

Department of Health  
Notice of Rulemaking Hearing  
Tennessee Medical Laboratory Board  
Division of Health Related Boards

There will be a hearing before the Tennessee Medical Laboratory Board to consider the promulgation of amendments to rules pursuant to T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, 68-29-105, 68-29-111, 68-29-112, 68-29-113, 68-29-114, and 68-29-118. The hearing will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204 and will take place in the Cumberland Room of the Cordell Hull Building located at 425 Fifth Avenue North, Nashville, TN at 2:30 p.m. (CST) on the 17th day of March, 2006.

Any individuals with disabilities who wish to participate in these proceedings (review these filings) should contact the Department of Health, Division of Health Related Boards to discuss any auxiliary aids or services needed to facilitate such participation or review. Such initial contact may be made no less than ten (10) days prior to the scheduled meeting date (the date such party intends to review such filings), to allow time for the Division to determine how it may reasonably provide such aid or service. Initial contact may be made with the ADA Coordinator at the Division of Health Related Boards, 1<sup>st</sup> Flr., Cordell Hull Building, 425 5<sup>th</sup> Ave. N., Nashville, TN 37247-1010, (615) 532-4397.

For a copy of the entire text of this notice of rulemaking hearing contact: Jerry Kosten, Regulations Manager, Division of Health Related Boards, 425 Fifth Avenue North, First Floor, Cordell Hull Building, Nashville, TN 37247-1010, (615) 532-4397.

Substance of Proposed Rules

Amendments

Rule 1200-6-1-.01 Definitions, is amended by adding the following language as new paragraph (32) and renumbering the current paragraphs (32) and (33) as paragraphs (33) and (34):

- (32) Special Analyst, Level II-Chemical Terrorism. Any qualified employee of the Tennessee Department of Health who performs analyses in the Chemical Terrorism Level II Laboratory limited to blood and urine analyses for heavy metals, cyanide and metabolites of nerve agents utilizing Inductively Coupled Plasma Mass Spectrometer with a Dynamic Reaction Cell (ICP/DRC/MS0), in tandem with High Performance Liquid Chromatography (HPLC) and Gas Chromatograph Mass Spectrometry (GC/MS), and such other analyses and such other equipment that may be developed and implemented as part of the bioterrorism efforts.

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

Rule 1200-6-1-.21 Qualifications and Duties of the Medical Laboratory Supervisor, is amended by deleting subparagraph (1) (b) in its entirety and substituting instead the following language, so that as amended, the new subparagraph (1) (b) shall read:

(1) (b) The medical laboratory supervisor shall meet one of the following requirements:

1. Be a physician licensed in Tennessee or hold a doctoral degree from an accredited college/university in a chemical, physical, biological, or clinical laboratory science. Subsequent to obtaining a doctoral degree the applicant must have at least two (2) years of full time clinical laboratory work experience as defined in Rule 1200-6-1-.22 (1) (h) in the area they wish to supervise.
2. Hold a valid general medical laboratory technologist license in Tennessee or meet one (1) of the requirements under Rule 1200-6-1-.22 (1) (a) 1. through 5. and provide all required documentation in support of that qualification and have at least four (4) years of full time clinical laboratory work experience as defined in Rule 1200-6-1-.22 (1) (h) in the area they wish to supervise.
3. Hold a valid general medical laboratory technologist license in Tennessee limited to one of the categories of chemistry, hematology, immunohematology, or microbiology and meet the requirements under Rule 1200-6-1-.22 (1) (c) and provide all required documentation in support of that qualification and have at least four (4) years of full time clinical laboratory work experience as defined in Rule 1200-6-1-.22 (1) (h) subsequent to qualifying as a technologist. The license shall be limited to the category for which the applicant is qualified.
4. Hold a valid special analyst license limited to one (1) subspecialty or meet one (1) of the requirements under Rule 1200-6-1-.22 (1) (d) or (e) and provide all required documentation in support of that qualification and have at least four (4) years of full time clinical laboratory work experience as defined in Rule 1200-6-1-.22 (1) (h) subsequent to qualifying as a special analyst. The license shall be limited to the subspecialty for which the applicant is qualified.

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

Rule 1200-6-1-.22 Qualifications, Responsibilities and Duties of Testing Personnel, is amended by deleting parts (1) (a) 2., (1) (a) 3. and (1) (a) 4., subparts (1) (a) 5. (i) and (1) (a) 5. (ii), and part (1) (b) 3. in their entirety and substituting instead the following language, and is further amended by adding the following language as subparagraph (1) (e) and renumbering the remaining subparagraphs accordingly, and is further amended by adding the following language as subparagraph (2) (d), so that as amended, the new parts

(1) (a) 2., (1) (a) 3. and (1) (a) 4., subparts (1) (a) 5. (i) and (1) (a) 5. (ii), part (1) (b) 3., and subparagraphs (1) (e) and subparagraph (2) (d) shall read:

- (1) (a) 2. 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
- (1) (a) 3. 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
- (1) (a) 4. 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); or
- (1) (a) 5. (i) additionally have received a passing grade on a Health and Human Services proficiency examination in clinical laboratory science and completion of five (5) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); or
- (1) (a) 5. (ii) have completed a minimum of ninety (90) semester hours including science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g) of this rule; and have 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.
- (1) (b) 3. 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).
- (1) (e) An individual may be issued a Special Analyst License, Level II-Chemical Terrorism upon meeting the following qualifications:

