RULES
OF
TENNESSEE MEDICAL LABORATORY BOARD

CHAPTER 1200-06-01
GENERAL RULES GOVERNING MEDICAL LABORATORY PERSONNEL

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1200-06-01-.01 DEFINITIONS. This section sets forth the more important and/or frequently used terms and acronyms used in these rules and the meanings to be ascribed to them.

(1) The Act. The Tennessee Medical Laboratory Act.

(2) Applicant. Any individual seeking licensure by the Board and who has submitted an official application and paid all required fees.

(3) Board. The Tennessee Medical Laboratory Board.

(4) Board Administrative Office - The office of the administrator assigned to the Board located at 665 Mainstream Drive, Nashville, TN 37243.

(5) CLIA. The Clinical Laboratory Improvement Amendments of 1988 as found in 42 CFR Part 493.

(6) Closed File. An administrative action which renders an incomplete or denied file inactive.

(7) Committee. The Personnel and Education Licensure Committee which oversees all matters pertaining to the licensure of medical laboratory personnel and of medical laboratory education programs.

(8) Cytology General Supervisor. A person who is responsible for day to day supervision or oversight of the cytology laboratory operation, personnel performing testing and reporting test results.

(9) Cytotechnologist. A person who performs slide interpretation in the cytology laboratory under the supervision of a cytology general supervisor.

(10) Department. Tennessee Department of Health.

(Rule 1200-06-01-.01, continued)

(11) Examination - Refers to National Certification exam or State administered exam or other exams approved by the Board.

(12) Full Time Work Experience. A minimum of thirty (30) hours per week or one thousand five hundred sixty (1,560) hours per year.

(13) Internationally Trained. Having graduated from a degree program and/or a laboratory training program outside of the United States or its territories.

(14) License. Document issued to an applicant who successfully completes the licensure process. The license takes the form of an “artistically designed” license as well as other versions bearing an expiration date.

(15) Licensee. Any person duly licensed by the Board to engage in the practice of laboratory medicine.

(16) May. Discretionary.

(17) Medical Laboratory. Any institution, building, or place in which operations and procedures for the microbiological, serological, chemical, hematological, immunohematological, or biophysical examination of 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 on 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 for the training of medical laboratory personnel.

(18) Medical Laboratory Director. A person who is responsible for the administration of the technical and scientific operation of a medical laboratory, including supervision of procedures for testing and the reporting of results.

(19) Medical Laboratory Professionals. Individuals, including the medical laboratory director, supervisor, technologist, or technician, but not including medical laboratory assistants, trainees or other persons employed by a medical laboratory to perform clerical or other administrative responsibilities involving no laboratory testing.

(20) Medical Laboratory Supervisor. A person who under the general supervision of a medical laboratory director, supervises technical personnel, performs tests requiring special scientific skills, and, in the absence of the director, is held responsible for the proper performance of all medical laboratory procedures and the reporting of results.

(21) Medical Laboratory Technician. Any person other than the medical laboratory director, supervisor, technologist, or trainee who functions under the supervision of a medical laboratory director, supervisor, or technologist and performs only those medical laboratory procedures which require limited skill, responsibility, and a minimal exercise of independent judgment.

(22) Medical Laboratory Technologist. A person who performs tests which require the exercise of independent judgment and responsibility with minimal supervision by the director or supervisor. in only those specialties or subspecialties in which the technologist is qualified by education, training, and experience.

(23) Medical Laboratory Trainee. Any person having qualifying education who is employed in a medical laboratory approved for training who is seeking experience required to meet minimum qualifications for license in the state. Trainees may perform procedures only under direct and responsible supervision of a duly licensed director, supervisor, or technologist.

(Rule 1200-06-01-.01, continued)

(24) Moderate Complexity. A clinical laboratory test category assigned by CLIA-88 based on the test characteristics. See 42 CFR § 493.17.

(25) National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). Accreditation agency that accredits laboratory training programs. The accreditation period begins 12 months prior to the training programs final approval.

(26) Person. Any individual, firm. partnership, association, corporation, municipality, political subdivision or any other entity whether organized for profit or not.

(27) Physician. Any doctor of medicine or doctor of osteopathy duly licensed to practice such doctor's profession in Tennessee.

(28) "Point of Care" laboratory testing. Laboratory testing performed by health care personnel/professionals not licensed by the Medical Laboratory Act, T.C.A. §§ 68-29-101, et seq., and performed outside the duly licensed laboratory and under the auspices of a laboratory required to be licensed by the Department, pursuant to the Medical Laboratory Act.

(29) Regionally Accredited College/University. An institution of higher education accredited by one of the following United States Associations of Colleges and Schools: Middle States, Northwest, North Central, New England, Southern or Western.

(30) Shall. Mandatory.

(31) Special Analyst. Any person performing a singular or limited type of medical laboratory test or group of tests, such as, but not limited to, blood gases or pH tests, Andrology, Embryology, Cytology, Molecular Diagnostics, Cytogenetics, Toxicology, Flow Cytometry, Virology, Histocompatability/ Immunogenetics, on human specimens but who is not trained to perform the broad range of tests required of licensed medical laboratory personnel.

(32) Trainee Permit. A permit that is issued to a trainee and is valid during the training period provided that the facility where the training is being gained is approved for practice training.

(33) "Waived" laboratory tests. Those tests, as defined by the Board, which may be performed by individuals not licensed under the Medical Laboratory Act, and which pose no reasonable risk of harm if performed incorrectly.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, 68-29-116, 68-29-117, 68-29-119, 68-29-120, and 68-29-134.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed March 4, 1998; effective May 20, 1998. Amendment filed April 29, 2002; effective July 13, 2002. Amendment filed August 25, 2003; effective November 8, 2003.*

1200-06-01-.02 SCOPE OF PRACTICE. Medical laboratory personnel and special analysts may perform clinical laboratory tests that provide vital information to the medical practitioner for the purpose of determining the nature, cause and extent of the patient's medical condition.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-102, 68-29-104, 68-29-105, 68-29-117, and 68-29-118.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed August 25, 2003; effective November 8, 2003.*

1200-06-01-.03 NECESSITY OF LICENSURE AND LICENSURE EXEMPTIONS.

(1) All medical laboratory personnel and special analysts in Tennessee must hold current Tennessee licensure, unless specifically exempt by statute or rules promulgated by the Board.

(Rule 1200-06-01-.03, continued)

(2) No person shall act as a medical laboratory director, supervisor, technologist, technician, laboratory trainee or a special analyst and accept a specimen for laboratory examination unless such person has obtained a license and is registered to act in such capacity by the board; provided, that this section shall not apply to pathologists certified or eligible for certification by the American Board of Pathology, or any other person recognized by the board as having special qualifications and who is duly licensed and registered to practice medicine in the state of Tennessee.

(3) Use of Titles - Any person who possesses a valid, unsuspended and unrevoked license issued by the Board has the right to use the title or acronym that represents being a medical laboratory director (Ph.D), medical laboratory technologist (M.T.), medical laboratory technician (M.L.T.) or special analyst (S.A.) as defined in T.C.A. § 68-29-103, or the title or acronym that represents being a cytotechnologist (C.T.) as defined in rule 1200-06-01-.01. Violation of this rule regarding use of titles shall constitute unethical conduct and subject the licensee to disciplinary action.

(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, 63-1-102, 68-29-103, 68-29-104, 68-29-105, 68-29-116, 68-29-127, and 68-29-129.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed March 16, 2007; effective May 30, 2007. Amendment filed April 1, 2009; effective June 15, 2009.*

1200-06-01-.04 RESERVED.

1200-06-01-.05 PROCEDURES FOR PERSONNEL LICENSURE. This section explains the procedures and requirements that are necessary for an applicant to become licensed.

(1) To perform the duties of a medical laboratory director, medical laboratory supervisor, medical laboratory technologist, medical laboratory technician, or special analyst, a person must possess a lawfully issued license from the Board.

(a) An application packet may be obtained from the Board’s administrative office or from the Board’s website at www.tennessee.gov.

(b) It is the intent of these rules that all requests for supporting documentation including but not limited to transcripts, training and national certification be completed prior to filing an application.

(c) It is the applicant’s responsibility to request an official college transcript from the college registrar’s office to be sent directly to the Board’s administrative office. The transcript must show that the degree has been conferred and carry the official seal of the institution. Internationally trained applicants must meet the requirements of Rule 1200-06-01-.05(2)(a).

(d) It is the applicant’s responsibility to request proof that the laboratory training program from which they graduated is accredited and from what agency. This must be submitted directly from the director of the training program, or a source acceptable to the Board, directly to the Board’s administrative office. Applicants trained in the military must present proof of training through official military documentation. Internationally trained applicants must meet the requirements of Rule 1200-06-01-.05(2).

(Rule 1200-06-01-.05, continued)

(e) It is the applicant's responsibility to request that proof of current national certification/qualification be submitted directly to the Board's administrative office from a certifying body that is acceptable to the Board. The national certification must be in the laboratory specialty in which licensure is being sought.

(f) It is the applicant's responsibility to request proof of clinical laboratory work experience from current and previous employers if required. The letter must state the applicant's name, job title and/or description of duties, dates of employment, and the number of hours worked per week.

(g) Applications will be accepted throughout the year.

(h) An applicant shall respond truthfully and completely to every question or request for information in the application form. The application form must be submitted with all required documentation and fees to the Board's administrative office.

(i) An applicant shall submit with the application the nonrefundable application fee and the state regulatory fee as provided in Rule 1200-06-01-.06.

(j) An applicant shall submit with the application a signed "passport" type photograph taken within the preceding twelve (12) months. The back of the photo shall be signed by the applicant.

(k) Personal resumes are not acceptable and will not be reviewed.

(l) An applicant shall disclose the circumstances surrounding any of the following:

1. Conviction of any crime in any country, state, or municipality, except for minor traffic violations.

2. The denial of licensure or the discipline of a licensee by any other state, country, or municipality.

3. Loss or restriction of licensure.

4. Any civil judgment or civil suit settlement in which the applicant was a party defendant including, without limitation, actions involving malpractice, breach of contract, antitrust activity, or any other civil action remedy recognized under that country's, state's, or municipality's statutory, common, or case law.

(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.

(n) The burden is on the applicant to prove by a preponderance of the evidence that his course work and credentials are equivalent to the Board's requirements.

(o) Application review and licensure decisions shall be governed by Rule 1200-06-01-.07.

(p) Compliance with Rule 1200-06-01-.08 is a prerequisite to licensure.

(q) A license will be issued after all requirements have been met.

