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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission: Department of Health
Division: Tennessee Medical Laboratory Board
Contact Person: Mollie Gass
Assistant General Counsel
Address: 665 Mainstream Drive, Nashville, Tennessee
Zip: 37243
Phone: (615) 741-1611
Email: Mollie.Gass@tn.gov

Revision Type (check all that apply):
X Amendment
___ New
___ Repeal

Rule(s) Revised (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1200-06-02	Training Programs for Medical Laboratory Personnel
Rule Number	**Rule Title**
1200-06-02-.01	General Requirements for All Programs
1200-06-02-.02	Faculty Requirements for Medical Laboratory Training Programs
1200-06-02-.03	The Medical Laboratory Technician Associate Degree Program Minimum Requirements
1200-06-02-.06	Contents of Applications for Admission to Training Programs
1200-06-02-.07	Curriculum Requirement for a Program for Training of Public Health Clinic Laboratory Practitioners

Chapter Number	**Chapter Title**
1200-06-03	General Rules Governing Medical Laboratories
Rule Number	**Rule Title**
1200-06-03-.13	Personnel Policies
1200-06-03-.16	Alternate Site Testing

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

Chapter 1200-06-02
Training Programs for Medical Laboratory Personnel

Amendments

Rule 1200-06-02-.01 General Requirements for All Programs is amended by deleting subparagraph (1)(d) in its entirety and substituting instead the following language, so that as amended, the new subparagraph (1)(d) shall read:

(d) The Special Analyst Program

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Rule 1200-06-02-.01 General Requirements for All Programs is amended by deleting subparagraph (2)(d) in its entirety and substituting instead the following language, so that as amended, the new subparagraph (2)(d) shall read:

(d) The Board shall be notified within thirty (30) days of any changes made in the operation of the training program such as a change of ownership, location, accreditation status, directorship, instructors and/or program closure. A new certificate of approval will be issued in the event of change in either ownership or directorship of the training program. A change in ownership shall also include an exchange of stock in an incorporated school.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Rule 1200-06-02-.01 General Requirements for All Programs is amended by deleting subparagraph (3)(b) in its entirety and renumbering the remaining subparagraph accordingly.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Rule 1200-06-02-.01 General Requirements for All Programs is amended by deleting subparagraphs (4)(a), (4)(g), part (4)(k)4, and subparagraph (4)(m), in their entirety and substituting instead the following language, and is further amended by adding new subparagraph (4)(n) so that as amended, the new subparagraphs and part shall read:

(a) The Training Program must insure that adequate space, light, and modern operable equipment is available in the teaching laboratory and medical laboratory's clinical rotation sites. All equipment used in the training program shall be subject to inspection and approval by the Board.

(g) Demonstration materials and multimedia instructional material shall be available as provided under other sections of these regulations.

(k) 4. Records of students, including:

(i) A complete application form;

(ii) Transcript of academic credit;

(iii) Written evidence the student can reasonably be expected to perform the medical laboratory work for which he/she is trained which must include a recent complete physical examination performed by a licensed physician or nurse practitioner prior to beginning clinical rotation;

(iv) Record of attendance, including excused and unexcused absences;

(v) Evaluation by instructors based on appropriate written, practical, and oral examinations covering all types of structured learning experiences (clinical and classroom) related to the medical laboratory; and

(vi) Written criteria for passing, failing, and progression in the program must be provided. These must be given to each student at the time of entry into the program and may be provided either electronically or by hard copy.

(m) There shall be an affiliation agreement between the educational institution and the licensed laboratory agreeing to serve as the clinical rotation site. The agreement shall state the responsibilities of each party regarding the clinical training of the students enrolled in that program and instructions from each clinical facility for exchange of information and views. The affiliation agreement shall be submitted to the Board upon initial application for training program approval and thereafter prior to any change in clinical rotation sites. A clinical rotation fact sheet must accompany the affiliation agreement for each rotation site.

(n) Each student must have access to and experience with contemporary computer technology.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Rule 1200-06-02-.01 General Requirements for All Programs is amended by deleting paragraph (7) in its entirety and substituting instead the following language, so that as amended, the new paragraph (7) shall read:

(7) Copies of the Law and Regulations to be made available to the students. A copy of the Tennessee Medical Laboratory Act and the regulations promulgated thereunder shall be made available to each student in either an electronic format or a hard copy format.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Rule 1200-06-02-.01 General Requirements for All Programs is amended by deleting subparagraph (9)(f) in its entirety and substituting instead the following language, so that as amended, the new subparagraph (9)(f) shall read:

(f) The program must culminate in an associate degree or higher. The granting of the degree must not be contingent upon the student's passing any type of external certification or licensure examination.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Rule 1200-06-02-.01 General Requirements for All Programs is amended by adding a new paragraph (10) which shall read:

(10) Curricular Structure. The applied courses must be taught in a clinically equipped teaching laboratory on the college campus, in an affiliated clinical facility, or in both facilities sufficient for developing basic skills, understanding principles, and mastering the procedures.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Rule 1200-06-02-.02 Faculty Requirements for Medical Laboratory Training Programs is amended by adding new part (1)(a)4, and by deleting parts (1)(b)1 and (1)(b)2 in their entirety and substituting instead the following language, and is further amended by deleting subparagraph (1)(c) in its entirety, so that as amended, the new parts shall read:

(a) 4. The Special Analyst Program

(b) 1. The medical director/advisor shall be a physician who is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or who possesses qualifications which are equivalent to those required for such certification (Board eligible) and shall be licensed to practice medicine in Tennessee.

2. The medical director/advisor of the Program for Training Medical Laboratory Specialties shall meet one of the minimum qualifications of Medical Laboratory Director, as set forth in Rule 1200-06-01-.20. The program he/she directs must be related to his/her training. Special analyst training programs must comply with this rule.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Rule 1200-06-02-.02 Faculty Requirements for Medical Laboratory Training Programs is amended by deleting parts (2)(a)1 but not its subparts, (2)(a)2, and (2)(c)1, and substituting instead the following language, and by deleting subpart (2)(a)1.(iv) and substituting instead the following language, and is further amended by adding a new subpart (2)(c)2.(iv) and new subparagraph (2)(d), so that as amended, the new parts, subparts, and subparagraph shall read:

(a) 1. A program director is defined as the responsible licensed technologist based in a university, community college, or hospital program who meets the following criteria:

1. (iv) Is a licensed technologist with a master's degree or doctoral degree.

2. In consultation with the medical director for the specialty, the education coordinator, and the faculty, the program director is responsible for overall direction of the program.

(c) 1. All instructors of medical laboratory subjects shall be licensed medical laboratory personnel or have met the education requirements of not less than those required in these Rules for a medical laboratory technologist. Credentials for qualification must be submitted on forms supplied by the Board. The Board may query instructors during the on-site inspection. Such information gained from an instructor may be used in the determination, approval, or denial of the training program's application if there is a doubt about his/her knowledge of a subject.

2. (iv) Student experiences at different clinical sites must be comparable to enable all students to achieve entry level competencies.

(d) Advisory Committee

(1) There must be an advisory committee composed of individual(s) from the community of interest (i.e. pathologists, other physicians, scientific consultants, academic professionals, administrators, practicing clinical laboratory scientists/medical technologists, practicing clinical laboratory technicians/medical laboratory technicians and other professionals) who have knowledge of clinical laboratory science education.

(2) Responsibilities: The advisory committee of the program shall have input into any aspect of the program/curriculum with regard to its current relevancy and effectiveness.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Rule 1200-06-02-.03 The Medical Laboratory Technician Associate Degree Program Minimum Requirements is amended by deleting subparagraph (1)(a) in its entirety and substituting instead the following, so that as amended, the new subparagraph (1)(a) shall read:

(a) Programs for the Medical Laboratory Technician-Associate Degree Program shall be conducted by accredited community colleges, technical institutes, or universities and colleges offering an associate degree.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Rule 1200-06-02-.06 Contents of Applications for Admission to Training Programs is amended by deleting subparagraph (1)(c) in its entirety, and substituting instead the following language, so that as amended, the new subparagraph (1)(c) shall read:

(c) Evidence of good health which shall consist of a record of medical history and a complete physical examination certified by a licensed physician or nurse practitioner.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.

1200-06-02-.07 Curriculum Requirement for a Program for Training of Public Health Clinic Laboratory Practitioners is repealed.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.

Chapter 1200-06-03
General Rules Governing Medical Laboratories

Amendments

Rule 1200-06-03-.13 Personnel Policies is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the new rule shall read:

1200-06-03-.13 Personnel Policies. Personnel policies, practices, and procedures that adequately support sound laboratory practice shall be available in written form. A current record shall be maintained on each employee and shall include evidence of current licensure, and a resume of training and experience, competency assessment, annual safety training and annual review of policies and procedures, as it pertains to the individual's job responsibilities. Employee health records may be maintained in a separate file.

