

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-.20 Qualifications and Duties of the Medical Laboratory Director, is amended by deleting part (5) (e) 15. in its entirety and substituting instead the following language, so that as amended, the new part (5) (e) 15. shall read:

- (5) (e) 15. Ensure, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results; and

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, 68-29-116, and 68-29-118.

Rule 1200-6-1-.21 Qualifications and Duties of the Medical Laboratory Supervisor, is amended by deleting subparagraph (2) (b) but not its parts, and substituting instead the following language, so that as amended, the new subparagraph (2) (b) but not its parts shall read:

- (2) (b) The medical laboratory director may delegate, pursuant to written policy, to the medical laboratory supervisor specific duties that do not comprise the practice of medicine, including but not limited to the following:

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, and 68-29-116.

The rulemaking hearing rules set out herein were properly filed in the Department of State on the 15th day of February, 2006, and will become effective on the 1st day of May, 2006.

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Chapter 1200-6-3
General Rules Governing Medical Laboratories

Amendments

Rule 1200-6-3-.09 Quality Control, is amended by deleting paragraph (8) but not its subparagraphs, and substituting instead the following language, so that as amended, the new paragraph (8) but not its subparagraphs shall read:

- (8) Standard: Control Procedures – Control procedures are performed on a routine basis to monitor the stability of the method or test system; control materials provide a means to indirectly assess the accuracy and precision of patient test results. Control procedures must be performed as defined in this paragraph unless otherwise specified in paragraphs 1200-6-3-.09 (12) through 1200-6-3-.09 (34).

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

Rule 1200-6-3-.12 Referrals of Cultures to the Department of Health, is amended by deleting subparagraph (1) (o) in its entirety and substituting instead the following language, and is further amended by adding the following language as new subparagraphs (1) (u), (1) (v), (1) (w), (1) (x) and (1) (y), so that as amended, the new subparagraphs (1) (o), (1) (u), (1) (v), (1) (w), (1) (x) and (1) (y) shall read:

(1) (o) Escherichia coli O157:H7

(1) (u) Bacillus anthracis

(1) (v) Burkholderia mallei

(1) (w) Burkholderia pseudomallei

(1) (x) Vancomycin resistant staphylococcus aureus (VRSA)

(1) (y) Vancomycin intermediate staphylococcus aureus (VISA)

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-107.

Rule 1200-6-3-.16 Alternate Site Testing, is amended by deleting part (1) (c) 5. in its entirety and substituting instead the following language, so that as amended, the new part (1) (c) 5. shall read:

- (1) (c) 5. The Medical Laboratory Director, once having established critical values, shall have the discretion to determine if, consistent with good patient care, there is a need for verification by the clinical laboratory when values fall above or below the established critical values.

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 15th day of February, 2006, and will become effective on the 1st day of May, 2006.