(2) Internationally trained applicants.

(Rule 1200-06-01-.05, continued)

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

1. Have all educational credentials evaluated by a foreign evaluation company approved by the Board. The foreign evaluation company must submit directly to the Board's administrative office the results of the evaluation. The evaluation must clearly indicate that the applicant's education is equivalent to that which is required for licensure of United States graduates at the level of licensure being sought. A list of approved foreign evaluation companies can be obtained from the Board's administrative office.

2. Submit to the Board's administrative office current documentation of legal entry and right to work in the United States if not a U.S. citizen.

(b) An internationally trained applicant who is a citizen of Mexico or Canada may apply as a professional under the North American Free Trade Agreement (NAFTA) when all federal requirements have been met; and

1. The profession is on the NAFTA list; and

2. The applicant possesses the specific criteria for that profession; and

3. The prospective position requires someone in that professional capacity; and

4. The applicant is going to work for a U.S. employer.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-104, 68-29-105, 68-29-116, 68-29-117, 68-29-118, and 68-29-127.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 11, 1996; effective November 25, 1996. Amendment filed March 4, 1998; effective May 20, 1998. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed March 14, 2006; effective May 28, 2006.*

1200-06-01-.06 FEES.

(1) The fees authorized by the Tennessee Medical Laboratory Act *(T.C.A. §§ 68-29-101, et seq.)* and other applicable statutes, to be established by the Board for personnel licensure are established as follows:

(a) Application Fee - A nonrefundable fee to be paid by all licensure and examination applicants. It must be paid each time an application for licensure is filed.

(b) License Renewal Fee - A nonrefundable fee to be paid biennially (every other year) by all licensees. This fee also applies to all licensees who reactivate a retired or lapsed license.

(c) Late Licensure Renewal Fee - To be paid when a licensee fails to timely renew licensure biennially (every other year).

(d) State Regulatory Fee - To be paid biennially (every other year) by all licensees with all renewal applications, and by all individuals at the time of application.

(e) Replacement License Fee - A non-refundable fee to be paid when an individual requests a replacement for a lost or destroyed "artistically designed" wall license.

(f) Duplicate Certificate Fee - A non-refundable fee to be paid when an individual requests a duplicate renewal certificate.

(Rule 1200-06-01-.06, continued)

(2) Fees may be paid in the following manner:

(a) All fees paid by money order, certified, personal, or corporate check must be submitted to the Board's Administrative Office and made payable to the Tennessee Medical Laboratory Board.

(b) Fees may be paid by Division-approved credit cards or other Division-approved electronic methods.

(3) Fee Schedule:		Amount
(a)	Application	$ 50.00
(b)	Late Renewal	$ 60.00
(c)	Renewal	$ 90.00 (Biennially)
(d)	State Regulatory	$ 10.00 (Biennially)
(e)	Replacement License	$ 40.00
(f)	Duplicate Certificate	$ 25.00

(4) All fees shall be established, reviewed and changed by the Board.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, and 68-29-105.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed March 4, 1998; effective May 20, 1998. Amendment filed August 31, 2001; effective November 14, 2001. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed April 17, 2007; effective July 1, 2007.*

1200-06-01-.07 APPLICATION, REVIEW, APPROVAL AND DENIAL.

(1) Initial review of all applications to determine whether or not the application file is complete may be delegated to the Board's administrator provided that final approval of all applications is made and ratified by the Board.

(2) If an application is incomplete when received in the Board's administrative office, a deficiency letter will be sent to the applicant notifying him of the deficiency. Applications are not considered complete until all information including fees has been received by the Board's administrative office.

(3) The Board may at its discretion delay a decision on eligibility for licensure for any applicant for whom the Board wishes additional information.

(4) If a completed application has been denied and ratified as such by the Board, the action shall become final and the following shall occur:

(a) A notification of the denial shall be sent by the Board's administrative office by certified mail return receipt requested. Specific reasons for denial will be stated, such as incomplete information, unofficial records, examination failure, or other matters judged insufficient for licensure, and such notification shall contain all the specific statutory or rule authorities for the denial.

(b) The notification, when appropriate, shall also contain a statement of the applicant's right to request a contested case hearing under the Tennessee Administrative Procedures

(Rule 1200-06-01-.07, continued)

Act (T.C.A. §§ 4-5-301, *et seq.)* to contest the denial and the procedure necessary to accomplish that action.

(c) An applicant has a right to a contested case hearing if the licensure denial was based on subjective or discretionary criteria.

(d) An applicant has a right to a contested case hearing if the licensure denial is based on objective, clearly defined criteria only if, after review and attempted resolution by the Board's administrative staff, the licensure application can not be approved for reasons which present a genuine issue of fact and/or law which is appropriate for appeal.

(e) Requests for appeals of licensure denials must be made in writing to the Office of General Counsel, Department of Health, within 30 days of the receipt of the notice of denial from the Board.

(5) Any person furnishing false information or omitting pertinent information in such application shall be denied the right to sit for the examination or if the applicant has already-been licensed before the falseness of such information has been made known to the Board, such license shall be subject to suspension or revocation by the Board.

(6) If the Board finds it has erred in the issuance of a license, the Board will give written notice by certified mail of its intent to annul the license. The notice will allow the applicant the opportunity to meet the requirements of licensure within thirty (30) days from date of receipt of the notification.

(7) Whenever requirements for licensure except passing examination are not completed within sixty (60) days from the date of the initial review of application and credentials, written notification will be mailed to the applicant and the application file will be closed. An applicant whose file has been closed shall subsequently be considered for licensure only upon the filing of a new application and payment of all appropriate fees.

(8) Supporting documents can be accessed up to a year after being received in the Board's administrative office.

(9) Abandonment of Application

(a) An application shall be deemed abandoned and closed if the application has not been completed by the applicant within sixty (60) days after it was initially reviewed by the Board.

(b) Whenever the applicant fails to complete the application process as stated above, written notification will be mailed to the applicant notifying him that the file has been closed. The determination of abandonment must be ratified by the Board.

(10) If an applicant requests an entrance for licensure and, after Board review, wishes to change that application to a different type of entrance, the applicant must then submit a request in writing to the Board's administrative office. Any additional supporting documents necessary for the new type of licensure must also be submitted.

(11) An approved application will remain open until passing examination or a period of one year whichever comes first.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 4-5-301, 68-29-105, 68-29-117, 68-29-118, and 68-29-127.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed March 4, 1998; effective May 20, 1998.*

1200-06-01-.08 EXAMINATIONS. The Board adopts the examinations utilized by all nationally recognized medical laboratory personnel certifying agencies in each classification of licensure for issuance of national certification as its licensure examinations for the specified licensure classification. Whenever an applicant is required to take an examination offered by any nationally recognized medical laboratory personnel certifying agency the following shall apply:

(1) The exam administration schedule is determined by each national certification agency.

(2) It is the applicant's responsibility to request the national certification agency or certified training program approved by the Board to submit verification to the board administrative office that the applicant is scheduled on a date specified to challenge the exam.

(3) Applicants that do not successfully pass the national certification exam or fail to appear for the examination will need to reschedule with the national certification agency.

(4) The passing score for the national certification exam is determined by each national certification agency.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-117, and 68-29-118.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed March 4, 1998; effective May 20, 1998. Amendment filed August 25, 2003; effective November 8, 2003.*

1200-06-01-.09 RENEWAL OF LICENSE.

(1) Renewal Application

(a) The due date for renewal is the last day of the month in which a licensee's birthdate falls pursuant to the Division of Health Related Board's biennial birthdate renewal system.

(b) Methods of Renewal - Licensees may accomplish renewal by one (1) of the following methods:

1. Internet Renewals - Individuals may apply for renewal and pay the necessary fees via the Internet. The application to renew can be accessed at:

https://apps.tn.gov/hlrs/

2. Paper Renewals - Licensees who have not renewed their authorization online via the Internet will have a renewal application form mailed to them at the last address provided by them to the Board prior to the expiration date of their current license. Failure to receive such notification does not relieve the individual of the responsibility of timely meeting all requirements for renewal.

(c) The due date for license renewal is the expiration date indicated on the licensee's renewal certificate. To be eligible for renewal, an individual must submit to the Division of Health Related Boards on or before the expiration date all of the following:

1. A completed and signed renewal application form; and

2. The renewal and State regulatory fees as provided in Rule 1200-06-01-.06.

(d) Anyone submitting a signed renewal form or letter which is found to be untrue may be subject to disciplinary action as provided in Rule 1200-06-01-.15.

(Rule 1200-06-01-.09, continued)

(e) Licensees who 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 1200-10-1-.10.

(f) For persons licensed under national certification requirements as provided in Rules 1200-06-01-.20, 1200-06-01-.22, or 1200-06-01-.24, proof of current national certification must be submitted, if requested by the Board, with the renewal application.

(2) Reinstatement of an Expired License

(a) Licenses that have expired may be reinstated upon meeting the following conditions:

1. Payment of all past due renewal and State regulatory fees;

2. Payment of the late renewal fee provided in Rule 1200-06-01-.06.

3. Submission of evidence of successful completion of the continuing education requirements pursuant to Rule 1200-06-01-.12.

4. Completion of a reinstatement form.

(b) Renewal issuance decisions pursuant to this rule may be made administratively or upon review by any Board member or the Board's designee.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 63-1-107, 68-29-104, 68-29-105, 68-29-119, and 68-29-129.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 11, 1996; effective November 25, 1996. Amendment filed April 29, 2002; effective July 13, 2002. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed August 8, 2005; effective October 22, 2005.*

1200-06-01-.10 RESERVED.

1200-06-01-.11 RETIREMENT AND REACTIVATION.

(1) A person who holds a current license and does not intend to practice as a Medical Laboratory Professional in Tennessee may apply to convert an active license to retired status. An individual who holds a retired license will not be required to pay a renewal fee.

(2) A person who holds an active license may apply for retired status in the following manner:

(a) Obtain from the Board's administrative office an affidavit of retirement form; and

(b) Complete and submit the affidavit affirming that, while in retired status, the licensee will not practice or in any way indicate or imply that he holds an active Tennessee license or use within Tennessee any works, letters, titles, or figures which indicate or imply that he is currently licensed.

(3) License holders whose licenses have been retired may reactivate their licenses in the following manner:

(a) Submit a written request for licensure reactivation to the Board's administrative office;

(b) Pay the current licensure renewal fees and State regulatory fee as provided in Rule 1200-06-01-.06. If retirement reactivation is requested prior to the expiration of one year from the date of retirement the Board will require payment of the late renewal fee and all past due licensure renewal fees as prescribed in Rule 1200-06-01-.06.