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

Rule 1200-06-03-.16 Alternate Site Testing is amended by deleting subparagraph (2)(a) in its entirety including its parts, and substituting instead the following language, so that as amended, the new subparagraph (2)(a) and its parts shall read:

(a) To be eligible for this exemption, the following conditions must be met:

1. The laboratory collects, accepts, and tests only specimens from the private and personal patients of the physician who operates the practice or from the private and personal patients of any physician who is a member of a medical/physician group practice that operates the laboratory regardless of the distance of any member physician's practice location from the group practice's laboratory or the number of specimens collected, accepted, and/or tested; and

2. The laboratory must be operated by the physician or through the employees of the physician. In a medical/physician group practice, one (1) of the group's physicians must be designated to operate the laboratory. The designated physician is responsible for actual supervision and direct responsibility for the performance of the laboratory and its personnel which includes, but is not limited to, actual supervision and direct responsibility for quality assurance, quality control, and test management; and

3. The tests performed in the laboratory are used only for diagnosis and/or treatment of patients of the individual or group practice and are maintained in the practice's medical records for the patients for whom the tests were performed.

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

Chapter 1200-06-02
Training Programs for Medical Laboratory Personnel

New Rule
1200-06-02-.07
Medical Laboratory Special Analyst Program Minimum Requirements

1200-06-02-.07 Medical Laboratory Special Analyst Program Minimum Requirements.

(1) Special Analyst Programs

(a) Molecular Diagnostics Training Program

1. Medical Director

(i) The medical director shall be a physician who is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or who possesses qualifications which are equivalent to those required for such certification (Board eligible).

(ii) The medical director shall be licensed to practice medicine in Tennessee.

(iii) The medical director shall meet one of the minimum qualifications of Medical Laboratory Director, as set forth in Rule 1200-06-01-.20. The program he or she directs must be related to his or her training.

2. Program Director

(i) The program must have a qualified program director.

(ii) The program director must be a medical laboratory professional who:

(I) has an earned master's or doctoral degree;

(II) holds nationally recognized certification. (The certification examination must be accredited and require a bachelor's degree for eligibility.) If the program director is not certified in the same discipline as the program, a qualified professional who holds nationally recognized certification in the program discipline must be appointed as Education Coordinator;

(III) regularly engages in continuing professional education as documented by the certification maintenance program or other sources;

(IV) has three years of teaching experience; and

(V) has knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.

(iii) The program director must:

(I) be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program;

(II) provide evidence that he or she participates in the budget preparation process;

(III) be responsible for maintaining NAACLS accreditation of the program; and

(IV) have regular and consistent contact with students, faculty, and program personnel.

3. Education Coordinator (when required)

(i) The Education Coordinator must be a medical laboratory professional who:

(I) has at least a baccalaureate degree and three years of experience in the program discipline;

(II) holds nationally recognized certification in the program discipline, e.g., MB(ASCP)CM;

(III) has completed thirty-six hours of professional continuing education within the past three years;

(IV) has three years of experience in medical laboratory science education; and

(V) has knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.

(ii) The Education Coordinator must provide supervision and coordination of the instructional faculty in the academic and clinical phases of the education program.

4. On-site Program Coordinator (when required, one at each participating entity in a consortium or joint venture)

(i) The on-site program coordinator must:

(I) have an academic degree appropriate to the program level;

(II) hold an appropriate nationally recognized certification required of a program director; and

(III) have at least one year of experience in medical laboratory science education.

(ii) The on-site program coordinator, when required, is responsible for:

(I) coordinating teaching and clinical education;

(II) evaluating program effectiveness; and

(III) maintaining appropriate communications with the program director.

5. Didactic Instructor

(i) The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). The program must ensure and document ongoing professional development of the program faculty/instructors.

(ii) Faculty/instructors designated by the program must:

(I) demonstrate adequate knowledge and proficiency in their content areas and

(II) demonstrate the ability to teach effectively at the appropriate level.

(iii) The responsibilities of the faculty/instructors must include:

(I) participation in teaching courses;

(II) evaluation of student achievement;

(III) development of curriculum, policy and procedures; and

(IV) assessment of program outcomes.

6. Clinical Coordinator

(i) At least one clinical coordinator must be designated at each clinical site affiliated with the program to provide clinical experience to students.

(ii) The Clinical Coordinator must:

(I) be a medical laboratory professional who holds nationally recognized certification and professional licensure in the program discipline;

(II) demonstrate proficiency in and adequate knowledge of the program discipline;

(III) have at least one year experience as a practicing professional in the program discipline; and

(IV) demonstrate ability to teach clinical skills/content effectively at the appropriate level.

(iii) The Clinical Coordinator must be responsible for:

(I) coordinating and ensuring effectiveness of clinical instruction at the site;

(II) evaluating effectiveness of clinical instruction;

(III) monitoring and evaluating students' clinical performance; and

(IV) maintaining effective communication with the program director.

7. Advisory Committee

(i) There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, and public members) who have knowledge of clinical laboratory science education.

(ii) The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

8. Instructional Areas

(i) Prerequisite courses in biology including genetics, chemistry and mathematics that provide the foundation for course work required in the laboratory science program.

(ii) The curriculum must address pre-analytical, analytical and post-analytical components of diagnostic molecular laboratory services covering diagnostic molecular tests used to detect or diagnose acquired (infectious and non-infectious) diseases and genetic predisposition or disorders. This includes principles and methodologies, performance of assays, problem-solving, troubleshooting techniques, interpretation and evaluation of clinical procedures and results, statistical approaches to data evaluation, principles and practices of quality assurance/quality improvement, and continuous assessment of laboratory services.

(iii) The program curriculum must include the following scientific content:

(I) Organic and/or biochemistry, genetics, cell biology, microbiology, immunology, and diagnostic molecular biology;

(II) Principles, methodologies, and applications of molecular microbiology (infectious diseases), molecular pathology (hematology/oncology), and

molecular genetics. Techniques of molecular science must include current techniques in each of the following areas: separation and detection, amplification, and sequence analysis;

(III) Clinical significance of laboratory procedures in diagnosis and treatment;

(IV) Application of safety and governmental regulations and standards as applied to diagnostic molecular science;

(V) Principles and practices of professional conduct and the significance of continuing professional development;

(VI) Communications sufficient to serve the needs of patients, the public and members of the health care team;

(VII) Principles and practices of administration, supervision, and quality management as applied to diagnostic molecular science;

(VIII) Evaluation of laboratory information systems;

(IX) Educational methodologies and terminology sufficient to train/educate users and providers of laboratory services; and

(X) Principles and practices of applied study design, implementation and dissemination of results.

9. Institutional Requirements

(i) A specialty program may be conducted in one of the following ways:

(I) An integrated program in an accredited college or university that will culminate in at least a baccalaureate degree in one of the medical laboratory specialties.

(II) A one year program for students (trainees) who already possess a baccalaureate degree in a chemical, physical or biological science. The program shall consist of appropriate didactic classroom instruction. The remainder of the year shall be spent in gaining meaningful clinical laboratory experience in the applicable specialty.

(b) Cytogenetic Technology Training Program

1. Medical Director

(i) The medical director shall be a physician who is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or who possesses qualifications which are equivalent to those required for such certification (Board eligible).

(ii) The medical director shall be licensed to practice medicine in Tennessee.

(iii) The medical director shall meet one of the minimum qualifications of Medical Laboratory Director, as set forth in Rule 1200-06-01-.20. The program he or she directs must be related to his or her training.

2. Program Director

(i) The program director must be a medical laboratory professional who:

(I) has an earned master's or doctoral degree;

(II) maintains current certification or licensure in cytogenetic technology, medical genetics, or another human genetics area;

(III) regularly engages in continuing professional education as documented by the certification maintenance program or other sources;

(IV) has three years of teaching experience; and

(V) has knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.

(ii) The program director must:

(I) be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program;

(II) provide evidence that he or she participates in the budget preparation process;

(III) be responsible for maintaining NAACLS accreditation of the program. Training programs licensed prior to June 1, 2014 are not required to obtain or maintain NAACLS accreditation;

(IV) have regular and consistent contact with students, faculty, and program personnel.

3. On-site Program Coordinator (required for consortia or multi-location only; one at each participating site)

(i) The on-site program coordinator must:

(I) have an academic degree appropriate to the program level;

(II) hold an appropriate nationally recognized certification required of a program director; and

(III) have at least one year of experience in medical laboratory science education.

(ii) The on-site program coordinator, when required, is responsible for:

(I) coordinating teaching and clinical education;

(II) evaluating program effectiveness; and

(III) maintaining appropriate communications with the program director.

4. Didactic Instructor

(i) The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). The program must ensure and document ongoing professional development of the program faculty/instructors.

(ii) Faculty/instructors designated by the program must:

(I) demonstrate adequate knowledge and proficiency in their content areas and

(II) demonstrate the ability to teach effectively at the appropriate level.

