

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

Chapter 1200-6-1
General Rules Governing Medical Laboratory Personnel

Amendments

Rule 1200-6-1-.05 Procedures for Personnel Licensure, is amended by adding the following language as subparagraph (1) (m) and re-lettering the remaining subparagraphs accordingly, and is further amended by deleting subparagraph (2) (a) in its entirety and substituting instead the following language, so that as amended, the new subparagraphs (1) (m) and (2) (a) shall read:

(1) (m) The applicant shall cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials, the result of a criminal background check.

(2) (a) In addition to fulfilling the above requirements in paragraph (1), an internationally trained applicant must also:

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-116, 68-29-117, 68-29-118, and 68-29-127.

The rulemaking hearing rules set out herein were properly filed in the Department of State on the 14th day of March, 2006, and will become effective on the 28th day of May, 2006.

Department of Health
Rulemaking Hearing Rules
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Chapter 1200-6-3
General Rules Governing Medical Laboratories

Amendments

Rule 1200-6-3-.01 Definitions, is amended by deleting paragraph (23) in its entirety and renumbering the remaining paragraphs accordingly, and is further amended by adding the following language as new paragraph (6) and renumbering the remaining paragraphs accordingly:

(6) CLSI – The Clinical Laboratory and Standards Institute.

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

Rule 1200-6-3-.09 Quality Control, is amended by deleting subparagraph (4) (a) and part (8) (e) 4. in their entirety and substituting instead the following language, so that as amended, the new subparagraph (4) (a) and the new part (8) (e) 4. shall read:

(4) (a) A written procedure manual for the performance of all analytical methods used by the laboratory must be readily available and followed by laboratory personnel. Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens. Procedure should be substantially in compliance with the CLSI, GP-2A, current version, or any subsequent version.

(8) (e) 4. The laboratory must check each batch or shipment of media for sterility, if it is intended to be sterile and if sterility is required for testing. Media must also be checked for its ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response. The laboratory may use manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the current standards of the Clinical and Laboratory Standards Institute (CLSI) for media quality control. The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer. The laboratory must follow the manufacturer's specifications for using the media and be responsible for the test results.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-125.

Rule 1200-6-3-.16 Alternate Site Testing, is amended by deleting paragraph (3) but not its subparagraphs and substituting instead the following language, and is further amended by adding the following language as new subparagraph (3) (a) and re-lettering the remaining subparagraphs accordingly, so that as amended, the new paragraph (3) but not its subparagraphs and the new subparagraph (3) (a) shall read:

- (3) Screening Programs – Screening programs are offerings of specified medical laboratory tests to the general public, the purpose of which is educational rather than for diagnosis of disease, and the results of which are immediately available on the site of the program to the person being tested except for those tests which for methodological reasons must be submitted to a medical laboratory in which case they shall be sent to a Tennessee licensed medical laboratory.
- (3) (a) Screening programs conducted by for-profit hospitals or nonprofit organizations are exempt from the licensure requirements of the Medical Laboratory Act, pursuant to T.C.A. § 68-29-104(6), when the following conditions are met:

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

The rulemaking hearing rules set out herein were properly filed in the Department of State on the 14th day of March, 2006, and will become effective on the 28th day of May, 2006.