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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. TCA Section 4-5-205

<b>Agency/Board/Commission:</b>	Tennessee Medical Laboratory Board
<b>Division:</b>	Division of Health Related Boards
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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. Please enter only ONE Rule Number/RuleTitle per row)**

Chapter Number	Chapter Title
1200-06-01	General Rules Governing Medical Laboratory Personnel
Rule Number	Rule Title
1200-06-01-.03	Necessity of Licensure
1200-06-01-.12	Continuing Education
1200-06-01-.22	Qualifications, Responsibilities and Duties of Testing Personnel
1200-06-01-.18	Unethical Conduct

Chapter Number	Chapter Title
1200-06-03	General Rules Governing Medical Laboratories
Rule Number	Rule Title
1200-06-03-.02	Licensing Procedures

## Amendments

Rule 1200-06-01-.03 Necessity of Licensure, is amended by deleting the catchline in its entirety and substituting instead the catchline Necessity of Licensure and Licensure Exemptions, and is further amended by adding the following language as new paragraph (4):

- (4) The following personnel are exempt from the licensure requirements imposed pursuant to the "Tennessee Medical Laboratory Act":
  - (a) All personnel performing the testing described in rule 1200-06-03-.02 (5) in the laboratory or portion of the otherwise licensed laboratory exempted from licensure pursuant to that rule.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, and 68-29-105.

Rule 1200-06-01-.12 Continuing Education, is amended by adding the following introductory language immediately after the catchline, so that as amended, the catchline and the introductory language shall read:

1200-06-01-.12 Continuing Education. Continuing education is planned, organized learning acts acquired during licensure to maintain, improve or expand a licensee's knowledge and skills relevant to medical laboratory practice in order for the licensee to develop new knowledge and skills relevant to the practice, education or theory development to improve the safety and welfare of the public.

Authority: T.C.A. §§ 4-5-202, 4-5-204, and 68-29-105.

Rule 1200-06-01-.22 Qualifications, Responsibilities and Duties of Testing Personnel, is amended by deleting subparagraph (1) (a) in its entirety and substituting instead the following language, and is further amended by inserting the following language as subparagraph (1) (b) and renumbering the remaining subparagraphs accordingly, and is further amended by deleting the subpart which is to be renumbered as (1) (c) 2. (iii) in its entirety and substituting instead the following language, so that as amended, the new subparagraphs (1) (a) and (1) (b), and the new subpart (1) (c) 2. (iii) shall read:

- (1) (a) To become licensed as a medical laboratory technologist an applicant must:
  - 1. Submit satisfactory evidence of successfully completing and passing a national certifying examination and being nationally certified at the technologist level by either the ASCP, NCA, NRCC, NRM, ABB, AMT or any other national certifying agency recognized by the Board (Successful completion of the Health and Human Services proficiency examination in clinical laboratory science does not meet this criteria for licensure); and
  - 2. In addition to possessing the national certification required by part 1. of this subparagraph, submit satisfactory evidence of having met one (1) of the following educational criteria:
    - (i) A baccalaureate degree in medical technology or in one of the biological, chemical or physical sciences, and completion of a medical laboratory technologist training program that was, at the time of graduation, either

- (I) approved or under the auspice of the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS); or
  - (II) approved by a national accrediting agency acceptable to the Board; or
  - (III) completed in a specialty program conducted by a hospital or other institution approved pursuant to Rule 1200-6-2-.04; or
- (ii) A baccalaureate degree from an accredited college/university, completion of an accredited MLT/CLT training program and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g); or
  - (iii) A baccalaureate degree from an accredited college/university, completion of an official military laboratory procedures course of at least fifty (50) weeks duration in residence and have held the military enlisted occupational specialty of Medical Laboratory Specialist, and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g); or
  - (iv) A baccalaureate degree from an accredited college/university and five (5) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g).
- (b) Those applicants for medical laboratory technologist licensure who do not possess a baccalaureate degree may be approved for licensure upon having submitted to the Board's administrative office directly from the national certifying agency satisfactory proof of having successfully completed on or before September 1, 1997 (the date on which CLIA required at a minimum an associate's degree or its equivalent for those who would be performing high complexity testing and the date on which the Board ceased providing the state licensure examination) a medical laboratory technologists national certification examination and submission to the Board's administrative office directly from the issuing authorities of satisfactory proof that the applicant met one (1) of the following criteria:
1. The applicant had, on or before September 1, 1997, received a passing grade on a Health and Human Services proficiency examination in clinical laboratory science and had completed five

(5) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); or

2. The applicant had, on or before September 1, 1997, completed a minimum of ninety (90) semester hours including science course work equivalent to that required in a laboratory science education program as defined by (1) (g) of this rule; and had, on or before September 1, 1997, completed a medical laboratory technologist training program that was approved at the time of graduation by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) or a national accrediting agency acceptable to the Board.