(iii) The responsibilities of the faculty/instructors must include:

(I) participation in teaching courses;

(II) evaluation of student achievement;

(III) development of curriculum, policy and procedures; and

(IV) assessment of program outcomes.

5. Clinical Coordinator

(i) At least one clinical coordinator must be designated at each clinical site affiliated with the program to provide clinical experience to students.

(ii) The Clinical Coordinator must:

(I) be a medical laboratory professional who holds nationally recognized certification and professional licensure in the program discipline;

(II) demonstrate proficiency in and adequate knowledge of the program discipline;

(III) have at least one year experience as a practicing professional in the program discipline; and

(IV) demonstrate ability to teach clinical skills/content effectively at the appropriate level.

(iii) The Clinical Coordinator must be responsible for:

(I) coordinating and ensuring effectiveness of clinical instruction at the site;

(II) evaluating effectiveness of clinical instruction;

(III) monitoring and evaluating students' clinical performance; and

(IV) maintaining effective communication with the program director.

6. Advisory Committee

(i) There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, and public members) who have knowledge of clinical laboratory science education.

(ii) The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

7. Instructional Areas

(i) Prerequisite content in biology, chemistry and mathematics that provides the foundation for course work required in the laboratory science program.

(ii) The program curriculum must include the following scientific content:

(I) Specimen Preparation (sample acquisition, transport/storage, preparation, culture, harvest, slide preparation, and staining);

(II) Molecular Cytogenetic Testing (utilize appropriate techniques for preparation and analysis of molecular cytogenetic specimens);

(III) Chromosome Analysis and Imaging (selection, analysis, and description of suitable metaphase or interphase cells using microscopy and imaging);

(IV) Laboratory Operations (general laboratory skills, guidelines/ government regulations, safety, quality assurance/control and professional standards and conduct);

(V) Principles of interpersonal and interdisciplinary communication and team-building skills and the significance of continuing professional development;

(VI) Principles and practices of administration and supervision;

(VII) Educational methodologies and terminology sufficient to train/educate users and providers of laboratory services sufficient for future clinical faculty); and

(VIII) Principles and practices of applied study design, implementation and dissemination of results.

8. Institutional Requirements

(i) A specialty program may be conducted in one of the following ways:

(I) An integrated program in an accredited college or university that will culminate in at least a baccalaureate degree in one of the medical laboratory specialties.

(II) A one year program for students (trainees) who already possess a baccalaureate degree in a chemical, physical or biological science. The program shall consist of appropriate didactic classroom instruction. The remainder of the year shall be spent in gaining meaningful clinical laboratory experience in the applicable specialty.

Authority: T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Royce E. Joyner, M.D.	x				
Annie R. Washington, MT	x				
Patti Walton	x				
Stephanie Dolsen	x				
Reginna Bartlett	x				
Pamela S. Bullock, MD	x				
Gloria L. Jenkins				x	
Kathy Kenwright	x				
Cheryl K. Arnott, CT	x				
Jerry Miller, MD				x	
Vacant					
Vacant					
Vacant					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Medical Laboratory Board (board/commission/ other authority) on 10/17/2013 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *08/22/13 (mm/dd/yy)*

Rulemaking Hearing(s) Conducted on: (add more dates). *10/17/13 (mm/dd/yy)*

Date: 9/4/14

Signature: Mollie A Gass

Name of Officer: Mollie Gass

Title of Officer: Assistant General Counsel
Department of Health

Subscribed and sworn to before me on: 9-4-14

Notary Public Signature: Suzanne Mechkowski

My commission expires on: MY COMMISSION EXPIRES APRIL 19, 2017

ZANNE MECHKOWSKI STATE OF TENNESSEE NOTARY PUBLIC SUMNER COUNTY

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

R E Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

9-30-14
Date

Department of State Use Only

Filed with the Department of State on: 10/3/14

Effective on: 1/1/15

Tre Hargett
Secretary of State

2014 OCT -3 PM 4:20
SECRETARY OF STATE

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

The Notice for Rulemaking Hearing, as filed with the Secretary of State's Office on August 22, 2013, contained amendments for Chapters 1200-06-01, 1200-06-02, and 1200-06-03. The amendments for Chapter 1200-06-01 [General Rules Governing Medical Laboratory Personnel] were withdrawn from the Office of the Attorney General on August 28, 2014.

The Board received no written comments with regards to Chapters 1200-06-02 and 1200-06-03.

Regulatory Flexibility Addendum
Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

REGULATORY FLEXIBILITY ANALYSIS

(1) The extent to which the rule or rule may overlap, duplicate, or conflict with other federal, state, and local governmental rules.

The proposed rules do not overlap, duplicate, or conflict with other federal, state, or local government rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

The proposed rules exhibit clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

The proposed rules are not written with special consideration for the flexible compliance and/or reporting requirements because the Tennessee Medical Laboratory Board has, as its primary mission, the protection of the health, safety and welfare of Tennesseans.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

The compliance requirements throughout the proposed rules are as user-friendly as possible while still allowing the Board to achieve its mandated mission. There is sufficient notice between the rulemaking hearing and the final promulgation of rules to allow those affected by the rules to come into compliance.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

Compliance requirements are simplified.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

The performance standards required in the proposed rules are basic and do not necessitate the establishment of design or operational standards.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

There are no unnecessary entry barriers or other effects in the proposed rules that would stifle entrepreneurial activity or curb innovation.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Tennessee Medical Laboratory Board

Rulemaking hearing date: 10/17/2013

1. **Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:**

   Training programs for medical laboratory personnel and licensed medical laboratories will be affected by these proposed rule amendments. These training programs would bear the costs of and/or directly benefit from the proposed rule.

2. **Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:**

   There is no reporting, recordkeeping and other administrative costs required for compliance with this proposed rule amendment.

3. **Statement of the probable effect on impacted small businesses and consumers:**

   Small businesses should not be adversely impacted by the proposed rule amendments, nor should consumers.

4. **Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:**

   There are no less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule.

5. **Comparison of the proposed rule with any federal or state counterparts:**

   Federal: None.

   State: None.

6. **Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.**

   These rule amendments may not provide exemptions for small businesses as the rule amendments are needed to protect the health, safety and welfare of Tennesseans.

Impact on Local Governments

Pursuant to T.C.A. § 4-5-228(a), "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected financial impact on local governments."

(Insert statement here)

The proposed rule amendments should not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Rule 1200-06-02-.01, General Requirements for All Programs: The rules are being amended (1) to delete the Public Health Clinic Laboratory Practitioner Program, which was only available to local health departments, as a type of training program and substitutes The Special Analyst Program, as a new program; (2) to require notification within thirty days of any change made in the operation of the training program, such as change of ownership; (3) to correct a typographical error; and (4) to add additional requirements for all programs.

Rule 1200-06-02-.02, Faculty Requirements for Medical Laboratory Training Programs: The rules (1) add The Special Analyst Program to the list of training programs for which a Medical Director/Advisor is required; (2) set the standard for the Medical Director/Advisor for the Special Analyst Program; (3) substitute the phrase "community college" for "junior college"; (4) delete the baccalaureate degree from the list of acceptable degrees for a program director; (5) delete the reference to the State Licensure Examination, which is no longer offered; (6) require each training program to create an Advisory Committee to help ensure that the program/curriculum has relevancy to the current practice of medical laboratory testing and is effective in teaching the skills required.

Rule 1200-06-02-.03, The Medical Laboratory Technician Associate Degree Program Minimum Requirements: The rules are being amended to delete the phrase "junior college."

Rule 1200-06-02-.06, Contents of Applications for Admission to Training Programs: The rules are being amended to permit nurse practitioners to complete the physical examination required.

Rule 1200-06-02-.07, The Medical Laboratory Special Analyst Program Minimum Requirements: The rules are being amended to delete curriculum requirements for the Public Health Clinic Laboratory Practitioner because the program is no longer in operation and replaces the section with requirements for The Special Analyst Program, a new program needed to meet current standards in medical laboratory practice.

Rule 1200-06-03-.13, Personnel Policies: The rules are being amended to clarify that the employee's current record shall include annual review of policies and procedures that pertain to the employee's job responsibilities.

Rule 1200-06-03-.16, Alternate Site Testing: The rules are being amended to track the statutory language and to delete the rule requirement that the physician "own" the practice.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

None.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The proposed rule amendments affect Tennessee licensed medical laboratory personnel, Tennessee training programs for medical laboratory personnel, and Tennessee licensed medical laboratories.

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

None.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

The proposed rule amendments will create no increase or decrease in government expenditures and revenue.

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

Mollie Gass, Department of Health, possesses substantial knowledge and understanding of the rule.

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

Mollie Gass, Department of Health, will explain the rule at a scheduled meeting of the committees.

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

Department of Health, Office of General Counsel, 665 Mainstream Drive, Nashville, Tennessee 37243, Mollie.Gass@tn.gov.

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

None.