(Rule 1200-06-01-.11, continued)

(c) Submit evidence of successful completion of the continuing education requirements pursuant to Rule 1200-06-01-.12.

(4) Licensure reactivation applications shall be treated as licensure applications and review and decisions shall be governed by Rule 1200-06-01-.07.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 63-1-111, 68-29-105, and 68-29-119.* ***Administrative History:*** *Original rule filed September 9, 1996; effective November 23, 1996. Amendment filed August 8, 2005; effective October 22, 2005.*

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.

(1) Basic requirements – Beginning January 1, 2006, the Tennessee Medical Laboratory Board requires each licensee to successfully complete twenty-four (24) hours of approved continuing education pertaining to laboratory technology or laboratory management for the two (2) calendar year (January 1-December 31) period that precedes the licensure renewal year.

(a) The following organizations, entities, and their affiliates and chapters are authorized to present, sponsor, or approve continuing education courses:

1. American Association of Blood Banks.

2. American Board of Bioanalysis.

3. American Board of Clinical Chemistry.

4. American Board of Histocompatibility and Immunogenetics.

5. American Board of Medical Genetics.

6. American Board of Medical Laboratory Immunology.

7. American Board of Medical Microbiology.

8. American Board of Oral and Maxillofacial Pathology.

9. American Board of Pathology.

10. American College of Health Care Executives.

11. American Medical Association.

12. American Medical Technologists (AMT).

13. American Osteopathic Board of Pathology.

14. American Red Cross.

15. American Society for Clinical Laboratory Science.

16. American Society for Clinical Pathologists (ASCP).

(Rule 1200-06-01-.12, continued)

17. American Society of Cytopathology.
18. American Society for Cytotechnology.
19. American Society for Microbiology.
20. Center for Phlebotomy Education.
21. Centers for Disease Control.
22. Centers for Medicare and Medicaid Services.
23. Clinical Laboratory Management Association.
24. Clinical and Laboratory Standards Institute (CLSI).
25. College of American Pathologists.
26. Greater Memphis Association of Blood Banks.
27. International Academy of Cytology.
28. National Credentialing Agency for Medical Laboratory Professionals (NCA).
29. National Laboratory Training Network (NLTN).
30. Southern Association of Clinical Microbiologists.
31. Southern Association of Cytotechnologists.
32. Tennessee Association of Blood Banks.
33. Tennessee Department of Health.
34. Tennessee Hospital Association.
35. Tennessee Medical Association.
36. Tennessee Professional Assistance Program (TN-PAP) or any Board-approved peer assistance program.
37. Tennessee Society of Pathologists.
38. Tennessee State Society of American Medical Technologists.
39. Accredited colleges and universities.
40. Hospitals licensed by the Tennessee Department of Health, Division of Health Care Facilities.
41. Laboratories, blood donor centers, plasmapheresis centers, ambulatory surgical treatment centers, and collection stations licensed by the Board whose continuing education courses have been approved by the medical laboratory director or his/her designee.

(Rule 1200-06-01-.12, continued)

42. Organizations and entities approved by other state laboratory personnel licensing agencies.

43. Organizations and entities approved as P.A.C.E.® (Professional Acknowledgment for Continuing Education) course providers.

(b) Continuing education credit for preparing and teaching continuing education courses – Credit may be earned by preparing and teaching a course presented, sponsored, or approved by an organization or entity listed in subparagraph (a). Documentation of preparing and teaching continuing education courses shall be required as provided in paragraph (3).

1. Courses that were prepared by developing thorough, high quality, readable and carefully prepared written materials will qualify for continuing education credit on the basis of four (4) hours of credit for each hour taught.

2. Courses that were prepared by developing less than five (5) pages of outlines, or not accompanied by written materials, will qualify for continuing education credit on the basis of two (2) credits for each hour taught.

3. Repeat courses qualify for one-half (½) of the credits awarded for the initial course.

4. On-site commentators at multi-media courses will receive credit at the rate of two (2) hours for each hour of the program if they have either viewed the course in advance or otherwise engaged in preparation appropriate to the role of commentator.

5. Each teacher involved in a joint or panel portion of an approved activity shall receive credit as though he or she were the only teacher.

6. No more than eight (8) hours of continuing education credit shall be awarded for preparing and teaching continuing education courses during any two (2) calendar year period.

(c) Continuing education credit for published articles – Four (4) hours credit may be earned by preparing and writing an article pertaining to laboratory technology or laboratory management that is published in a peer review journal.

(d) Continuing education credit will be assigned on the following basis:

1. Any single session lasting not less than two and one-half (2½) clock hours will be assigned three (3) hours of continuing education credit.

2. Any single session lasting not less than one (1) clock hour and forty (40) clock minutes will be assigned two (2) hours of continuing education credit.

3. Any single session lasting not less than fifty (50) clock minutes will be assigned one (1) hour of continuing education credit.

4. The hours assigned shall be based on actual instruction or program time, excluding registration time and breaks, but including question and answer time.

(2) New licensee requirements

(Rule 1200-06-01-.12, continued)

(a) Continuing education is not required until the new licensee has twenty-four (24) months to successfully complete the two (2) calendar year requirement.

(b) The continuing education that may be required to become licensed as a medical laboratory supervisor or as a cytology general supervisor, as provided in Rules 1200-06-01-.21 and 1200-06-01-.23 shall not count towards completion of the reoccurring continuing education required by this rule.

(3) Documentation

(a) Each licensee must retain proof of attendance and completion of all continuing education requirements for a period of three (3) years from the end of the two (2) calendar year period in which the continuing education was required. This documentation must be produced for inspection and verification, if requested in writing by the Board during its verification process. The Board will not maintain continuing education files for individual licensees.

(b) The individual must, within thirty (30) days of a request from the board, provide evidence of continuing education activities. Such evidence must be by submission of one (1) or more of the following:

1. Photocopies of certificates verifying the licensee's attendance at continuing education program(s). The certificate photocopies must include the following: continuing education program's provider, date, clock hours awarded (continuing education units must be converted to clock hours), program title, and licensee's name.

2. Photocopies of original letters on official stationery from the continuing education program's provider indicating, date, clock hours awarded (continuing education units must be converted to clock hours), program title, and licensee's name.

3. Photocopies of certificates or letters verifying successful completion of a written post experience examination to evaluate material retention upon completion of a multi-media and/or electronic course, as provided in paragraph (4). The certificate or letter photocopies must include the clock hours awarded (continuing education units must be converted to clock hours), program title, and licensee's name.

4. Preparing and teaching continuing education courses [subparagraph (1) (b)] – A letter from the education director, laboratory director, department head, dean of the institution, or officer of the approved organization attesting that the course was presented and including time spent in classroom, date and location of course presentation, course title, and licensee’s name; and

(i) Copy of written course materials or course outline; or

(ii) Copy of summary of on-site commentary at multi-media courses.

5. Published articles [subparagraph (1)(c)] – Copies of published articles.

(c) If a licensee submits documentation for training that is not clearly identifiable as appropriate continuing education, the Board will request a written description of the training and its applicability. If the Board determines that the training can not be considered appropriate continuing education, the individual will be given ninety (90) days to replace the hours not allowed. Those hours will be considered replacement

(Rule 1200-06-01-.12, continued)

hours and cannot be counted toward completion of any other continuing education requirement.

(4) Continuing Education Formats

(a) Continuing education courses may be presented in the traditional lecture and classroom formats or, with successful completion of a written post experience examination to evaluate material retention, in multi-media and/or electronic formats.

(b) Notwithstanding the provisions of subparagraph (4)(a), if a continuing education course includes a laboratory experience as a component of the course, the laboratory experience must occur at or be provided by a CLIA-approved site or an accredited college or university.

(5) Continuing education credit will not be allowed for the following:

(a) Membership in, holding office in, or participation on boards or committees, business meetings of professional organizations, or banquet speeches.

(b) Regular work activities, administrative staff meetings, case staffing/reporting, etc., except as provided in subparagraph (1)(b).

(6) Continuing Education for Reactivation or Reinstatement of Retired, Revoked, or Expired License.

(a) Reactivation of Retired Licensure - An individual whose license has been retired for two (2) years or less will be required to fulfill continuing education requirements as outlined in this rule.

(b) Reinstatement of Revoked Licensure – No person whose license has been revoked for failure to comply with continuing education may be reinstated without complying with these requirements. Continuing education requirements will accumulate at the same rate as that for those licenses which are active. The required clock hours of continuing education must have begun and been successfully completed before the date of reinstatement.

(c) Reinstatement of Expired Licensure – No person whose license has expired may be reinstated without submitting evidence of continuing education. The continuing education hours documented at the time of reinstatement must equal the hours required, had the license remained in an active status, and must have begun and been successfully completed before the date of reinstatement.

(d) Continuing education hours obtained as a prerequisite for reactivating or reinstating a license may not be counted toward completion of any current two (2) calendar year requirement.

(e) Unless the licensee has actively practiced in another state while the licensee's Tennessee license has been retired, revoked or expired, then no more than one-half of the required continuing medical education for licensure reinstatement or reactivation shall be taken via the Internet, in multi-media and/or electronic formats as provided in subparagraph (4)(a).

(7) Violations

(a) Any licensee who falsely certifies attendance and completion of the required hours of continuing education requirements, or who does not or can not adequately substantiate

(Rule 1200-06-01-.12, continued)

completed continuing education hours with the required documentation, may be subject to disciplinary action.

(b) Prior to the institution of any disciplinary proceedings, a letter shall be issued to the last known address of the individual stating the facts or conduct which warrant the intended action.

(c) The licensee has thirty (30) days from the date of notification to show compliance with all lawful requirements for the retention of the license.

(d) Any licensee who fails to show compliance with the required continuing education hours in response to the notice contemplated by subparagraph (b) may be subject to disciplinary action.

(e) Continuing education hours obtained as a result of compliance with the terms of a Board Order in any disciplinary action shall not be credited toward any continuing education requirement.

(8) Deadline Extension of Continuing Education Requirements

(a) The Board may grant for no more than six (6) months an extension of the deadline to complete the required hours of continuing education if it can be shown that compliance was beyond the physical or mental capabilities of the licensee seeking the deadline extension.

(b) Extension of the deadline will be considered only on an individual basis and may be requested by submitting the following items to the Board's administrative office:

1. A written request for a deadline extension which specifies which deadline is sought to be extended and a written and signed explanation of the reason for the request; and

2. Any documentation which supports the reason(s) for the deadline extension requested or which is subsequently requested by the Board.