(c) 2. (iii) An associate degree from an accredited college/university which included at least six (6) semester hours of chemistry and six (6) semester hours of biology and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1)(h).

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, and 68-29-118.

Rule 1200-06-03-.02 Licensing Procedures is amended by deleting the catchline in its entirety and substituting instead the catchline Licensing Procedures and Licensure Exemptions, and is further amended by adding the following language as new paragraph (5):

(5) Pursuant to T.C.A. § 68-29-104(8) the Board hereby exempts the following laboratories (or portions of otherwise licensed laboratories) and the personnel performing tests in those laboratories (or portions of otherwise licensed laboratories) from the requirements imposed pursuant to the "Tennessee Medical Laboratory Act":

(a) Any laboratory (or portion of an otherwise licensed laboratory) which is operated by the Tennessee Department of Health and in which the only testing on human specimens is that which is required pursuant to an investigation ordered by or in cooperation with the State Epidemiologist or law enforcement agency the results of which are reported only to the State Epidemiologist, CDC or law enforcement officials as required by federal law.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, and 68-29-105.

## New Rule

### Table of Contents

1200-06-01-.18 Unethical Conduct

1200-06-01-.18 Unethical Conduct.

(1) Unethical conduct shall include, but not be limited to:

(a) Failing to exercise reasonable diligence to prevent partners, associates, and employees from engaging in conduct which would violate any

provisions of the Tennessee Medical Laboratory Act or any rule, regulation, or order of the Board.

(b) Penalizing medical laboratory personnel for reporting violations of any provisions of the Tennessee Medical Laboratory Act or any rule, regulation, or order of the Board.

(2) Violations of this rule shall subject a licensee to disciplinary action, as provided in Rule 1200-06-01-.15.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-127, and 68-29-129.

\* 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)
Thomasa Cooper	X				
Norman Crowe	X				
Yvonne Davis	X				
Martha Duncan	X				
Linda Lahr	X				
Alison K. McDonald-Spakes	X				
Trudy A. Papuchis, M.D.	X				
Delores W. Voigt	X				
Dennis C. Carter, M.D.	X				
Jere Ferguson, M.D.	X				
Edward McDonald, M.D.				X	
John C. Neff, M.D.	X				
Gloria L. Jenkins	X				

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 01/26/2007, and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 10/12/06

Notice published in the Tennessee Administrative Register on: 11/15/06

Rulemaking Hearing(s) Conducted on: (add more dates). 12/19/06

Date: ~~03/04/09~~ 3/6/09

Signature: Ernest Sykes, Jr.

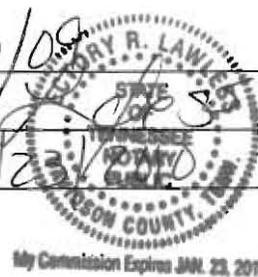
Name of Officer: Ernest Sykes, Jr.

Title of Officer: Assistant General Counsel, Department of Health

Subscribed and sworn to before me on: 3/6/09

Notary Public Signature: \_\_\_\_\_

My commission expires on: \_\_\_\_\_



Legal Contact: Nicole Armstrong, Associate General Counsel, Office of General Counsel, 220 Athens Way, Suite 210, Plaza I, MetroCenter, Nashville, TN 37243, (615) 741-1611.

Contact for disk acquisition and/or party who will approve final copy for publication: Jerry Kosten, Regulations Manager, Division of Health Related Boards, 227 French Landing, Suite 300, Heritage Place, Nashville, TN 37243, (615) 532-4397.

Signature of the agency officer or officers directly responsible for proposing and/or drafting these rules:

  
Norman Crowe, Chair  
Tennessee Medical Laboratory Board

The roll call vote by the Tennessee Medical Laboratory Board on these rulemaking hearing rules was as follows:

Board Members	Aye	No	Abstain	Absent
Thomasa Cooper	<u>X</u>	___	___	___
Norman Crowe	<u>X</u>	___	___	___
Yvonne Davis	<u>X</u>	___	___	___
Martha Duncan	<u>X</u>	___	___	___
Linda Lahr	<u>X</u>	___	___	___
Alison K. McDonald-Spakes	<u>X</u>	___	___	___
Trudy A. Papuchis, M.D.	<u>X</u>	___	___	___
Delores W. Voigt	<u>X</u>	___	___	___
Dennis C. Carter, M.D.	<u>X</u>	___	___	___
Jere Ferguson, M.D.	<u>X</u>	___	___	___
Edward McDonald, M.D.	___	___	___	<u>X</u>
John C. Neff, M.D.	<u>X</u>	___	___	___
Gloria L. Jenkins	<u>X</u>	___	___	___

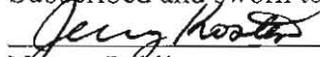
I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Medical Laboratory Board on the 26th day of January, 2007.