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SECRETARY OF STATE

RULES
OF
THE TENNESSEE MEDICAL LABORATORY BOARD
DIVISION OF HEALTH RELATED BOARDS

CHAPTER 1200-06-02
TRAINING PROGRAMS FOR MEDICAL LABORATORY PERSONNEL

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1200-06-02-.01 GENERAL REQUIREMENTS FOR ALL PROGRAMS.

(1) The Board shall approve the training programs which meet the requirements of one of the four (4) following general types:

(a) The Medical Laboratory Technologist Program

(b) The Medical Laboratory Technician - Associate Degree Program

(c) The Medical Laboratory Technologist Specialties Program

~~(d) The Public Health Clinic Laboratory Practitioner Program (only available to Local Health Departments operated by the State for training practitioners in each clinic laboratory.)~~

(d) The Special Analyst Program

(2) All Programs for the training of Medical Laboratory Personnel to Apply for Approval.

(a) The owner and/or the director of a training program for medical laboratory personnel shall make application for approval to operate that program on forms provided by the Board at least six (6) months prior to anticipated first day of instruction.

(b) Each school shall be subject to on-site inspection by representatives of the Board and/or complete such paper surveys as requested.

(c) A scheduled on-site inspection to validate the initial application shall be conducted by representatives of the Board.

~~(d) The Board shall be notified immediately of any changes made in the operation of the training program such as a change of ownership, location, accreditation status, directorship, and/or instructors. A new certificate of approval will be issued in the event of change in either ownership or directorship of the training program. A change in ownership shall also include an exchange of stock in an incorporated school.~~

(d) The Board shall be notified within thirty (30) days of any changes made in the operation of the training program such as a change of ownership, location, accreditation status,

directorship, instructors and/or program closure. A new certificate of approval will be issued in the event of change in either ownership or directorship of the training program. A change in ownership shall also include an exchange of stock in an incorporated school.

(3) Fees Amount

(a)	Initial Training Program Application Fee	$200.00
	Annual Registration (Renewal) Fee	$100.00
	State Regulatory Fee	$ 5.00

~~(b) Initial application fee for a Public Health Clinic Laboratory Practitioner Program $100.00~~

(b)~~(c)~~ The Certificate of Approval shall be for one (1) year and shall expire on December 3lst of any given year.

(4) Minimum Standards for Facilities, Equipment, and Materials for all Training Programs for Medical Laboratory Personnel.

~~(a) The Training Program must insure that adequate space, light, and modern operable equipment is available in the teaching laboratory and medical laboratory(ies) clinical rotation sites. All equipment used in the training program shall be subject to inspection and approval by the Board.~~

(a) The Training Program must insure that adequate space, light, and modern operable equipment is available in the teaching laboratory and medical laboratory's clinical rotation sites. All equipment used in the training program shall be subject to inspection and approval by the Board.

(b) Each training program for medical laboratory personnel shall have adequate classroom, laboratory, office, storage, and sanitary facilities which shall be subject to inspection and approval by the Board.

(c) A designated student laboratory area shall be available for teaching basic techniques, instrumentation and problem solving for procedures not available in the clinical facility(ies).

(d) Each training program facility for medical laboratory personnel must provide written documentation of compliance with local and state fire codes to the Board upon request.

(e) Written fire and safety procedures shall be made available to each student. Pertinent fire safety procedures shall be displayed in conspicuous places in the training program facility.

(f) A library containing up-to-date texts, references, and scientific periodicals pertinent to laboratory medicine as well as the latest editions of books and journals on laboratory technology shall be accessible to the Students. Texts required to be purchased by students must not be a substitute library [Older reference texts of value may be retained. Up-to-date is defined as published within the last five (5) years].

~~(g) Demonstration materials and multimedia instructional material shall be available as Rather provided under other sections of these regulations.~~

(g) Demonstration materials and multimedia instructional material shall be available as provided under other sections of these regulations.

(Rule 1200-06-02-.01, continued)

(h) An outline of the instruction provided, including a structured clinical laboratory practicum, shall be filed with the Board. When major revisions/changes are made in the curriculum, a new outline shall be submitted to the Board.

(i) A description of evaluation procedures for both student and program shall be submitted to the Board upon making application for approval of the Training Program. These evaluations shall be maintained for future inspection by the Board or its designee. Provision must be included for periodic review of the effectiveness of the program by members of the faculty and/or other appropriate groups. Student evaluation procedures must include mechanisms to measure cognitive knowledge, psychomotor and affective behavior.

(j) Student recruitment, admission and matriculation must be nondiscriminatory with respect to color, creed, race, sex, age, handicap(s), and national origin.

(k) Satisfactory records must be kept and shall be available for inspection by the Board. These shall include but not be limited to:

1. A list of instructors, by category, in the training program and clinical laboratory facilities. This list shall be submitted with initial application and thereafter upon request;

2. Current examinations given to students;

3. Scores on licensure examinations;

~~4. Records of students, including:~~

~~(i) A complete application form;~~

~~(ii) Transcript of academic credit;~~

~~(iii) Written evidence the student can reasonably be expected to perform the medical laboratory work for which he/she is trained which must include a recent complete physical examination performed by a licensed medical practitioner prior to beginning clinical rotation;~~

~~(iv) Record of attendance, including excused and unexcused absences; and~~

~~(v) Evaluation by instructors based on appropriate written, practical, and oral examinations covering all types of structured learning experiences (clinical and classroom) related to the medical laboratory.~~

4. Records of students, including:

(i) A complete application form;

(ii) Transcript of academic credit;

(iii) Written evidence the student can reasonably be expected to perform the medical laboratory work for which he/she is trained which must include a recent complete physical examination performed by a licensed physician or nurse practitioner prior to beginning clinical rotation;

(iv) Record of attendance, including excused and unexcused absences;

(Rule 1200-06-02-.01, continued)

(v) Evaluation by instructors based on appropriate written, practical, and oral examinations covering all types of structured learning experiences (clinical and classroom) related to the medical laboratory; and

(vi) Written criteria for passing, failing, and progression in the program must be provided. These must be given to each student at the time of entry into the program and may be provided either electronically or by hard copy.

(l) The program shall be approved for a specific number of students which shall not be exceeded without prior approval by the Board.

~~(m) There shall be an affiliation agreement between the educational institution and the licensed laboratory agreeing to serve as the clinical rotation site. The agreement shall state the responsibilities of each party regarding the clinical training of the students enrolled in that program and instructions from each clinical facility for exchange of information and views. The affiliation agreement shall be submitted to the Board upon initial application for training program approval and thereafter prior to any change in clinical rotation sites.~~

(m) There shall be an affiliation agreement between the educational institution and the licensed laboratory agreeing to serve as the clinical rotation site. The agreement shall state the responsibilities of each party regarding the clinical training of the students enrolled in that program and instructions from each clinical facility for exchange of information and views. The affiliation agreement shall be submitted to the Board upon initial application for training program approval and thereafter prior to any change in clinical rotation sites. A clinical rotation fact sheet must accompany the affiliation agreement for each rotation site.

(n) Each student must have access to and experience with contemporary computer technology.

(5) Clinical Facilities and Approved Laboratory Experience - Practicum (bench training).

(a) Programs for the training of medical laboratory personnel shall be approved only when they are affiliated with a hospital(s) or a medical laboratory(ies) for clinical experience (practicum).

The training program may be affiliated with in-state licensed laboratories or out-of-state CLIA certified laboratories. The clinical facility(ies) shall be approved in advance by the Board.

(b) Clinical facilities with a balanced distribution of clinical laboratory material shall meet the following minimum standards in order to train students:

1. Medical laboratory technologist (general and specialties) and associate degree technician: The medical laboratory(ies) must be associated with, or connected to, a general medical and surgical hospital with a minimum of 7,500 annual admissions and must perform a minimum of 200,000 laboratory procedures a year to qualify to train a student body of ten (10) students.

Larger student bodies will require proportionately larger number of annual admissions and laboratory procedures. The total number of admissions and laboratory procedures need not all be in the same facility/laboratory, but may be the sum of the admissions and laboratory procedures in two or more institutions.

(Rule 1200-06-02-.01, continued)

2. The medical laboratory training program Director and/or Education Coordinator must assume responsibility for arranging the approved clinical laboratory experience (practicum) for the student with an affiliated facility(ies). It shall be a violation of these regulations to grant a diploma to any student who has not completed an approved clinical laboratory experience (practicum).

3. Trainee applications shall be submitted for each student prior to the beginning of the approved clinical laboratory experience (practicum). The Board will then issue a trainee permit to the applicant provided they are in an approved facility. No student shall perform laboratory tests without a valid trainee permit.

4. If there is a change in the clinical rotation site at which the student will gain the clinical laboratory experience (practicum), the Board shall be notified before the student is placed in the new facility.

(6) The Use of Students as Substitutes for Licensed Medical Laboratory Personnel. No training program substituting students (trainees) for licensed medical laboratory personnel shall be approved. Using students (trainees) to perform laboratory procedures without adequate supervision shall result in withdrawal of training program approval and shall subject the training program to disciplinary action as provided for in the Tennessee Medical Laboratory Act.