(c) A deadline extension approved by the Board is effective only for the two (2) calendar year period for which the deadline extension is sought.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-119.* ***Administrative History:*** *Original rule filed August 8, 2005; effective October 22, 2005. Amendment filed April 17, 2007; effective July 1, 2007. Amendment filed April 1, 2009; effective June 15, 2009. Amendment filed April 22, 2010; effective July 21, 2010.*

1200-06-01-.13 TEMPORARY LICENSE.

(1) Applicants who have applied and are approved pursuant to Rule 1200-06-01-.05 to challenge a specific national certification examination and meet the minimum education and/or experience requirements as described in Rule 1200-06-01-.22 will be issued a temporary license by the Board administrative office upon approval.

(2) No application other than required by Rule 1200-06-01-.05 is required.

(3) Individuals who possess a state laboratory personnel license in one category will not be eligible for a temporary license in a different category.

(4) The validity and duration of temporary licenses shall be governed by T.C.A. § 68-29-117(d).

(Rule 1200-06-01-.13, continued)

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-117.* ***Administrative History:*** *Original rule filed September 9, 1996; effective November 23, 1995. Amendment filed March 4, 1998; effective May 20, 1998. Amendment filed Amrch 16, 2007; effective May 30, 2007.*

1200-06-01-.14 TRAINEE PERMITS.

(1) Each trainee must submit a trainee application when he begins his practice training in a medical laboratory.

(2) The Board will issue the trainee a trainee permit that will be valid during the training period provided the facility where the training is being gained is approved for practice training.

(3) Trainees may use a trainee permit to work and receive remuneration in those specialties for which they have completed their classroom lectures and clinical practicum, provided they are under direct supervision of licensed medical laboratory personnel at the technologist level or higher. Trainees may only work in the facility in which the specific specialty training was obtained and may begin training only if the facility has possession of a copy of the valid trainee permit.

(4) A trainee permit is void the day the trainee completes or withdraws from the training program.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-120.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed October 11, 2004; effective December 25, 2004.*

1200-06-01-.15 PERSONNEL LICENSURE DISCIPLINE, CIVIL PENALTIES, ASSESSMENT OF COSTS, AND SUBPOENAS.

(1) Upon a finding by the Board that a licensee has violated any provision of the Tennessee Medical Laboratory Act *(T.C.A. §§ 68-29-101, et seq.)* or the rules promulgated pursuant thereto, the Board may impose any of the following actions separately or in any combination which is deemed appropriate to the offense:

(a) Private Censure - This is a written action issued to the licensee for minor or near infractions. It is informal and advisory in nature and does not constitute a formal disciplinary action.

(b) Public Censure or Reprimand - This is a written action issued to a licensee for one time and less severe violations. It is a formal disciplinary action.

(c) Probation - This is a formal disciplinary action which places a licensee on close scrutiny for a fixed period of time. This action may be combined with conditions which must be met before probation will be lifted and/ or which restrict the licensee's activities during the probationary period.

(d) Licensure Suspension - This is a formal disciplinary action which suspends a licensee's right to practice medical technology for a fixed period of time. It contemplates the reentry of the licensee into practice under the license previously issued.

(e) Licensure Revocation - This is the most severe form of disciplinary action which removes a licensee from the practice of medical technology and terminates the license previously issued. If revoked, it relegates the violator to the status he or she possessed prior to application for licensure. However, the Board may in its discretion allow the reinstatement of a revoked license upon conditions and after a period of time it deems appropriate. No petition for reinstatement and no new application for licensure from a

(Rule 1200-06-01-.15, continued)

person whose license was revoked shall be considered prior to the expiration of at least one (1) year unless otherwise stated in the Board's revocation order.

(f) Conditions - Any action deemed appropriate by the Board to be required of a disciplined licensee during any period of probation or suspension or as a prerequisite to the lifting of probation or suspension or the reinstatement of a revoked license.

(g) Once ordered, probation, suspension, revocation, assessment of a civil penalty, or any other condition of any type of disciplinary action may not be lifted unless and until the licensee petitions, pursuant to paragraph (2) of this rule, and appears before the Board after the period of initial probation, suspension, revocation, or other conditioning has run and all conditions placed on the probation, suspension, revocation, have been met, and after any civil penalties assessed have been paid.

(2) Order of Compliance - This procedure is a necessary adjunct to previously issued disciplinary orders and is available only when a petitioner has completely complied with the provisions of a previously issued disciplinary order, including an unlicensed practice civil penalty order, and wishes or is required to obtain an order reflecting that compliance.

(a) The Board will entertain petitions for an Order of Compliance as a supplement to a previously issued order upon strict compliance with the procedures set forth in subparagraph (b) in only the following three (3) circumstances:

1. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued reflecting that compliance; or

2. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued lifting a previously ordered suspension or probation; or

3. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued reinstating a license previously revoked.

(b) Procedures

1. The petitioner shall submit a Petition for Order of Compliance, as contained in subparagraph (c), to the Board's Administrative Office that shall contain all of the following:

(i) A copy of the previously issued order; and

(ii) A statement of which provision of subparagraph (a) the petitioner is relying upon as a basis for the requested order; and

(iii) A copy of all documents that prove compliance with all the terms or conditions of the previously issued order. If proof of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed statements from every individual the petitioner intends to rely upon attesting, under oath, to the compliance. The Board's consultant and administrative staff, in their discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

(Rule 1200-06-01-.15, continued)

2. The Board authorizes its consultant and administrative staff to make an initial determination on the petition and take one of the following actions:

   (i) Certify compliance and have the matter scheduled for presentation to the Board as an uncontested matter; or

   (ii) Deny the petition, after consultation with legal staff, if compliance with all of the provisions of the previous order is not proven and notify the petitioner of what provisions remain to be fulfilled and/or what proof of compliance was either not sufficient or not submitted.

3. If the petition is presented to the Board the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.

4. If the Board finds that the petitioner has complied with all the terms of the previous order an Order of Compliance shall be issued.

5. If the petition is denied either initially by staff or after presentation to the Board and the petitioner believes compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223 and rule 1200-10-01-.11.

(c) Form Petition

Petition for Order of Compliance
Tennessee Medical Laboratory Board

Petitioner's Name: _____
Petitioner's Mailing Address: _____
_____
_____
Petitioner's E-Mail Address: _____
Telephone Number: _____

Attorney for Petitioner: _____
Attorney's Mailing Address: _____
_____
_____
Attorney's E-Mail Address: _____
Telephone Number: _____

The petitioner respectfully represents, as substantiated by the attached documentation, that all provisions of the attached disciplinary order have been complied with and I am respectfully requesting: (circle one)

1. An order issued reflecting that compliance; or

2. An order issued reflecting that compliance and lifting a previously ordered suspension or probation; or

3. An order issued reflecting that compliance and reinstating a license previously revoked.

(Rule 1200-06-01-.15, continued)

Note - You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show compliance is the testimony of any individual, including yourself, you must enclose signed statements from every individual you intend to rely upon attesting, under oath, to the compliance. The Board's consultant and administrative staff, in their discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted this the _____day of _____, 20___.

_____
Petitioner's Signature

(3) Order Modifications - This procedure is not intended to allow anyone under a previously issued disciplinary order, including an unlicensed practice civil penalty order, to modify any findings of fact, conclusions of law, or the reasons for the decision contained in the order. It is also not intended to allow a petition for a lesser disciplinary action, or civil penalty other than the one(s) previously ordered. All such provisions of Board orders were subject to reconsideration and appeal under the provisions of the Uniform Administrative Procedures Act (T.C.A. §§ 4-5-301, et seq.). This procedure is not available as a substitute for reconsideration and/or appeal and is only available after all reconsideration and appeal rights have been either exhausted or not timely pursued. It is also not available for those who have accepted and been issued a reprimand.

(a) The Board will entertain petitions for modification of the disciplinary portion of previously issued orders upon strict compliance with the procedures set forth in subparagraph (b) only when the petitioner can prove that compliance with any one or more of the conditions or terms of the discipline previously ordered is impossible. For purposes of this rule the term "impossible" does not mean that compliance is inconvenient or impractical for personal, financial, scheduling or other reasons.

(b) Procedures

1. The petitioner shall submit a written and signed Petition for Order Modification on the form contained in subparagraph (c) to the Board's Administrative Office that shall contain all of the following:

(i) A copy of the previously issued order; and

(ii) A statement of why the petitioner believes it is impossible to comply with the order as issued; and

(iii) A copy of all documents that proves that compliance is impossible. If proof of impossibility of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed and notarized statements from every individual the petitioner intends to rely upon attesting, under oath, to the reasons why compliance is impossible. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

2. The Board authorizes its consultant and administrative staff to make an initial determination on the petition and take one of the following actions:

(Rule 1200-06-01-.15, continued)

(i) Certify impossibility of compliance and forward the petition to the Office of General Counsel for presentation to the Board as an uncontested matter; or

(ii) Deny the petition, after consultation with legal staff, if impossibility of compliance with the provisions of the previous order is not proven and notify the petitioner of what proof of impossibility of compliance was either not sufficient or not submitted.

3. If the petition is presented to the Board the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.

4. If the petition is granted a new order shall be issued reflecting the modifications authorized by the Board that it deemed appropriate and necessary in relation to the violations found in the previous order.

5. If the petition is denied either initially by staff or after presentation to the Board and the petitioner believes impossibility of compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223 and rule 1200-10-01-.11.

(c) Form Petition

Petition for Order Modification
Tennessee Medical Laboratory Board

Petitioner's Name: _____
Petitioner's Mailing Address: _____
_____
_____
Petitioner's E-Mail Address: _____
Telephone Number: _____

Attorney for Petitioner: _____
Attorney's Mailing Address: _____
_____
_____
Attorney's E-Mail Address: _____
Telephone Number: _____

The petitioner respectfully represents that for the following reasons, as substantiated by the attached documentation, the identified provisions of the attached disciplinary order are impossible for me to comply with:

_____
_____
_____
_____

Note - You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show impossibility is the testimony of any individual, including yourself, you must enclose signed and notarized statements from every individual you intend to rely upon attesting, under oath, to the reasons why compliance is impossible. No documentation or testimony other

(Rule 1200-06-01-.15, continued)

than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted this the _____day of _____, 20___.

_____
Petitioner's Signature

(4) Civil Penalties.

(a) Purpose - The purpose of this rule is to set out a schedule designating the minimum and maximum civil penalties which may be assessed.