Further, I certify that the provisions of T.C.A. § 4-5-222 have been fully complied with, that these rules are properly presented for filing, a notice of rulemaking hearing has been filed in the Department of State on the 16th day of October, 2006 and such notice of rulemaking hearing having been published in the November 15th, 2006 issue of the Tennessee Administrative Register, and such rulemaking hearing having been conducted pursuant thereto on the 19th day of December, 2006.

  
\_\_\_\_\_  
Robbie H. Bell, Director  
Division of Health Related Boards

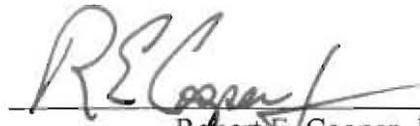


Subscribed and sworn to before me this the 26th day of January, 2007.

  
\_\_\_\_\_  
Notary Public

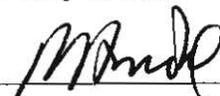
My commission expires on the 20th day of March, 2010.

All rulemaking hearing 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.

  
\_\_\_\_\_  
Robert E. Cooper, Jr.  
Attorney General and Reporter

The rulemaking hearing rules set out herein were properly filed in the Department of State on the 1 day of April, 2009, and will become effective on the 15 day of June, 2009.

  
\_\_\_\_\_  
Tre Hargett  
Secretary of State

By: \_\_\_\_\_

## **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.

### Regulatory Flexibility Addendum

Pursuant to Public Chapter 464 of the 105<sup>th</sup> General Assembly, prior to initiating the rule making process as described in § 4-5-202(a)(3) and § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

#### Regulatory flexibility analysis

Tennessee Medical Laboratory Board; Rule Nos. 1200-06-01-.03, .12, .18, .22, and 1200-06-03-.02.

Pursuant to the Regulatory Flexibility Act of 2007, T.C.A. §§ 4-5-401, *et seq.*, the Department of Health submits the following regulatory flexibility analysis:

- (1) The proposed rule amendment does not overlap, duplicate, or conflict with other federal, state, and local governmental rules.
- (2) The proposed rule amendment exhibits clarity, conciseness, and lack of ambiguity.
- (3) The proposed rule amendment exempts from licensure persons who are testing specimens in a Department of Health laboratory pursuant to an ordered investigation for which the reported results are restricted. It also exempts from licensure laboratories which perform such testing. The amendment defines the purpose of continuing education. The amendment also clarifies the requirements for licensure as a medical laboratory technologist, in that it specifies acceptable types of national certification and also specifies licensure requirements for applicants who have not earned a baccalaureate degree. Finally, the new rule defines unethical conduct and expressly makes unethical conduct by medical lab personnel grounds for disciplinary action by the Board. The proposed rules thereby increase the availability of certain kinds of legally-ordered laboratory testing, and they provide greater clarity for both licensure requirements and prohibited conduct by licensees. The Department of Health and the Tennessee Medical Laboratory Board believe that this is necessary to better protect the health and safety of the citizens of the state.
- (4) The proposed rule amendment does not affect any schedules or deadlines for compliance and/or reporting requirements for small businesses.
- (5) The proposed rule amendment does not affect compliance or reporting requirements for small businesses.
- (6) The proposed rule amendment does not establish performance standards for small businesses as opposed to design or operational standards; and
- (7) The proposed rule amendments ensure that all medical laboratory personnel have clear guidance with respect to (i) the pathways to licensure, (ii) the patient safety purpose undergirding CE requirements, and (iii) conduct which the Board deems professionally unethical. The proposed amendments also provide a licensure exemption for certain kinds of narrowly defined court-ordered lab testing. The Department of Health and the Medical Laboratory Board believe that these provisions better serve the interest of public health, and that they do so without causing a meaningful entry barrier for either lab personnel or laboratory businesses.

**Additional Information Required by Joint Government Operations Committee**

All agencies, upon filing a rule, must also submit the following pursuant to TCA 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;

The proposed rule amendment exempts from licensure persons who are testing specimens in a Department of Health laboratory pursuant to an ordered investigation for which the reported results are restricted. It also exempts from licensure laboratories which perform such testing. The amendment defines the purpose of continuing education. The amendment also clarifies the requirements for licensure as a medical laboratory technologist, in that it specifies acceptable types of national certification and also specifies licensure requirements for applicants who have not earned a baccalaureate degree. Finally, the new rule defines unethical conduct and expressly makes unethical conduct by medical lab personnel grounds for disciplinary action by the Board.

- (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;

None known.

- (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;

Medical laboratory personnel and medical laboratories would be the most affected. No comments were submitted to the Board regarding these rules.

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

None known.

- (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;

No impact expected on government revenues or expenditures.

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

Ernest Sykes, Jr., Assistant General Counsel, Tennessee Department of Health

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

Ernest Sykes, Jr., Assistant General Counsel, Tennessee Department of Health

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

Tennessee Department of Health, Office of General Counsel; Plaza One, Suite 210; 220 Athens Way; Nashville, TN 37243

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