~~(7) Copies of the Law and Regulations to be given to the students. A copy of the Tennessee Medical Laboratory Act and the regulations promulgated thereunder shall be given to each student. The Board shall provide the training program with copies of these documents upon request.~~

(7) Copies of the Law and Regulations to be made available to the students. A copy of the Tennessee Medical Laboratory Act and the regulations promulgated thereunder shall be made available to each student in either an electronic format or hard copy format.

(8) Training Programs for Medical Laboratory Technologists and Technicians to be separate. Training Programs for the training of medical technologists and technicians shall be separate and distinct, and students in each class should have separate instruction in the classroom and in the clinical facility(ies).

(9) Penalty for making misrepresentations to prospective students. Any owner, director, personnel, or agent of a school for the training of medical laboratory personnel who misrepresents facts concerning the facility(ies), student training, or any other facet of the school to prospective students shall be subject to withdrawal of approval of said school. This shall include but not be limited to:

(a) Announcements and advertising must accurately reflect the program offered.

(b) Student recruitment and academic policies shall be non-discriminatory with respect to race, color, creed, sex, age, handicap(s), and national origin.

(c) Academic credit and costs to the student shall be accurately stated, published and made known to all applicants.

(d) Policies and procedures for student withdrawal and refunds of tuition and fees shall be published and made known to all applicants upon admission-

(e) If more than one level of medical laboratory educational program is offered at one institution, e.g., Medical Technology and Medical Laboratory Technician, the institution

(Rule 1200-06-02-.01, continued)

must demonstrate that each program is being conducted to assure appropriate instruction for the students at the different educational levels.

~~(f) The program must culminate in either a baccalaureate or an associate degree. The granting of the degree must not be contingent upon the student's passing any type of external certification or licensure examination.~~

(f) The program must culminate in an associate degree or higher. The granting of the degree must not be contingent upon the student's passing any type of external certification or licensure examination.

(g) In the event that the program is discontinued or restructured, the program should provide a plan for the protection of its students accepted or enrolled in the program.

(10) Curricular Structure. The applied courses must be taught in a clinically equipped teaching laboratory on the college campus, in an affiliated clinical facility, or in both facilities sufficient for developing basic skills, understanding principles, and mastering the procedures.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed June 30, 1987; effective August 14, 1987. Amendment filed July 13, 1990; effective August 27, 1990. Amendment filed February 21, 1991; effective April 7, 1991. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*

1200-06-02-.02 FACULTY REQUIREMENTS FOR MEDICAL LABORATORY TRAINING PROGRAMS.

(1) Medical Director/Advisor

(a) The following programs shall have a medical director/advisor:

1. The Medical Laboratory Technologist Program

2. The Medical Laboratory Technician Program - Associate Degree

3. The Medical Laboratory Technologist Specialty Training Program

4. The Special Analyst Program

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(b) Qualifications:

~~1. The medical director/advisor shall be a physician who is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or who possesses qualifications which are equivalent to those required for such certification (Board eligible).~~

1. The medical director/advisor shall be a physician who is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or who possesses qualifications which are equivalent to those required for such certification (Board eligible) and shall be licensed to practice medicine in Tennessee.

~~2. The medical director/advisor shall be licensed to practice medicine in Tennessee.~~

(Rule 1200-06-02-.02, continued)

2. The medical director/advisor of the Program for Training Medical Laboratory Specialties shall meet one of the minimum qualifications of Medical Laboratory Director, as set forth in Rule 1200-06-01-.20. The program he/she directs must be related to his/her training. Special analyst training programs must comply with this rule.

~~(c) The director of the Program for Training Medical Laboratory Specialties shall meet one of the minimum qualifications of Medical Laboratory Director, as set forth in Rule 1200-06-01-.20 of the regulations governing the Tennessee Medical Laboratory Act. The program he or she directs must be related to his/her training.~~

(2) Program Director/Education Coordinator. Each Program shall have either a Program Director or Education Coordinator. In the case of a program for the training of medical laboratory specialties, the director may serve as program director.

(a) Program Director.

~~1. A program director is defined as the responsible licensed technologist based in a university, junior college, or hospital program who meets the following criteria:~~

1. A program director is defined as the responsible licensed technologist based in a university, community college, or hospital program who meets the following criteria:

(i) Has a faculty appointment either in the approved academic institution or an affiliated institution.

(ii) Has documented evidence of continuing education in technical and educational methodologies to provide adequate and appropriate training in the areas of curriculum design and teaching techniques for medical laboratory personnel.

(iii) Has the major responsibility for directing the educational program.

~~(iv) Is at least a licensed technologist with a baccalaureate degree. A master's degree or higher is recommended.~~

(iv) Is a licensed technologist with a master's degree or doctoral degree.

(v) Has at least three (3) years experience in a clinical laboratory, including teaching experience acceptable to the Board in a clinical laboratory under the supervision of a licensed physician who meets the qualifications of Medical Laboratory Director as set forth in Rule 1200-06-01-.20 promulgated pursuant to Tennessee Medical Laboratory Act.

(vi) Is free from service responsibilities to accomplish his/her teaching, educational, and administrative responsibilities with the medical or specialty director of the program.

~~2. Duties of the program director. In consultation with the medical of specialty director, education coordinator, and faculty, the program director is responsible for overall direction of the program.~~

2. In consultation with the medical director for the specialty, the education coordinator, and the faculty, the program director is responsible for overall direction of the program.

(Rule 1200-06-02-.02, continued)

(b) Education Coordinator.

1. Education Coordinator is defined as the responsible licensed technologist serving as liaison between the program administration and other institutions involved in the clinical experience.

2. The education coordinator shall be at least a licensed technologist and have a baccalaureate degree plus three (3) years of experience in a clinical laboratory

3. The education coordinator must be sufficiently free from service responsibilities to accomplish teaching, educational, and administrative responsibilities.

4. The education coordinator will share responsibilities with the program director for the organization and operation of the program, including classroom and laboratory instruction.

(c) Instructor (Classroom and Clinical) Credentials:

~~1. All instructors of medical laboratory subjects shall be licensed medical laboratory personnel or have met the education requirements of not less than those required in these Rules for a medical laboratory technologist. Credentials for qualification must be submitted on forms supplied by the Board. The Board may query instructors during the on-site inspection. Such information gained from an instructor may be used in the determination, approval, or denial of the training program's application if there is a doubt about his knowledge of a subject. The Board will require all unlicensed instructors to take and pass the State Licensure Examination at the technologist level in the specialty(ies) taught.~~

1. All instructors of medical laboratory subjects shall be licensed medical laboratory personnel or have met the education requirements of not less than those required in these Rules for a medical laboratory technologist. Credentials for qualification must be submitted on forms supplied by the Board. The Board may query instructors during the on-site inspection. Such information gained from an instructor may be used in the determination, approval, or denial of the training program's application if there is a doubt about his/her knowledge of a subject.

2. Instructor Student Ratio: In the clinical laboratory training facility(ies), the number of licensed qualified personnel must be adequate to meet both service and teaching responsibilities. It shall be the responsibility of the medical and program directors to insure that the number of instructors is adequate to provide appropriate instruction in all areas of the program. When students are present in the laboratory, a licensed technologist shall be present and shall be responsible for supervising their education.

(i) For classroom didactic instruction, there must be a student-faculty ratio of no more than 30: 1.

(ii) Student laboratories must have a student-instructor ratio of no more than 10: 1.

(iii) Clinical laboratory experience (internship) must not exceed a ratio of two students to one (2: 1) qualified instructor in any rotation area.

(iv) Student experiences at different clinical sites must be comparable to enable all students to achieve entry level competencies.

(Rule 1200-06-02-.02, continued)

(d) Advisory Committee

(1) There must be an advisory committee composed of individual(s) from the community of interest (i.e. pathologists, other physicians, scientific consultants, academic professionals, administrators, practicing clinical laboratory scientists/medical technologist, practicing clinical laboratory technicians/medical laboratory technicians and other professionals) who have knowledge of clinical laboratory science education.

(2) Responsibilities: The advisory committee of the program shall have input into any aspect of the program/curriculum with regard to its current relevancy and effectiveness.

(3) The medical or specialty director/advisor shall share with the program director and/or education coordinator the responsibility for the organization and operation of the program including classroom and laboratory instruction. The medical or specialty director should be available for orientation and available as a student advisor for clinical problems as needed. The medical or specialty director shall give a minimum of one (1) lecture to each class of students.

(4) The division of responsibility and authority between the medical or specialty director and program director or education coordinator within each institution shall be clearly established in writing.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-10, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*

1200-06-02-.03 THE MEDICAL LABORATORY TECHNICIAN ASSOCIATE DEGREE PROGRAM MINIMUM REQUIREMENTS.