(b) Schedule of Civil Penalties

1. The Type A Civil Penalty may be imposed whenever the Board finds a person who is required to be licensed by the Board guilty of a willful and knowing violation of the Medical Laboratory Act, or regulations promulgated pursuant thereto, to such an extent that there is. or is likely to be, an imminent, substantial threat to the health, safety and welfare of an individual patient or the public. For purposes of this section, willfully and knowingly practicing in the medical laboratory without a license from the Board when licensure is required, is one of the violations of the Medical Laboratory Act for which a Type A Civil Penalty is assessable.

2. A Type B Civil Penalty may be imposed whenever the Board finds the person required to be licensed by the Board guilty of a violation of the Medical Laboratory Act or regulations promulgated pursuant thereto in such a manner as to impact directly on the care of patients or the public.

3. A Type C Civil Penalty may be imposed whenever the Board finds the person required to be licensed by the Board guilty of a violation of the Medical Laboratory Act or regulations promulgated pursuant thereto, which are neither directly detrimental to patients or the public, nor directly impact their care, but have only an indirect relationship to patient care or the public.

(c) Amount of Civil Penalties

1. Type A Civil Penalties shall be assessed in the amount of not less than $500 nor more than $1,000.

2. Type B Civil Penalties may be assessed in the amount of not less than $100 and not more than $500.

3. Type C Civil Penalties may be assessed in the amount of not less than $50 and not more than $100.

(d) Procedures for Assessing Civil Penalties

1. The Division of Health Related Boards may initiate a civil penalty assessment by filing a Memorandum of Assessment of Civil Penalty. The Division shall state in the memorandum the facts and law upon which it relies in alleging a violation, the proposed amount of the civil penalty and the basis for such penalty. The Division may incorporate the Memorandum of Assessment of Civil Penalty with a Notice of Charges which may be issued attendant thereto.

(Rule 1200-06-01-.15, continued)

2. Civil Penalties may also be initiated and assessed by the Board during consideration of any Notice of Charges. In addition, the Board may, upon good cause shown, assess a type and amount of civil penalty which was not recommended by the Division.

3. In assessing the civil penalties pursuant to these rules the Board may consider the following factors:

(i) Whether the amount imposed will be a substantial economic deterrent to the violator;

(ii) The circumstances leading to the violation,

(iii) The severity of the violation and the risk of harm to the public;

(iv) The economic benefits gained by the violator as a result of noncompliance; and

(v) The interest of the public.

4. All proceedings for the assessment of civil penalties shall be governed by the contested case provisions of Title 4, Chapter 5, *Tennessee Code Annotated.*

(5) Assessment of costs in disciplinary proceedings shall be as set forth in T.C.A. §§ 63-1-144 and 68-29-136.

(6) Subpoenas

(a) Purpose - Although this rule applies to persons and entities other than medical laboratory personnel, it is the Board's intent as to medical laboratory personnel that they be free to practice their profession without fear that such practice or its documentation will be unduly subjected to scrutiny outside the profession. Consequently, balancing that intent against the interest of the public and patients to be protected against substandard care and activities requires that persons seeking to subpoena such information and/or materials must comply with the substance and procedures of these rules.

It is the intent of the Board that the subpoena power outlined herein shall be strictly proscribed. Such power shall not be used by the Division or Board investigators to seek other incriminating evidence against medical laboratory personnel when the Division or Board does not have a complaint or basis to pursue such an investigation. Thus, unless the Division or its investigators have previously considered, discovered, or otherwise received a complaint from either the public or a governmental entity, then no subpoena as contemplated herein shall issue.

(b) Definitions - As used in this chapter of rules the following words shall have the meanings ascribed to them:

1. Probable Cause

(i) For Investigative Subpoenas - shall mean that probable cause, as defined by case law at the time of request for subpoena issuance is made, exists that a violation of the Medical Laboratory Practice Act or rules promulgated pursuant thereto has occurred or is occurring and that it is more probable than not that the person(s), or items to be subpoenaed possess or contain evidence which is more probable than not relevant to the conduct constituting the violation.

(Rule 1200-06-01-.15, continued)

(ii) The utilization of the probable cause evidentiary burden in proceedings pursuant to this rule shall not in any way, nor should it be construed in any way to establish a more restrictive burden of proof than the existing preponderance of the evidence in any civil disciplinary action which may involve the person(s) or items that are the subject of the subpoena.

2. Presiding Officer - For investigative subpoenas shall mean any elected officer of the Board, or any duly appointed or elected chairperson of any panel of the Board.

(c) Procedures

1. Investigative Subpoenas

(i) Investigative Subpoenas are available only for issuance to the authorized representatives of the Tennessee Department of Health, its investigators and its legal staff.

(ii) An applicant for such a subpoena must either orally or in writing notify the Board's Unit Director of the intention to seek issuance of a subpoena. That notification must include the following:

(I) The time frame in which issuance is required so the matter can be timely scheduled; and

(II) A particular description of the material or documents sought, which must relate directly to an ongoing investigation or contested case, and shall, in the instance of documentary materials, be limited to the records of the patient or patients whose complaint, complaints, or records are being considered by the Division or Board.

I. In no event shall such subpoena be broadly drafted to provide investigative access to medical laboratory records of other patients who are not referenced in a complaint received from an individual or governmental entity, or who have not otherwise sought relief, review, or Board consideration of any medical laboratory personnel's conduct, act, or omission; and

II. If the subpoena relates to the prescribing practices of a licensee, then it shall be directed solely to the records of the patient(s) who received the pharmaceutical agents and whom the board of pharmacy or issuing pharmacy(ies) has so identified as recipients; and

(III) Whether the proceedings for the issuance is to be conducted by physical appearance or electronic means; and

(IV) The name and address of the person for whom the subpoena is being sought, or who has possession of the items being subpoenaed.

(iii) The Board's Unit Director shall cause the following to be done:

(Rule 1200-06-01-.15, continued)

(I) In as timely a manner as possible arrange for either an elected officer of the Board or any duly appointed or elected chairperson of any panel of the Board to preside and determine if issuing the subpoena should be recommended to the full Board; and

(II) Establish a date, time and place for the proceedings to be conducted and notify the Presiding Officer, the applicant and the court reporter; and

(III) Maintain a complete record of the proceedings including an audio tape in such a manner as to:

I. Preserve a verbatim record of the proceeding; and

II. Prevent the person presiding over the proceedings and/or signing the subpoena from being allowed to participate in any manner in any resulting disciplinary action of any kind, formal or informal, which involves either the person or the documents or records for which the subpoena was issued.

(iv) The Proceedings

(I) The applicant shall do the following:

I. Provide for the attendance of all persons whose testimony is to be relied upon to establish probable cause; and

II. Produce and make part of the record copies of all documents to be utilized to establish probable cause; and

III. Obtain, complete and provide to the Presiding Officer a subpoena which specifies the following:

A. The name and address of the person for whom the subpoena is being sought or who has possession of the items being subpoenaed; and

B. The location of the materials, documents or reports for which production pursuant to the subpoena is sought if that location is known; and

C. A brief, general description of any materials, documents or items to be produced pursuant to the subpoena; and

D. The date, time and place for compliance with the subpoena.

IV. Provide the Presiding Officer testimony and/or documentary evidence which, in good faith, the applicant believes is sufficient to establish that probable cause exists for issuance of the subpoena as well as sufficient proof that all other reasonably available alternative means of securing the materials, documents or items have been unsuccessful.

(II) The Presiding Officer shall do the following:

I. Be selected only after assuring the Board's Unit Director that he or she has no prior knowledge of or any direct or indirect

(Rule 1200-06-01-.15, continued)

interest in or relationship with the person(s) being subpoenaed and/or the licensee who is the subject of the investigation; and

II. Commence the proceedings and swear all necessary witnesses; and

III. Hear and maintain the confidentiality, if any, of the evidence presented at the proceedings and present to the full Board only that evidence necessary for an informed decision; and

IV. Control the manner and extent of inquiry during the proceedings and be allowed to question any witness who testifies; and

V. Determine, based solely on the evidence presented in the proceedings, whether probable cause exists and if so, make such recommendation to the full Board; and

VI. Not participate in any way in any other proceeding whether formal or informal, which involves the matters, items or person(s) which are the subject of the subpoena. This does not preclude the Presiding Officer from presiding at further proceedings for issuance of subpoenas in the matter.

(III) The Board shall do the following:

I. By a vote of two thirds (2/3) of the Board members issue the subpoena for the person(s) or items specifically found to be relevant to the inquiry, or quash or modify an existing subpoena by a majority vote; and

II. Sign the subpoena as ordered to be issued, quashed or modified.

2. Post-Notice of Charges Subpoenas - If the subpoena is sought for a contested case being heard with an Administrative Law Judge from the Secretary of State's office presiding, this definition shall not apply and all such post-notice of charges subpoenas should be obtained from the office of the Administrative Procedures Division of the Office of the Secretary of State pursuant to the Uniform Administrative Procedures Act and rules promulgated pursuant thereto.

(d) Subpoena Forms

1. All subpoenas shall be issued on forms approved by the Board.

2. The subpoena forms may be obtained by contacting the Board's Administrative Office.

(e) Subpoena Service - Any method of service of subpoenas authorized by the Tennessee Rules of Civil Procedure or the rules of procedure for contested cases of the Tennessee Department of State, Administrative Procedures Division may be utilized to serve subpoenas pursuant to this rule.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 4-5-311, 4-5-217, 4-5-223, 63-1-122, 65-1-134, 63-1-144, 68-29-104, 68-29-105, 68-29-109, 69-29-127, 68-29-128, 68-29-129, 68-29-130, 68-29-131, 68-29-132, and 68-29-136.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 9, 1996; effective November 23, 1996. Amendment filed December 1, 2000; effective February*

(Rule 1200-06-01-.15, continued)
14, 2001. Amendment filed March 22, 2001; effective June 5, 2001. Amendment filed July 8, 2004; effective September 21, 2004.

1200-06-01-.16 REPLACEMENT LICENSE.

(1) A license holder whose "artistically designed" license has been lost or destroyed may be issued a replacement document upon receipt in the Board's administrative office of a notarized written request and a photograph of the licensee. Such request shall state the facts concerning the loss or destruction of the original document and shall be accompanied by the required fee, pursuant to Rule 1200-06-01-.06.

