyner, M.D.	X				
Vacant					
Vacant					
Vacant					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Medical Laboratory Board (board/commission/ other authority) on 07/18/2014 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 04/07/14 (mm/dd/yy)

Rulemaking Hearing(s) Conducted on: (add more dates). 07/18/2014 (mm/dd/yy)

Date: 3/24/15

Signature: Mollie Gass

Name of Officer: Mollie Gass

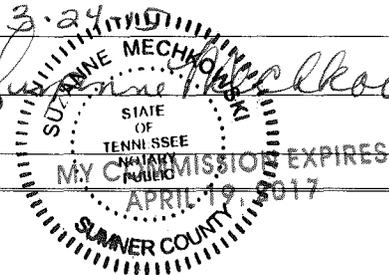
Assistant General Counsel

Title of Officer: Department of Health

Subscribed and sworn to before me on: 3-24-15

Notary Public Signature: [Signature]

My commission expires on: APRIL 19, 2017



All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Herbert H. Slatery III
Attorney General and Reporter
3/30/2015
Date

Department of State Use Only

Filed with the Department of State on: 4/1/15

Effective on: 6/30/15

Tre Hargett
Tre Hargett
Secretary of State

RECEIVED
2015 APR - 1 PM 4: 02
SECRETARY OF STATE
PUBLICATIONS

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

There were no public comments, either written or oral.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(1) The extent to which the rule or rules may overlap, duplicate, or conflict with other federal, state, and local governmental rules.

These proposed rule amendments do not overlap, duplicate, or conflict with other federal, state, or local governmental rules. Upon passage of these proposed rule amendments, there will be two separate licensure categories for medical laboratories, which is necessary in order to separately regulate a facility which is not required to employ licensed personnel.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

These proposed rule amendments exhibit clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

These proposed rule amendments do not create flexible compliance and/or reporting requirements for small businesses. The purpose of these rule amendments is to regulate medical laboratories utilizing unlicensed personnel, as well as what tests are performed in order to comply with the Medical Laboratory Act requirements.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

These proposed rule amendments do not establish reporting requirements.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

All medical laboratories are required to be licensed regardless of business size, and these proposed rule amendments and additions do not complicate the compliance or reporting requirements. The purpose of a separate license for laboratories utilizing individuals who are not licensed medical laboratory personnel is to regulate tests non-licensed personnel are performing by creating a separate licensure category.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

These proposed rule amendments do not establish performance, design, or operational standards.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

These proposed rule amendments do not create unnecessary barriers or stifle entrepreneurial activity or innovation. The statutory change encourages medical laboratories participating in leading edge technology to be located in Tennessee.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: *Medical Laboratory Board*

1. Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:

These proposed rule amendments will only affect medical laboratories performing esoteric testing that utilize unlicensed personnel, and at this time, the number of laboratories intending to pursue such licensure is unknown. If an esoteric laboratory chooses to employ licensed personnel, these proposed rule amendments would not affect that lab.

2. Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:

These proposed rule amendments do not affect the reporting requirements or other administrative costs for compliance. Although the licensure application and annual renewal fees are \$1,000.00, this cost is the same for all medical laboratories.

3. Statement of the probable effect on impacted small businesses and consumers:

These proposed rule amendments should not have a specific effect on small businesses. The proposed rule amendments create a new category of medical laboratory license; however, there has always been a requirement that the facility be licensed regardless of the size of the lab or business.

4. Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:

These proposed rule amendments are not burdensome or intrusive. Although these rules will require a medical laboratory engaged in esoteric testing to apply for a license at a cost of \$1,000.00, the proposed rule amendments are required to effectively regulate exceptions created by Public Chapter No. 213. The application and renewal costs are the same for each type of medical laboratory, whether or not the lab is engaged in esoteric testing.

5. Comparison of the proposed rule with any federal or state counterparts:

Federal: The United States Code Annotated requires medical laboratories to be certified. See 42 U.S.C.A. § 263a. Medical laboratories licensed under these proposed rules amendments are still required to be federally certified, just as all medical laboratories in Tennessee.

State: In order to operate a medical laboratory in Tennessee, the lab is required to obtain a license from the Board pursuant to T.C.A. § 68-29-111. These proposed rule amendments require medical laboratories engaged in esoteric testing be licensed under a separate licensure category from a typical medical laboratory due to the difference in requirements for personnel. However, the process for labs engaged in esoteric testing is identical to any other lab obtaining licensure; the procedures for obtaining such license are found at Tenn. Comp. R. & Regs. 1200-06-03-.02.

States such as Kentucky and Maryland also require medical laboratories to require a state level license. However, this is not true for all states. Arizona, for example, defines medical laboratory as one certified by the United States Department of Health and Human Services. A.R.S. § 36-451.

Not all states require personnel in medical laboratories to obtain state licensure. Instead of totally removing licensure requirements for medical laboratory personnel, Public Chapter No. 213 creates an exception for personnel engaged in certain types of testing not be required to obtain a state license. In order to ensure medical laboratories not engaged in esoteric testing described in Public Chapter No. 213 are

utilizing licensed personnel, two separate facility licensure categories are necessary to enforce this new exception.

6. Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

These proposed rule amendments do not provide exemptions. All medical laboratories are required to be licensed, and the proposed rule amendments simply add a licensure category.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The proposed rule amendments should not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Rule 1200-06-03-.22 is being added to provide necessary regulations required pursuant to T.C.A. § 68-29-138, which provides medical laboratories performing certain types of testing are not required to employ licensed personnel.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

T.C.A. § 68-29-138, which provides medical laboratories performing certain types of testing are not required to employ licensed personnel.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

These proposed rule amendments will only affect medical laboratories performing esoteric testing that utilize unlicensed personnel, and at this time, the number of laboratories intending to pursue such licensure is unknown. If an esoteric laboratory chooses to employ licensed personnel, these proposed rule amendments would not affect that lab.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

None.

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

These rules should not result in any increase or decrease in state and local government revenues and expenditures.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Mollie Gass, Assistant General Counsel, Department of Health.

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Mollie Gass, Assistant General Counsel, Department of Health.

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Department of Health, Office of General Counsel, 665 Mainstream Drive, Nashville, Tennessee 37243, (615) 741-1611, Mollie.Gass@tn.gov.

- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

None.

**RULES
OF
TENNESSEE MEDICAL LABORATORY BOARD**

**CHAPTER 1200-06-03
GENERAL RULES GOVERNING MEDICAL LABORATORIES**

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1200-06-03-.11	Facilities, Safety, Infectious and Hazardous Waste Disposal		

1200-06-03-.01 DEFINITIONS. As used in this chapter of Rules the following terms and acronyms shall have the following meanings ascribed to them:

- (1) ASTC - Ambulatory Surgical Treatment Center, specifically any institution, place or building devoted primarily to the maintenance and operation of a facility for the performance of surgical procedures or any facility in which a medical or surgical procedure is utilized to terminate a pregnancy and is licensed by the Tennessee Board for Licensing Health Care Facilities under Rule 1200-8-10.
- (2) Anatomic laboratory - Any medical laboratory performing only the biophysical examination of specimens pertaining to the clinical specialty of pathology, to include histopathology, oral pathology, and cytopathology. The examination of these specimens taken from the human body are performed to obtain information for diagnosis, prophylaxis, or treatment or where any examination, determination or test is made of any sample used as a basis for health advice, or where any sample is collected for the purpose of transfusion or processing of blood or blood fractions, or the training of medical laboratory personnel. Compliance with Rule 1200-6-1-.20 is required to be the director of an anatomic laboratory.
- (3) Authorized person - A physician or intern or resident in an American Medical Association approved training program or a duly licensed optometrist or a duly licensed dentist or a duly licensed chiropractic physician or other health care professional legally permitted to submit to a medical laboratory a written request for tests appropriate to that professional's practice or a law enforcement officer acting in accordance with T.C.A. § 55-10-406.
- (4) Board - The Tennessee Medical Laboratory Board.
- (5) CLIA - The Clinical Laboratory Improvement Amendments as found in 42 CFR 493.
- (6) CLSI - The Clinical Laboratory and Standards Institute.

(Rule 1200-06-03-.21, continued)

2. Paper Renewals - For laboratories or collection stations that have not renewed their license online via the Internet, a renewal application form will be mailed to each laboratory and collection station licensed by the Board at least sixty (60) days prior to the expiration date to the last address provided to the Board. Failure to receive such notification does not relieve the laboratory or collection station from the responsibility of meeting all requirements for renewal.
- (3) To be eligible for renewal, a laboratory or collection station must submit to the Division of Health Related Boards on or before the expiration date all of the following:
1. A completed renewal application form, signed by the owner and director of the medical laboratory or public official responsible for the operation of a city or county medical laboratory or institution that contains a medical laboratory; and
 2. In alphabetical order, a roster of all personnel currently employed in the laboratory, the classification/category in which the employee functions and is licensed, license number, expiration date and social security number. This shall include all medical laboratory directors, consultants, supervisors and testing personnel; and
 3. The renewal and state regulatory fees as provided in Rule 1200-06-03-.02.
- (4) All laboratories performing tests must file a separate renewal application for each laboratory address.
- (5) Laboratories within a hospital that are located in contiguous buildings on the same campus and under common direction may file a single renewal application or multiple renewal applications for the laboratory sites within the same physical location or street address.
- (6) Laboratories and collection stations which submit a signed renewal form or letter that is found to be untrue may be subject to disciplinary action as provided in Rule 1200-06-03-.05.
- (7) Laboratories and collection stations which fail to comply with the renewal rules or notification received by them concerning failure to timely renew shall have their licenses processed pursuant to rule 1200-10-01-.10.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-113, and 68-29-126. **Administrative History:** Original rule filed April 17, 2007; effective July 1, 2007.

Rule 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

(Rule 1200-06-03-.21, continued)

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.