(1) Minimum Institutional Requirements:

~~(a) Programs for the Medical Laboratory Technician-Associate Degree Program shall be conducted by accredited junior or community colleges, technical institutes, or universities and colleges offering an associate degree.~~

(a) Programs for the Medical Laboratory Technician-Associate Degree Program shall be conducted by accredited community colleges, technical institutes, or universities and colleges offering an associate degree.

(b) The Medical Laboratory Technician - Associate Degree Program must result in the granting of an associate degree.

(c) Where part of the instruction is provided by an educational institution and part is provided in a hospital or other laboratory facility(ies), approval shall be given to the educational institution's program- The parent educational institution may affiliate with several laboratories, and shall be responsible for coordinating instruction, maintaining standards, and evaluating student progress.

(2) Minimum Prerequisites for Admission of Students:

(a) Applicants for medical laboratory technician-associate degree programs must meet the admission requirements established by the sponsoring educational institution.

(Rule 1200-06-02-.03, continued)

Arrangements shall be available whereby student credits can be accepted from other medical laboratory programs; or,

(b) Students may be accepted with advanced standing by one of the institutions mentioned in subparagraph (1)(a) (above) on the basis of transfer credits or equivalent examinations but not on the basis of experience alone. Documentation of such arrangements shall also be a part of the student's record.

(3) Minimum Curriculum Requirements and Standards:

(a) The medical laboratory technician-associate degree program is a total educational program; hence, the general educational and clinical laboratory segments shall be integrated to the greatest extent possible.

(b) Occupational competence in the medical laboratory shall be the prime objective of the total program and curriculum shall be planned to achieve this objective.

(c) The program shall be a structured educational curriculum comprised of general education, laboratory sciences (including clinical laboratory) and related subjects.

(d) The student's training must be limited to medical laboratory procedures and related subjects. No other subjects covering unrelated fields of study, such as x-ray, can be taught during this period of time.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*

1200-06-02-.04 THE MEDICAL LABORATORY TECHNOLOGIST SPECIALTY PROGRAM M1NIMUM REQUIREMENTS.

(1) Minimum Institutional Requirements:

(a) A specialty program may be conducted in one of the following ways:

1. An integrated program in an accredited college or university that will culminate in at least a baccalaureate degree in one of the medical laboratory specialties.

2. A one year program for students (trainees) who already possess a baccalaureate degree in a chemical, physical or biological science. The program shall consist of appropriate didactic classroom instruction. The remainder of the year shall be spent in gaining meaningful clinical laboratory experience in the applicable specialty.

(b) Specialty programs may be conducted by hospitals or other institutions approved in advance by the Board.

(c) The program shall consist of a minimum of six (6) months of clinical laboratory experience in an approved clinical facility.

(2) Minimum prerequisites for admission of students: The prerequisites for all specialty programs shall be those approved in advance by the Board.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*

(rule 1200-06-02-.05, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105 and 68-29-110.* ***Administrative History:*** *Original rule filed October 26,1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997*

1200-06-02-.06 CONTENTS OF APPLICATIONS FOR ADMISSION TO TRAINING PROGRAMS

(1) The applicant to each program for the training of medical laboratory personnel shall submit the following information:

(a) Personal history data:

1. Name, permanent address, local address, telephone number, parent's or guardian's name (address and telephone number if appropriate);

2. Date of birth, place of birth, citizenship status, and marital status;

3. Employment record;

4. Military service record (form DD214); and

5. Social Security Number;

(b) A transcript of college credits where indicated; and

~~(c) Evidence of good health which shall consist of a record of medical history and a complete physical examination certified by a physician as defined in the Tennessee Medical Laboratory Act. Included in the medical record shall be the results of a recent tuberculin test and also the results of a roentgenogram examination of the chest if the tuberculin test is found positive.~~

(c) Evidence of good health which shall consist of a record of medical history and a complete physical examination certified by a licensed physician or nurse practitioner.

(2) All records of students shall be kept on file for a minimum of ten (10) years.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*

~~**1200-06-02-.07 CURRICULUM REQUIREMENT FOR A PROGRAM FOR TRAINING OF PUBLIC HEALTH CLINIC LABORATORY PRACTITIONERS.**~~

~~(1) A Public Health Clinic Laboratory Practitioner must complete Public Health Clinic Laboratory Practitioner Training Program consisting of a general laboratory practice core. The procedures will be standardized across the state to ensure continuity and conformity. Proof of training in the following areas will be maintained in the Practitioner's file on site:~~

~~(a) Laboratory Procedures;~~

~~(b) Quality Control;~~

~~(c) Instrumentation;~~

~~(d) Preventive Maintenance;~~

(rule 1200-06-02-.07, continued)

~~(e) Laboratory Safety;~~

~~(f) Mathematics;~~

~~(g) Medical Terminology; and~~

~~(h) Phlebotomy~~

~~(2) After completion of the appropriate training, the Public Health Clinic Laboratory Practitioner must competently:~~

~~(a) Prepare and/or instruct a patient correctly for collection of laboratory specimens;~~

~~(b) Obtain specimens from patients, including specimens to be sent to referral laboratories, and process them according to acceptable procedures for the given test methodology;~~

~~(c) Record appropriate information that will correctly identify the patient and test performed, or referred, according to acceptable standards;~~

~~(d) Perform tests designated in Rule 1200-06-01-.25(4);~~

~~(e) Explain and perform quality control procedures appropriate for a Public Health Clinic Laboratory Practitioner. If quality control results are outside established limits, the Public Health Clinic Laboratory Practitioner must document that the appropriate corrective action has been taken before any test result is reported;~~

~~(f) Document quality control and instrument preventive maintenance according to acceptable standards;~~

~~(g) Demonstrate satisfactory performance on unknown sample(s);~~

~~(h) Follow safe laboratory practices to prevent infection and/or exposure to self and others; and~~

~~(i) Implement an appropriate inventory control system.~~

~~(3) All Training will be performed by qualified instructors under the direction of the Training Section of the Tennessee Department of Health, Laboratory Services, 630 Hart Lane, Nashville, TN 37247-0801.~~

~~***Authority:*** *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*~~

1200-06-02-.07 Medical Laboratory Special Analyst Program Minimum Requirements

(1) Special Analyst Programs

(a) Molecular Diagnostics Training Program

1. Medical Director

(i) The medical director shall be a physician who is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or who possesses qualifications which are equivalent to those required for such certification (Board eligible).

(rule 1200-06-02-.07, continued)

(ii) The medical director shall be licensed to practice medicine in Tennesee.

(iii) The medical director shall meet one of the minimum qualifications of Medical Laboratory Director, as set forth in Rule 1200-06-01-.20. The program he or she directs must be related to his or her training.

2. Program Director

(i) The program must have a qualified program director.

(ii) The program director must be a medical laboratory professional who:

(I) has earned a master's or doctoral degree;

(II) holds nationally recognized certification. (The certification examination must be accredited and require a bachelor's degree for eligibility.) If the program director is not certified in the same discipline as the program, a qualified professional who holds nationally recognized certification in the program discipline must be appointed as Education Coordinator;

(III) regularly engages in continuing professional education as documented by the certification maintenance program or other sources;

(IV) has three years of teaching experience; and

(V) has knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.

(iii) The program director must:

(I) be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program;

(II) provide evidence that he or she participates in the budget preparation process;

(III) be responsible for maintaining NAACLS accreditation of the program; and

(IV) have regular and consistent contact with students, faculty, and program personnel.

3. Education Coordinator (when required)

(i) The Education Coordinator must be a medical laboratory professional who:

(I) has at least a baccalaureate degree and three years of experience in the program discipline;

(rule 1200-06-02-.07, continued)

(II) holds nationally recognized certification in the program discipline, e.g., MB(ASCP)CM;

(III) has completed thirty-six hours of professional continuing education within the past three years;

(IV) has three years of experience in medical laboratory science education; and

(V) has knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.

(ii) The Education Coordinator must provide supervision and coordination of the instructional faculty in the academic and clinical phases of the education program.

~~(i) The Education Coordinator must be a medical laboratory professional who:~~

~~(I) has at least a baccalaureate degree and three years of experience in the program discipline;~~

~~(II) holds nationally recognized certification in the program discipline, e.g. MB(ASCP)CM; and~~

~~(III) has knowledge of NAACLS accreditation and current certification procedures.~~

~~(ii) The Education Coordinator must provide supervision and coordination of the instructional faculty in the academic and clinical phases of the education program, and~~

~~(I) complete thirty-six hours of professional continuing education within the past three years;~~

~~(II) has three years of experience in medical laboratory science education; and~~

~~(III) has knowledge of NAACLS accreditation and current certification procedures.~~

4. On-site Program Coordinator (when required, one at each participating entity in a consortium or joint venture)

(i) The on-site program coordinator must:

(I) have an academic degree appropriate to the program level;

(II) hold an appropriate nationally recognized certification required of a program director; and

(III) have at least one year of experience in medical laboratory science education.