(2) A license holder whose renewal certificate has been lost or destroyed may be issued a replacement document upon receipt in the Board's administrative office of a notarized written request and a photograph of the licensee. Such request shall state the facts concerning the loss or destruction of the original document and shall be accompanied by the required fee, pursuant to Rule 1200-06-01-.06.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 63-1-106, and 68-29-105.* ***Administrative History:*** *Original rule filed September 9, 1996; effective November 23, 1996. Amendment filed August 25, 2003; effective November 8, 2003.*

1200-06-01-.17 CHANGE OF ADDRESS AND/OR NAME.

(1) Change of Address. A licensee who has had a change of address shall file in writing with the Board his or her current mailing address, giving both the old and new addresses and new phone number. Such notification should be received in the Board's administrative office no later than thirty (30) days after such change is effective and must reference the individual's name, profession, and license number.

(2) Change of Name. A licensee shall provide a certified copy of the marriage certificate, divorce decree, or court order indicating a name change within thirty (30) days of the change. The licensee shall provide both the old and new name and must reference the individual's profession and license number. Under no circumstances shall a licensee change his/her name online via the Internet.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 63-1-106, and 68-29-105.* ***Administrative History:*** *Original rule filed September 9, 1996; effective November 23, 1996. Amendment filed August 25, 2003; effective November 8, 2003.*

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.* ***Administrative History:*** *Original ruled filed April 1, 2009; effective June 15, 2009.*

1200-06-01-.19 BOARD MEETINGS, OFFICERS, CONSULTANTS, DECLARATORY ORDERS, AND SCREENING PANELS.

(1) Board Meeting:

(a) The time, place, and frequency of Board meetings shall be at the discretion of the Board except at least one meeting shall be held annually. All meetings of the Board shall be open to the public.

(b) Special meetings are called at the discretion of the Chair or at the request of two members of the Board, provided all members are adequately notified.

(c) Non-Board members present at meetings may address the Board only on recognition by the Chairperson.

(2) The Board shall elect annually from its members the following officers:

(a) Full Board Chair - who shall preside at all Board meetings.

(b) Personnel and Education Licensure Committee Chair - who shall preside at Personnel and Education Licensure Committee meetings.

(c) Vice-Chairperson - who shall preside in the absence of the Chair.

(3) The Board has the authority to select a Board consultant who shall serve as a consultant to the Division and who is vested with the authority to do the following acts:

(a) Recommend whether and what type disciplinary actions should be instituted as the result of complaints received or investigations conducted by the Division.

(b) Recommend whether and under what terms a complaint case or disciplinary action might be settled. Any matter proposed for settlement must be subsequently ratified by the full Board before it will become effective.

(c) Undertake any other matters authorized by a majority vote of the Board.

(4) Records and Complaints

(a) All requests, applications, notices, other communications and correspondence shall be directed to the Board's administrative office. Any requests or inquiries requiring a Board decision or official Board action. except documents relating to disciplinary actions or hearing requests, must be received 14 days prior to the scheduled Board meeting and will be retained in the administrative office and presented to the Board at the meeting. Such documentation not timely received may be set over to the next Board meeting.

(b) All records of the Board, except those made confidential by law, are open for inspection and examination under the supervision of an employee of the Division at the Board's administrative office.

(c) Copies of public records shall be provided to any person upon payment of the cost of copying.

(5) Declaratory Orders - The Board adopts, as if fully set out herein, rule 1200-10-1-.11 Declaratory Orders of the Division of Health Related Boards and as it may from time to time be amended, as its rule governing the declaratory order process. All declaratory order petitions involving statutes, rules or orders within the jurisdiction of the Board shall be

(Rule 1200-06-01-.19, continued)

addressed by the Board pursuant to that rule and not by the Division. Declaratory Order Petition forms can be obtained from the Board's administrative office.

(6) Screening Panels - The Board adopts, as if fully set out herein, rule 1200-10-01-.13, of the Division of Health Related Boards and as it may from time to time be amended, as its rule governing the screening panel process.

(7) The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-04-01-.18 regarding petitions for reconsiderations and stays in that case.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 4-5-223, 4-5-224, 63-1-105, 63-1-13, 68-29-105, 68-29-109, and 68-29-127.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 9, 1996; effective November 23, 1996. Amendment filed March 4, 1998; effective May 20, 1998. Amendment filed June 10, 1999; effective October 28, 1999. Amendment filed March 22, 2001; effective June 5, 2001. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed March 16, 2007; effective May 30, 2007.*

1200-06-01-.20 QUALIFICATIONS AND DUTIES OF THE MEDICAL LABORATORY DIRECTOR.

(1) Qualifications. It shall not be necessary for an individual who is licensed as a medical laboratory director to be licensed in any other category under these rules. Pathologists and any other person who is duly licensed and registered to practice medicine in the State of Tennessee and boarded by a national boarding agency acceptable to the Board will not be required to obtain a medical laboratory license in addition to their medical license. This medical license shall be current and in good standing. Individuals that hold an earned doctoral degree (non-medical) are required to obtain a license as a laboratory director from the Board. To be eligible to direct a medical laboratory a person shall meet one (1) or more of the following requirements:

(a) Be a physician licensed in Tennessee and certified or eligible for certification in anatomic or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology. Physicians who are eligible for certification must become certified within three (3) years of assuming directorship.

1. The director of an anatomic laboratory must be certified or eligible for certification in anatomic pathology, and may direct a cytopathology, histopathology, or oral pathology laboratory.

2. The director of a clinical laboratory must be certified or eligible for certification in clinical pathology.

3. The director of a laboratory that conducts anatomic and clinical pathology must be certified or eligible for certification in anatomic and clinical pathology.

(b) Be a physician licensed in Tennessee and certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other certifying boards acceptable to the Board in one or more of the laboratory specialties for which approval for directorship is being sought. Board certifications must be current.

(c) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science, from an accredited institution or equivalent and be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, American Board of Medical Laboratory Immunology or other

(Rule 1200-06-01-.20, continued)

certifying boards acceptable to the Board in one or more of the laboratory specialties for which approval for directorship is being sought. Board certifications must be current.

(d) Be a physician licensed in Tennessee, who subsequent to graduation has had four (4) years or more experience in pulmonary function. The directorship is limited to blood gas analysis (pH, pO2, pCO2) and co-oximetry analysis (measurement of oxygen saturation), and reporting of the measurement(s) to include carboxyhemoglobin, total hemoglobin, oxyhemoglobin, methemoglobin, and sulfhemoglobin on automated instruments.

1. The phrase “subsequent to graduation” means laboratory training and experience acquired after receipt of the specified degree.

2. The term “experience” means broad, relevant experience gained in a clinical laboratory located in the United States. The Board will evaluate the experience required for qualification within these rules.

(e) Hold an earned doctoral degree from an accredited college/university and, in the opinion of the Board, have appropriate work experience in a subspecialty for which there is no national certification. If boarding is available in a closely related field, that boarding must be sought. These individuals must obtain national boarding in the subspecialty when it becomes available.

(2) The Board shall review and approve all director licenses.

(3) A physician who was qualified and acting as a medical laboratory director at a facility on or before July 16, 1995, may continue acting as the medical laboratory director at that facility. Otherwise, to qualify as a medical laboratory director the individual must meet the minimum licensure requirements stated in Rule 1200-06-01-.20(1).

(4) Oral Pathology Laboratory Director

(a) A dentist may serve as a medical laboratory director limited to the specialty of oral pathology without obtaining medical laboratory licensure if

1. The dentist has a current, unrestricted, and unencumbered license to practice dentistry in Tennessee; and

2. The dentist is currently certified by the American Board of Oral and Maxillofacial Pathology; and

3. The dentist is currently certified in oral pathology by the Tennessee Board of Dentistry.

(b) Otherwise, to qualify as a medical laboratory director the individual must meet the minimum licensure requirements stated in Rule 1200-06-01-.20(1) or (3).

(c) Oral pathology laboratory directors shall limit their responsibilities to only those specimens obtained from the oral cavity.

(5) Duties. The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

(Rule 1200-06-01-.20, continued)

(a) The laboratory director, if qualified, may perform the duties of the medical laboratory supervisor and of testing personnel or may delegate those responsibilities to personnel meeting the qualifications for those respective positions.

(b) The laboratory director may delegate performance of his or her responsibilities to the medical laboratory supervisor however, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed. The director shall make periodic and documented on-site visits at a minimum of once per month.

(d) The laboratory director must not direct more than three (3) clinical labs without an exemption from the Board. Collection stations are not considered clinical laboratories.

(e) The laboratory director must -

1. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

2. Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical and biological hazards;

3. Ensure that -

(i) The test methodologies selected have the capability of providing the quality of results required for patient care,

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

4. Ensure that the laboratory is enrolled in a proficiency testing program approved by the U.S. Department of Health and Human Services for the testing which is performed and that -

(i) The proficiency testing samples are tested as required under these rules;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; and

(Rule 1200-06-01-.20, continued)

(v) The regional surveyor is notified in the event the proficiency testing scores are unacceptable or unsatisfactory. The response form shall be completed to include any corrective action implemented to solve the problem(s).

5. Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

6. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

7. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;

8. Ensure that reports of test results include pertinent information required for interpretation;

9. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

10. Ensure that a general supervisor provides supervision of test performance by testing personnel;

11. Ensure that a sufficient number of laboratory personnel are employed who possess the appropriate education and experience or training to provide appropriate consultation, to properly supervise and to accurately perform tests and report test results in accordance with the personnel responsibilities described in Rule 1200-06-01-.22;

12. Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and scope of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

13. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

14. Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process:

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

16. Provide consultation regarding the appropriateness of the testing ordered and interpretation of test results.

(Rule 1200-06-01-.20, continued)

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, 68-29-105, 68-29-111, 68-29-114, 68-29-116, 68-29-118, 68-29-129, and 68-29-137.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 11, 1996; effective November 25, 1996. Amendment filed January 7, 1997; effective March 23, 1997. Amendment filed March 4, 1998; effective May 20, 1998. Amendment filed April 29, 2002; effective July 13, 2002. Amendment filed May 23, 2003; effective August 6, 2003. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed June 2, 2004; effective August 16, 2004. Amendment filed October 11, 2004; effective December 25, 2004. Amendment filed February 15, 2006; effective May 1, 2006.*

1200-06-01-.21 QUALIFICATIONS AND DUTIES OF THE MEDICAL LABORATORY SUPERVISOR.

(1) Qualifications. An individual who qualifies as medical laboratory director is considered to be qualified as a medical laboratory supervisor.