1. The individual must be an employee of the Tennessee Department of Health Laboratory and perform analysis in the state's Chemical Terrorism Level II Laboratory; and
2. The individual must perform only blood and urine analyses for heavy metals, cyanide and metabolites of nerve agents utilizing Inductively Coupled Plasma Mass Spectrometer with a Dynamic Reaction Cell (ICP/DRC/MS0), in tandem with High Performance Liquid Chromatography (HPLC) and Gas Chromatograph Mass Spectrometry (GC/MS), and such other analyses and such other equipment that may be developed and implemented as part of the bioterrorism efforts; and
3. The individual must possess at least a baccalaureate degree in chemistry from an accredited college/university and be certified by a national certification body approved by the Board, where such certification or qualification exists; and
4. The individual must successfully demonstrate to the Board that he/she has at least one (1) year experience with the Inductively Coupled Plasma Mass Spectrometer with a Dynamic Reaction Cell (ICP/DRC/MS0), and with High Performance Liquid Chromatography (HPLC), and with Gas Chromatograph Mass Spectrometry (GC/MS); and
5. The individual must successfully demonstrate to the Board that he/she has at least one (1) year experience performing blood and urine analyses.

(2) (d) Responsibilities and duties of the Special Analyst License, Level II—Chemical Terrorism include all the responsibilities and duties for the Special Analyst listed in subparagraph (2) (c), but only as those responsibilities and duties pertain to the tests for which they are authorized to conduct pursuant to subparagraph (1) (e).

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

Rule 1200-6-3-.02 Licensing Procedures, is amended by adding the following language as new subparagraph (4) (h):

(4) (h) T.C.A. § 68-29-112 Fee – A nonrefundable fee to be paid when there \$ 100.00 is a change in laboratory ownership, directorship, or location.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-111, 68-29-112, and 68-29-113.

Rule 1200-6-3-.03 Change in Location, Director, Owner, Supervisor or Testing in a Medical Laboratory, is amended by deleting the language of the rule in its entirety and substituting instead the following language as new paragraphs (1) through (3):

- (1) It shall be the responsibility of the owner of a laboratory to notify the Department in writing of a change in the location, director, owners or supervisor of the laboratory within fifteen (15) days of the actual change.
- (2) If the matter involves a change of the owner, and/or director and/or the location an application for a new license, including payment of the T.C.A. § 68-29-112 Fee as provided in Rule 1200-6-3-.02 (4), must be filed and a new license obtained before the laboratory may provide services. That new license may be applied for and issued prior to the actual change but will be void should the change not actually take place.
- (3) It shall be the responsibility of the owner to notify the Department in writing in order to add a specialty or subspecialty not presently authorized by the facility's license prior to the commencement of testing and reporting patient test results. The Department must conduct an on-site inspection prior to the issuance of authorization for the specialty or subspecialty. A replacement license which includes new specialty or subspecialty shall be issued by the Department at no cost to the facility.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-112 and 68-29-114.

Rule 1200-6-3-.16 Alternate Site Testing, is amended by deleting paragraph (2) in its entirety and substituting instead the following language, so that as amended, the new paragraph (2) shall read:

- (2) Physician's Office Laboratories - Physician Office Laboratories (POLs) are exempt from licensure requirements of the Medical Laboratory Act
  - (a) To be eligible of this exemption, the following conditions must be met:
    1. The laboratory collects, accepts and tests only specimens from the private and personal patients of the physician who owns the practice or from the private and personal patients of any physician who is a member of a medical/physician group practice that owns and operates the laboratory regardless of the distance of any member physician's practice location from the group practice's laboratory or the number of specimens collected, accepted and/or tested; and
    2. The laboratory must be operated by the physician who owns the practice or through his own employees. In a medical/physician group practice, one (1) of the group's physicians must be designated to operate the laboratory. The designated physician is responsible for actual supervision and direct responsibility for the performance of the laboratory and its personnel which includes,

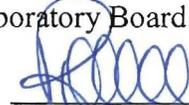
but is not limited to, actual supervision and direct responsibility for quality assurance, quality control, and test management; and

- 3. The tests performed in the laboratory are used only for diagnosis and/or treatment of patients of the individual or group practice and are maintained in the practice's medical records for the patients for whom the test were performed.
- (b) In the case of a medical/physician group practice, proof of affiliation with the group practice must be maintained at all offices in which the laboratory is not physically located and produced upon request by an authorized agent of the Department.
- (c) Industrial or company physician practices, student health services and other arrangements in which a licensed physician is responsible for the continuing care of a group of patients on an ongoing basis will be designated to be POLs.

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

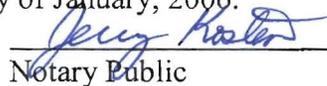
Contact who can answer questions concerning this notice of rulemaking hearing, technical contact for disk acquisition, and person who will approve final copy for publication: Jerry Kosten, Regulations Manager, Division of Health Related Boards, 1<sup>st</sup> Flr., Cordell Hull Building, 425 5<sup>th</sup> Ave. N., Nashville, TN 37247-1010 615-532-4397.

I certify that this is an accurate and complete representation of the intent and scope of rulemaking proposed by the Tennessee Medical Laboratory Board.



Robbie H. Bell, Director  
Health Related Boards

Subscribed and sworn to before me this the 13th day of January, 2006.

  
Notary Public

My commission expires on the 25<sup>th</sup> day of March, 2006.

The notice of rulemaking set out herein was properly filed in the Department of State on the 13 day of Jan, 2006.



Riley C. Darnell  
Secretary of State

By:



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