(ii) The on-site program coordinator, when required, is responsible for:

(I) coordinating teaching and clinical education;

(II) evaluating program effectiveness; and

(III) maintaining appropriate communications with the program director.

5. Didactic Instructor

(i) The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). The program must ensure and document ongoing professional development of the program faculty/instructors.

(ii) Faculty/instructors designated by the program must:

(I) demonstrate adequate knowledge and proficiency in their content areas and

(II) demonstrate the ability to teach effectively at the appropriate level.

(iii) The responsibilities of the faculty/instructors must include:

(I) participation in teaching courses;

(II) evaluation of student achievement;

(III) development of curriculum, policy and procedures; and

(IV) assessment of program outcomes.

6. Clinical Coordinator

(i) At least one clinical coordinator must be designated at each clinical site affiliated with the program to provide clinical experience to students.

(ii) The Clinical Coordinator must:

(I) be a medical laboratory professional who holds nationally recognized certification and professional licensure in the program discipline;

(II) demonstrate proficiency in and adequate knowledge of the program discipline;

(III) have at least one year experience as a practicing professional in the program discipline; and

(IV) demonstrate ability to teach clinical skills/content effectively at the appropriate level.

(iii) The Clinical Coordinator must be responsible for:

(rule 1200-06-02-.07, continued)

(I) coordinating and ensuring effectiveness of clinical instruction at the site;

(II) evaluating effectiveness of clinical instruction;

(III) monitoring and evaluating students' clinical performance; and

(IV) maintaining effective communication with the program director.

7. Advisory Committee

(i) There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and other physicians, and public members) who have knowledge of clinical laboratory science education.

(ii) The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

8. Instructional Areas

(i) Prerequisite courses in biology including genetics, chemistry and mathematics that provide the foundation for course work required in the laboratory science program.

(ii) The curriculum must address pre-analytical, analytical and post-analytical components of diagnostic molecular laboratory services covering diagnostic molecular tests used to detect or diagnose acquired (infectious and non-infectious) diseases and genetic predisposition or disorders. This includes principles and methodologies, performance of assays, problem-solving, troubleshooting techniques, interpretation and evaluation of clinical procedures and results, statistical approaches to data evaluation, principles and practices of quality assurance/quality improvement, and continuous assessment of laboratory services.

(iii) The program curriculum must include the following scientific content:

(I) Organic and/or biochemistry, genetics, cell biology, microbiology, immunology, and diagnostic molecular biology;

(II) Principles, methodologies, and applications of molecular microbiology (infectious diseases), molecular pathology (hematology/oncology), and molecular genetics. Techniques of molecular science must include current techniques in each of the following areas: separation and detection, amplification, and sequence analysis;

(III) Clinical significance of laboratory procedures in diagnosis and treatment;

(IV) Application of safety and governmental regulations and standards as applied to diagnostic molecular science;

(V) Principles and practices of professional conduct and the significance of continuing professional development;

(rule 1200-06-02-.07, continued)

(VI) Communications sufficient to serve the needs of patients, the public and members of the health care team;

(VII) Principles and practices of administration, supervision, and quality management as applied to diagnostic molecular science;

(VIII) Evaluation of laboratory information systems;

(IX) Educational methodologies and terminology sufficient to train/educate users and providers of laboratory services; and

(X) Principles and practices of applied study design, implementation and dissemination of results.

9. Institutional Requirements

(i) A specialty program may be conducted in one of the following ways:

(I) An integrated program in an accredited college or university that will culminate in at least a baccalaureate degree in one of the medical laboratory specialties.

(II) A one year program for students (trainees) who already possess a baccalaureate degree in a chemical, physical or biological science. The program shall consist of appropriate didactic classroom instruction. The remainder of the year shall be spent in gaining meaningful clinical laboratory experience in the applicable specialty.

(b) Cytogenetic Technology Training Program

1. Medical Director

(i) The medical director shall be a physician who is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or who possesses qualifications which are equivalent to those required for such certification (Board eligible).

(ii) The medical director shall be licensed to practice medicine in Tennessee.

(iii) The medical director shall meet one of the minimum qualifications of Medical Laboratory Director, as set forth in Rule 1200-06-01-.20. The program he or she directs must be related to his or her training.

2. Program Director

(i) The program director must be a medical laboratory professional who:

(I) has an earned master's or doctoral degree;

(II) maintains current certification or licensure in cytogenetic technology, medical genetics, or another human genetics area;

(rule 1200-06-02-.07, continued)

(III) regularly engages in continuing professional education as documented by the certification maintenance program or other sources;

(IV) has three years of teaching experience; and

(V) has knowledge of education methods and administration as well as current NAACLS accreditation procedures and certification procedures.

(ii) The program director must:

(I) be responsible for the organization, administration, instruction, evaluation, continuous quality improvement, curriculum planning and development, directing other program faculty/staff, and general effectiveness of the program;

(II) provide evidence that he or she participates in the budget preparation process;

(III) be responsible for maintaining NAACLS accreditation of the program. Training programs licensed prior to June 1, 2014 are not required to obtain or maintain NAACLS accreditation;

(IV) have regular and consistent contact with students, faculty, and program personnel.

3. On-site Program Coordinator (required for consortia or multi-location only; one at each participating site)

(i) The on-site program coordinator must:

(I) have an academic degree appropriate to the program level;

(II) hold an appropriate nationally recognized certification required of a program director; and

(III) have at least one year of experience in medical laboratory science education.

(ii) The on-site program coordinator, when required, is responsible for:

(I) coordinating teaching and clinical education;

(II) evaluating program effectiveness; and

(III) maintaining appropriate communications with the program director.

4. Didactic Instructor

(i) The program must have qualified faculty/instructors who hold appointments within the educational program (e.g., certified professionals in their respective or related fields). The program must ensure and document ongoing professional development of the program faculty/instructors.

(rule 1200-06-02-.07, continued)

(ii) Faculty/instructors designated by the program must:

(I) demonstrate adequate knowledge and proficiency in their content areas and

(II) demonstrate the ability to teach effectively at the appropriate level.

(iii) The responsibilities of the faculty/instructors must include:

(I) participation in teaching courses;

(II) evaluation of student achievement;

(III) development of curriculum, policy and procedures; and

(IV) assessment of program outcomes.

5. Clinical Coordinator

(i) At least one clinical coordinator must be designated at each clinical site affiliated with the program to provide clinical experience to students.

(ii) The Clinical Coordinator must:

(I) be a medical laboratory professional who holds nationally recognized certification and professional licensure in the program discipline;

(II) demonstrate proficiency in and adequate knowledge of the program discipline;

(III) have at least one year experience as a practicing professional in the program discipline; and

(IV) demonstrate ability to teach clinical skills/content effectively at the appropriate level.

(iii) The Clinical Coordinator must be responsible for:

(I) coordinating and ensuring effectiveness of clinical instruction at the site;

(II) evaluating effectiveness of clinical instruction;

(III) monitoring and evaluating students' clinical performance; and

(IV) maintaining effective communication with the program director.

6. Advisory Committee

(i) There must be an advisory committee composed of individuals from the community of interest (e.g. practicing professionals, academic professionals, scientific consultants, administrators, pathologists and

(rule 1200-06-02-.07, continued)

other physicians, and public members) who have knowledge of clinical laboratory science education.

(ii) The advisory committee of the program shall have input into the program/curriculum to maintain current relevancy and effectiveness.

7. Instructional Areas

(i) Prerequisite content in biology, chemistry and mathematics that provides the foundation for course work required in the laboratory science program.

(ii) The program curriculum must include the following scientific content:

(I) Specimen Preparation (sample acquisition, transport/storage, preparation, culture, harvest, slide preparation, and staining);

(II) Molecular Cytogenetic Testing (utilize appropriate techniques for preparation and analysis of molecular cytogenetic specimens);

(III) Chromosome Analysis and Imaging (selection, analysis, and description of suitable metaphase or interphase cells using microscopy and imaging);

(IV) Laboratory Operations (general laboratory skills, guidelines/ government regulations, safety, quality assurance/control and professional standards and conduct);

(V) Principles of interpersonal and interdisciplinary communication and team-building skills and the significance of continuing professional development;

(VI) Principles and practices of administration and supervision;

(VII) Educational methodologies and terminology sufficient to train/educate users and providers of laboratory services sufficient for future clinical faculty); and

(VIII) Principles and practices of applied study design, implementation and dissemination of results.

8. Institutional Requirements

(i) A specialty program may be conducted in one of the following ways:

(I) An integrated program in an accredited college or university that will culminate in at least a baccalaureate degree in one of the medical laboratory specialties.

(II) A one year program for students (trainees) who already possess a baccalaureate degree in a chemical, physical or biological science. The program shall consist of appropriate didactic classroom instruction. The remainder of the year shall be spent in gaining meaningful clinical laboratory experience in the applicable specialty.

(rule 1200-06-02-.07, continued)

1200-06-02-.08 ADVERTISING.