(a) The laboratory must have one or more medical laboratory supervisors who, under the direction of the laboratory director, provide day-to-day supervision of testing personnel and reporting of test results. In the absence of the director, the medical laboratory supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

(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 1200-06-01-22(1)(g) 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 1200-06-01-.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 1200-06-01-.22(1)(g) 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 1200-06-01-.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 1200-06-01-.22(1)(g) 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 1200-06-01-.22(1)(d) 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 1200-06-01-.22(1)(g) subsequent to qualifying as a special analyst. The license shall be limited to the subspecialty for which the applicant is qualified.

(c) Clinical laboratory work experience, as required in Rule 1200-06-01-.21(1)(b)2., 3., or 4. begins when the applicant either receives a national certification or state licensure at the technologist or special analyst level.

(Rule 1200-06-01-.21, continued)

(d) Unless qualified as a medical laboratory director, in addition to the requirements indicated in subparagraph (1)(b) to be licensed as a medical laboratory supervisor the individual must also provide the following documentation:

1. Proof of at least forty-five (45) contact/clock hours of management continuing education through attendance of professional workshops, seminars and/or courses conducted on subjects relevant to the managerial operation of a clinical/anatomic laboratory. Course content must relate to traditional management/supervisory skills in accordance with the topic guidelines established by the Board. A minimum of eight (8) contact hours must be obtained through formal workshop programs. Fifteen (15) contact hours will be awarded for each semester hour awarded by a college or university; and

2. Proof of at least fifteen (15) contact/clock hours of technical continuing education through attendance of professional workshops, seminars and/or courses. Technical course content should be at an intermediate/advanced level and include a variety of technical materials related to clinical laboratory practice.

3. The management and technical hours submitted for continuing education must be completed subsequent to qualifying as a medical technologist or special analyst as defined in subparagraph (1)(c).

4. Proof of attendance must be documented and submitted with all continuing education.

(2) Duties. The medical laboratory supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(a) The medical laboratory supervisor -

1. Must be a full-time employee of the facility and be on the laboratory premises during the regular working day. The employee must be readily available for personal or telephone consultations during all other hours when tests are performed.

2. Must be responsible for providing day-to-day supervision of test performance by testing personnel.

3. Must be responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

(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:

1. Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

2. Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

3. Providing orientation to all testing personnel, and

4. Annually evaluating and documenting the performance of all testing personnel.

(Rule 1200-06-01-.21, continued)

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, 68-29-105, 68-29-116, and 68-29-118.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 11, 1996; effective November 25, 1996. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed February 15, 2006; effective May 1, 2006.*

1200-06-01-.22 QUALIFICATIONS, RESPONSIBILITIES AND DUTIES OF TESTING PERSONNEL.

(1) Qualifications. All testing personnel must hold a valid Tennessee license issued by the Board to perform or report a laboratory test.

(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 1200-06-02-.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

(Rule 1200-06-01-.22, continued)

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) To become licensed as a medical laboratory technician an applicant must:

1. Submit satisfactory evidence of successfully completing and passing a national certifying examination and being nationally certified at the technician level; and

2. In addition to possessing the national certification required by part 1. of this subparagraph, submit satisfactory evidence of one (1) of the following educational criteria:

(i) Having received an associate degree from an accredited college/university and having completed an accredited medical laboratory technician 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; or

(ii) Having received an associate degree from an accredited college/university and having completed an official military laboratory procedures course of at least fifty (50) weeks duration in residence and having held the military enlisted occupational specialty of Medical Laboratory Specialist; or

(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).

(d) A medical laboratory technologist may obtain a license in any of the following categories: chemistry, hematology, immunohematology, or microbiology. The applicant must:

(Rule 1200-06-01-.22, continued)

1. Present proof of national certification by a certifying body acceptable to the Board in the laboratory specialty in which licensure is being sought at the technologist level; and

2. Meet one of the additional qualifications referred to in subparagraph (1)(a).

(e) An individual may be issued a special analyst license to perform tests in only a limited range (as listed on the license) if the procedure(s) for which licensure is being sought is a new, emerging technology in the clinical laboratory or represents a subspecialty not otherwise regulated. The procedure(s) must not be a component of the traditional clinical laboratory science body of knowledge contained in chemistry, hematology, microbiology or immunohematology; and

1. The individual must be certified by a national certification body approved by the Board, where such certification or qualification exists and must possess a baccalaureate degree from an accredited college/university relevant to the subspecialty in which licensure is being sought, or

2. In the absence of national certification the individual must possess at least a baccalaureate degree from an accredited college/university relevant to the subspecialty in which licensure is being sought and proof of three (3) years of relevant work experience as approved by the Board. The Board shall approve all individuals qualifying in this manner. Individuals must obtain national certification at such time as it becomes available and must request that proof of said national certification be sent directly to the Board's administrative office from the certifying agency in order to continue licensure. Failure to obtain national certification shall result in revocation of the license.

(f) Testing personnel performing blood gas (pCO2, pO2, and pH) analysis and co-oximetry analysis (measurement of oxygen saturation) and reporting of the measurement(s) to include carboxyhemoglobin, total hemoglobin, methemoglobin, and oxyhemoglobin and sulfhemoglobin on automated instruments shall:

1. Hold a valid laboratory license permitting performance of tests in the chemistry specialty, or

2. Hold a valid license as a special analyst limited to blood gases, or

3. Hold a valid arterial blood gas (ABG) endorsement issued by the Board of Respiratory Care, pursuant to the Respiratory Care Practitioner Act and rules promulgated by that board.

(g) The science coursework equivalent to that required in a laboratory science education program includes:

1. Sixteen (16) semester hours or twenty-four (24) quarter hours of chemistry which shall include one (1) full academic year of general chemistry courses including lectures and laboratory and one (1) course in organic chemistry or biochemistry including lectures and laboratory,

2. Sixteen (16) semester hours or twenty-four (24) quarter hours of biological sciences. Microbiology is required, including lectures and laboratory, and

3. Three (3) semester hours or six (6) quarter hours of mathematics.

(Rule 1200-06-01-.22, continued)

4. The college courses must be acceptable toward a major in those fields of study. Survey, audit, remedial, college level examination program, advanced placement, and clinical courses do not qualify as fulfillment of the chemistry, biology, or mathematics requirements.

(h) Clinical laboratory work experience includes:

1. That obtained in a medical laboratory which has a director at the doctoral level licensed under the Medical Laboratory Act and the regulations promulgated thereunder, or

2. That obtained in other laboratory facilities in which there is a director at the doctoral level and testing is done at least at a moderately complex level. The Board must approve these facilities for the purpose of clinical lab work experience.

3. For individuals seeking licensure in one of the following categories: chemistry, hematology, immunohematology, or microbiology, acceptable clinical laboratory work experience must be predominately in the category in which licensure is being sought.

4. Only the laboratory experience which occurs at a CLIA-approved site or at an accredited college or university.

5. Only the laboratory experience which has been properly documented to the Board's satisfaction.

(2) Responsibilities and Duties of Testing Personnel

(a) Responsibilities and duties of the medical laboratory technologist include:

1. Collecting and preparing specimens for analysis. Storing or transporting specimens using appropriate preservation methods.

2. Following prescribed procedures, performing any of the tests within any of the laboratory specialties. Calculating the results of the tests performed if necessary.

3. Operating, calibrating, conducting performance checks, and maintaining any clinical laboratory instrument or equipment.

4. Recognizing and correcting basic instrument malfunctions. Notifying supervisory personnel when appropriate.

5. Preparing reagents or media from a prescribed procedure, making any adjustments needed.

6. Evaluating media, reagents, and calibrators according to established criteria.

7. Conducting established quality control procedures on analytical tests, equipment, reagents, media, and products; evaluating results of quality control and implements corrective action when indicated.

8. Determining performance specifications for new methods.

9. Establishing basic quality control procedures.

(Rule 1200-06-01-.22, continued)

10. Performing comparison studies of precision, accuracy, linearity, cost, suitability, etc. on new or existing procedures and reporting results in an established format.

11. Correlating and interpreting data based on knowledge of physiological conditions affecting test results. Assessing plausibility of laboratory results through correlation of data.

12. Indicating the need for additional laboratory tests for definitive diagnostic information in prescribed instances.

13. Confirming and verifying results through knowledge of techniques, principles, and instruments.

14. Recognizing problems, identifying the cause, developing alternatives and determining solutions where no preset criteria are available.

15. Establishing and monitoring quality assurance/continuous quality improvement programs,

16. Establishing and monitoring safety programs in compliance with laboratory regulations.

17. Maintaining records that demonstrate the proficiency testing samples are tested in the same manner as patient specimens.

18. Utilizing laboratory information systems or other methods to accurately and effectively report patient results.

19. Writing laboratory procedures conforming to standardized format.

20. Performing clinical orientation and supervision for students and new or less skilled laboratory personnel.

21. Reporting test results conforming to established procedures.

(b) Responsibilities and duties of the medical laboratory technician include:

1. Collecting and preparing specimens for analysis. Storing and transporting specimens using appropriate preservation methods.

2. Following prescribed methods, performing high volume, less difficult analytical tests in laboratory specialties.

3. Making calculations as needed to report test results.

4. Operating equipment or instruments necessary to perform high volume, less difficult analytical tests. Recognizing instrument malfunction and making simple corrections using preset strategies or notifying a technologist or supervisor.

5. Preparing reagents and media according to prescribed procedures.

6. Performing and recording all quality control procedures required for tests assayed. Recognizing unacceptable quality control results. Correcting problems according to preset strategies or notifies a technologist or supervisor.

(Rule 1200-06-01-.22, continued)

7. Recognizing abnormal or unusual test results and following institutional procedures for reporting critical values.

8. Reporting test results conforming to established procedures.

9. Performing and recording routine instrument checks and maintenance procedures.

10. Performing inventory of supplies according to prescribed lists.

11. Observing all established laboratory safety procedures.

12. Participating in laboratory quality assurance/continuous quality improvement activities.

13. Maintaining records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens.

(c) Responsibilities and duties of the special analyst include:

1. Collecting and preparing specimens for analysis. Storing or transporting specimens using appropriate preservation methods.

2. Following prescribed procedures, performing any of the tests within the laboratory specialty's designated by licensure.

3. Operating, calibrating, conducting performance checks, and maintaining any clinical laboratory instrument or equipment in designated area.

4. Recognizing and correcting basic instrument malfunctions. Notifying supervisory personnel when appropriate.

5. Preparing reagents or media from a prescribed procedure, making any adjustments needed.

6. Evaluating media, reagents, and calibrators according to established criteria.

7. Conducting established quality control procedures on analytical tests, equipment, reagents, media, and products; evaluating results of quality control and implements corrective action when indicated.

8. Determining performance specifications for new methods.

9. Establishing basic quality control procedures.

10. Performing comparison studies of precision, accuracy, linearity, cost, suitability, etc. on new or existing procedures and reporting results in an established format.

11. Correlating and interpreting data based on knowledge of physiological conditions affecting test results. Assessing plausibility of laboratory results through correlation of data.

12. Indicating the need for additional laboratory tests for definitive diagnostic information in prescribed instances.

(Rule 1200-06-01-.22, continued)

13. Confirming and verifying results through knowledge of techniques, principles, and instruments.

14. Recognizing problems, identifying the cause, developing alternatives and determining solutions where no present criteria are available.

15. Establishing and monitoring quality assurance/continuous quality improvement programs.

16. Establishing and monitoring safety programs in compliance with laboratory regulations.

17. Maintaining records that demonstrate the proficiency testing samples are tested in the same manner as patient specimens.

18. Utilizing laboratory information systems or other methods to accurately and effectively report patient results.

19. Writing laboratory procedures conforming to standardized format.

20. Performing clinical orientation and supervision for students and new or less skilled laboratory personnel.

21. Reporting test results conforming to established procedures.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, and 68-29-118.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 9, 1996; effective November 23, 1996. Amendment filed January 7, 1997; effective March 23, 1997. Amendment filed March 25, 1997; effective June 6, 1997. Amendment filed March 4, 1998; effective May 20, 1998. Amendment filed August 23, 2001; November 6, 2001. Amendment filed January 31, 2003; effective April 16, 2003. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed April 17, 2007; effective July 1, 2007. Amendment filed April 1, 2009; effective June 15, 2009. Amendment filed April 22, 2010; effective July 21, 2010.*

1200-06-01-.23 QUALIFICATIONS AND DUTIES OF THE CYTOLOGY GENERAL SUPERVISOR.

(1) Qualifications. The laboratory must have a cytology general supervisor who meets the qualifications listed below and provides supervision in accordance with these rules. The cytology general supervisor must:

(a) Hold a valid Cytotechnologist license in Tennessee or meet one (1) of the requirements under Rule 1200-06-01-.24(1) and provide all required documentation in support of that qualification; and

(b) Have at least four (4) years of full-time work experience as a Cytotechnologist within the ten (10) years preceding the application. Experience must be obtained in an anatomic pathology laboratory which has a director at the doctoral level or other anatomic laboratories acceptable to the Board; and

(c) Unless qualified as an anatomic pathology laboratory director, in addition to the requirements indicated above to be licensed as a cytology general supervisor the individual must also provide the following:

1. Proof of at least forty-five (45) contact/clock hours of management continuing education through attendance of professional workshops, seminars and/or courses conducted on subjects relevant to the managerial operation of a

(Rule 1200-06-01-.23, continued)

laboratory. Course content must relate to traditional management/supervisory skills in accordance with the topic guidelines established by the Board. A minimum of eight (8) contact hours must be obtained through formal workshop programs. Fifteen (15) contact hours will be awarded for each semester hour awarded by a college or university; and

2. Proof of at least fifteen (15) contact/clock hours of technical continuing education through attendance of professional workshops, seminars and/or courses. Technical course content should be at an intermediate/advanced level and include a variety of technical materials related to anatomic pathology laboratory practice.

3. Proof of attendance must be documented and submitted with all continuing education.

4. The management and technical hours submitted for continuing education must be completed subsequent to qualifying as a cytotechnologist. “Qualifying as a cytotechnologist” is defined as that date upon which the applicant has completed all specified degree requirements and is eligible for national certification or state licensure at the cytotechnologist level.

(2) Duties. The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. Responsibilities and duties include:

(a) Being accessible to provide telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;

(b) Documenting the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed;

(c) For each twenty-four (24) hour period, documenting the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

(d) Documenting the number of hours spent examining slides in each twenty-four (24) hour period.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, and 68-29-118.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 11, 1996; effective November 25, 1996. Amendment filed August 25, 2003; effective November 8, 2003.*

1200-06-01-.24 QUALIFICATIONS AND DUTIES OF THE CYTOTECHNOLOGIST.

(1) Qualifications - Each person examining cytology slide preparations must possess a current special analyst license as a cytotechnologist issued by the Board. To be eligible for that license the applicant must provide proof of national certification by a certifying agency approved by the Board. All applicants for that license who were awarded national certification on or after August 1, 1988 must also submit proof that the certification was awarded based upon the applicant’s possession of a baccalaureate degree earned at a regionally accredited college/university and cytology training from a school accredited by the Committee on Allied Health Education and Accreditation (CAHEA), Commission of Accreditation of Allied Health Education Programs (CAAHEP) or other accrediting body acceptable to the Board. Applicants whose national certification was awarded prior to August 1, 1988 need only submit proof that national certification was awarded regardless of the prerequisites upon which it was based.

(Rule 1200-06-01-.24, continued)

(2) Responsibilities and duties of the cytotechnologist include:

(a) Assisting in the collection and preparation of cytologic specimens for analysis.

(b) Accepting or rejecting the cytologic specimen based upon established criteria.

(c) Storing or transporting specimens using appropriate preservation methods.

(d) Selecting the most appropriate preparation and staining techniques and preparing specimens for microscopic analysis.

(e) Operating, calibrating, conducting performance checks and maintaining any laboratory instrument or equipment.

(f) Recognizing and correcting basic instrument malfunctions. Notifying cytology general supervisor when appropriate.

(g) Preparing stains and reagents from a prescribed procedure, making any adjustments needed.

(h) Evaluating stains and reagents according to established criteria.

(i) Conducting established quality control procedures on equipment, stains, reagents; evaluating results of quality control and implementing corrective action when indicated.

(j) Determining performance specifications for new preparation techniques.

(k) Establishing basic quality control procedures.

(l) Performing comparison studies on new or existing procedures and reporting results in an established format.

(m) Utilizing the microscope properly for visualization of the specimen, applying basic knowledge of microscope care and maintenance.

(n) Determining specimen adequacy after microscopic examination.

(o) Screening, detecting, selecting, and marking areas most representative of any pathological process present.

(p) Making an interpretation based upon the microscopic appearance of the cytologic specimen.

(q) Establishing and monitoring quality assurance/continuous quality improvement programs.

(r) Establishing and monitoring safety programs in compliance with laboratory regulations.

(s) Utilizing laboratory information systems or other methods to accurately and effectively report patient results.

(t) Writing laboratory procedures conforming to a standardized format.

(u) Performing orientation and supervision for students and new or less skilled laboratory personnel.

(Rule 1200-06-01-.24, continued)

(v) Reporting test results conforming to established procedures.

(w) Documenting the slide interpretation results of each gynecologic and nongynecologic cytology case examined or reviewed.

(x) For each twenty-four (24) hour period, documenting the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer, and

(y) Documenting the number of hours spent examining slides in each twenty-four (24) hour period.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, and 68-29-118.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed September 9, 1996; effective November 23, 1996. Amendment filed August 25, 2003; effective November 8, 2003. Amendment filed July 8, 2004; effective September 21, 2004.*

1200-06-01-.25 PERSONNEL EXEMPT FROM LICENSURE. Medical laboratory personnel and certain other health care professionals shall be exempt from licensure to perform the following functions or specialties under the provisions and conditions as stated herein:

(1) (a) Personnel performing specimen collection shall be exempt from licensure, providing that the specimen collection procedure is performed under the supervision of a physician, medical laboratory director, supervisor or technologist.

(b) When blood is withdrawn from a patient in a home for the aged, nursing home, residential hospice, or recuperative center, or from a patient of a home care organization, the procedure must be performed by:

1. a trained phlebotomist, or

2. a person who has been properly trained to draw blood and who has been licensed in this state by the appropriate board for the respective health care profession of such person.

(c) Records verifying appropriate training of phlebotomists must be maintained by licensed facilities as listed in paragraph (1)(b) above and be available for inspection.

(2) Personnel performing Waived and Point of Care laboratory testing shall be exempt from licensure, provided such testing is performed in accordance with rules 1200-06-03-.16 and 1200-06-03-.17 governing Medical Laboratories.

(3) Public Health Clinic Laboratory Practitioners are exempt to perform public health clinic laboratory tests in state or county health departments.

(a) A Public Health Clinic Laboratory Practitioner is a person with at least a high school diploma who has successfully completed a Public Health Clinic Laboratory Practitioner training program approved by the Board. The practitioner’s scope of practice is limited to these laboratory procedures set-out below.

(b) Public health clinic laboratory tests are:

1. Hematocrit

2. Hemoglobin

(Rule 1200-06-01-.25, continued)

3. Qualitative Pregnancy Test

4. Blood Glucose/Semi-Quantitative

5. Wet Mount (Trichomonas and Yeast)

6. Mono Test

7. Fecal Occult Blood

8. Urine Dip Stick

9. Rapid Strep Test

(4) Medical students performing any laboratory tests on their own patients, provided that this performance is a function of their training, shall not be required to have a license; provided that results of such laboratory studies by medical students shall not constitute an official laboratory report and shall not be recorded on official laboratory report forms.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, and 68-29-105.* ***Administrative History:*** *Original rule filed May 3, 1995; effective July 17, 1995. Amendment filed January 7, 1997; effective March 23, 1997. Amendment filed February 14, 2000; effective April 29, 2000. Amendment filed August 25, 2003; effective November 8, 2003.*

1200-06-01-.26 CONSUMER RIGHT-TO-KNOW REQUIREMENTS.

(1) Malpractice reporting requirements. The threshold amount below which medical malpractice judgments, awards or settlements in which payments are awarded to complaining parties need not be reported pursuant to the "Health Care Consumer Right-To-Know Act of 1998" shall be ten thousand dollars ($10,000).

(2) Criminal conviction reporting requirements. For purposes of the "Health Care Consumer Right-To-Know Act of 1998," the following criminal convictions must be reported:

(a) Conviction of any felony.

(b) Conviction or adjudication of guilt of any misdemeanor, regardless of its classification, in which any element of the misdemeanor involves any one or more of the following:

1. Sex.

2. Alcohol or drugs.

3. Physical injury or threat of injury to any person.

4. Abuse or neglect of any minor, spouse or the elderly.

5. Fraud or theft.

(c) If any misdemeanor conviction reported under this rule is ordered expunged, a copy of the order of expungement signed by the judge must be submitted to the Department before the conviction will be expunged from any profile.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 63-51-101, et seq., 68-29-102, 68-29-104, and 68-29-105.* ***Administrative History:*** *Original rule filed December 1, 2000; effective February 14, 2001.*