(1) Policy Statement. The lack of sophistication on the part of many of the public concerning medical laboratory personnel training programs, the importance of the interests affected by the choosing of a medical laboratory personnel training program and the foreseeable consequences of unrestricted advertising by medical laboratory personnel training programs which is recognized to pose special possibilities for deception, require that special care be taken by medical laboratory personnel training programs to avoid misleading the public. Medical laboratory personnel training programs must be mindful that the benefits of advertising depend upon its reliability and accuracy. Since advertising by medical laboratory personnel training programs is calculated and not spontaneous, reasonable regulation designed to foster compliance with appropriate standards serves the public interest without impeding the flow of useful, meaningful, and relevant information to the public.

(2) Definitions

(a) Advertisement. Informational communication to the public in any manner designed to attract public attention to medical laboratory personnel training programs that are approved to educate in Tennessee.

(b) Licensee - Any medical laboratory personnel training programs holding a Certificate of Approval to educate in the State of Tennessee. Where applicable this shall include partnerships and/or corporations.

(c) Material Fact - Any fact which an ordinary reasonable and prudent person would need to know or rely upon in order to make an informed decision concerning the choice of medical laboratory personnel training programs to serve his or her particular needs.

(3) Advertising Tuition Fees and Services

(a) Fixed Tuition Fees - Fixed tuition fees may be advertised.

(b) Discount Tuition Fees. Discount tuition fees may be advertised if:

1. The discount tuition fee is in fact lower than the licensee's customary or usual tuition fee; and

2. The licensee provides the same quality and components of education at the discounted tuition fee that are normally provided at the regular, non-discounted tuition fee.

(c) Related Services and Additional Fees. Related services which may be required in conjunction with the advertised services for which additional fees will be charged must be identified as such in any advertisement.

(b) Time Period of Advertised Fees.

1. Advertised fees shall be honored for those seeking the advertised services during the entire time period stated in the advertisement whether or not the services are actually rendered or completed within that time.

2. If no time period is stated in the advertisement of fees, the advertised fee shall be honored for thirty (30) days from the last date of publication or until the next

(Rule 1200-06-03-.11, continued)

(3) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the packaging will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.

(a) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed.

(b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards.

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.

(d) Opaque packaging must be used for pathological waste.

(4) After packaging, waste must be handled and transported by methods ensuring containment and preservation of the integrity of the packaging, including the use of secondary containment where necessary. Plastic bags of infections waste must be transported by hand.

(5) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.

(a) Waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal.

(b) Plastic bags of infectious waste must be transported by hand.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, and 68-29-105.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal filed May 3, 1995; effective July 17,1995. New rule filed January 7, 1997; effective March 23, 1997. Amendment filed March 22, 2001; effective June 5, 2001. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-06-03-.12 REPORTABLE DISEASES.

The director of a medical laboratory shall submit reports and/or cultures of microorganisms of reportable diseases established by the Commissioner of Health to the Department in accordance with Tenn. Comp. R. & Regs. Chapter 1200-14-01.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-107.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002. Amendment filed September 17, 2003; effective December 1, 2003. Amendment filed February 15, 2006; effective May 1, 2006. Amendment filed July 10, 2006; effective September 23, 2006. Amendment filed August 19, 2010; effective November 17, 2010; however on October 26, 2010 a 10-day stay was filed by the Government Operations Committee; new effective date October 27, 2010.*

1200-06-03-.13 PERSONNEL POLICIES. ~~Personnel policies, practices, and procedures that adequately support sound laboratory practice shall be available in written form. A current record shall be~~

(Rule 1200-06-03-.13, continued)

~~maintained on each employee and shall include evidence of current licensure, and a resume of training and experience, competency assessment, annual safety training and annual review of polices and procedures. Employee health records may be maintained in a separate file.~~

Personnel policies, practices, and procedures that adequately support sound laboratory practice shall be available in written form. A current record shall be maintained on each employee and shall include evidence of current licensure, and a resume of training and experience, competency assessment, annual safety training and annual review of policies and procedures, as it pertains to the individual's job responsibilities. Employee health records may be maintained in a separate file.

Authority: *T.C.A. §§4-5-202, 4-5-204, and 68-29-105.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed December 14, 1981; effective January 28, 1982. Amendment filed April 25, 1985; effective May 25, 1985. Amendment filed July 13, 1990; effective August 27, 1990. Amendment filed February 26, 1991; effective April 12, 1991. Repeal filed May 3, 1995; effective July 17, 1995. New rule filed January 7, 1997; effective March 23, 1997. Amendment filed April 29, 2002; effective July 13, 2002. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-06-03-.14 PERSONNEL REQUIREMENTS FOR A MEDICAL LABORATORY.

(1) Condition: All laboratories regulated under T.C.A. 68, Chapter 29 shall meet the personnel standards in Chapter 1200-06-01.

(2) Condition: Each laboratory shall designate a medical laboratory director, general supervisor and testing personnel who meet the qualifications of each level and fulfill the listed responsibilities for each level. If so qualified, one (1) individual may serve in more than one (1) position.

(3) Condition: All individuals qualified to perform laboratory tests, including the medical laboratory director, shall possess a current license issued by the Department. Each individual shall be licensed at the highest level for which he qualified and functions. Laboratory procedures shall only be performed by appropriately licensed individuals, or personnel with a current trainee permit.

(4) Standard: An adequate number of qualified testing personnel shall be provided for the volume and diversity of procedures and tests performed, as determined by the Department by on site survey.

(5) A medical laboratory director may direct no more than three (3) laboratories unless authorized by the Board.

(6) The medical laboratory director shall make periodic on-site visits at a minimum of once per month.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105. 68-29-114, and 68-29-118.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal filed May 3, 1995; effective July 17,1995. New rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed June 18, 2002; effective September 1, 2002.*

1200-06-03-.15 SPECIAL REGULATIONS FOR ASTC, BLOOD DONOR CENTERS, AND PLASMAPHERESIS CENTERS.

(1) An exception to the requirements of 1200-06-03-.14 concerning direction and supervision may be made for a licensed Ambulatory Surgical Treatment Center (ASTC) providing the following are met:

(Rule 1200-06-03-.15, continued)

birth date and social security number of the donor and the name and address of the Center.

(h) Any inquiries and/or complaints referred to the Department in regard to donor selection, bleeding products, etc. will be referred to the U.S. Food and Drug Administration for investigation.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-104, and 68-29-105.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed December 14, 1981; effective January 28, 1982. Amendment filed September 30, 1987; effective November 14, 1987. Repeal and new rule filed January 7, 1997; effective March 23, 1997. Amendment filed February 14, 2000; effective April 29, 2000. Amendment filed December 1, 2000; effective February 14, 2001. Repeal and new rule filed June 18, 2002; effective September 1, 2002. Amendment filed August 25, 2003; effective November 8, 2003. Amendments filed May 16, 2005; effective July 30, 2005.*

1200-06-03-.16 ALTERNATE SITE TESTING.

(1) Point of Care Laboratory Testing.

(a) Definition: "Point of Care" laboratory testing is laboratory testing performed by health care personnel/professionals not licensed by the Medical Laboratory Act, T.C.A. §§ 68-29-101, et seq., and is 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.

(b) All point of care laboratory testing must be approved by the Board in accordance with the following guidelines.

1. For those tests determined by the Board to be appropriate for safe and accurate performance in a point of care setting (see waived test list) written notification shall be submitted on forms provided by the Board to the Administrative Office of the Board.

2. For all other tests not covered under part 1 of this subparagraph (above), a facility must petition, and appear before the Board and satisfy the Board that approval for point of care testing is appropriate. A facility that has received approval from the Board for instrument/method to be used by identified personnel and/or department(s) for point of care testing of an analyte does not have to appear before the Board again to add analytes to the approved instrument/method and may add them by submitting written notification to the Board's administrative office. It is only when the facility wants to change or add personnel or department(s) to the previously approve instrument/method that another hearing before the Board is required.

3. Requests to perform non-waived point of care tests must be submitted in writing and must include at least:

(i) Statement of medical need for performance outside a laboratory setting.

(ii) Analyte and methodology.

(iii) Personnel authority and responsibility.

(iv) Quality assurance protocols.

(v) Maintenance of records.

(Rule 1200-06-03-.16, continued)

(vi) Performance and improvement protocols.

(c) The performance of point of care laboratory testing must comply with the following minimum guidelines:

1. Documentation must show that the method used for testing has been approved by the Medical Laboratory Director.

2. Documentation must show that an adequate training protocol, demonstration of competency, and annual in-service with demonstration of competency for each person performing the testing, has been approved by the Medical Laboratory Director.

3. Records shall be retained for at least two (2) years, which show that manufacturer recommendations regarding the performance of quality control were met. Quality control records shall be reviewed by a person with appropriate authority according to an established performance improvement program.

4. Results of point of care laboratory testing must be recorded in an appropriate clinical record and include the identity of the patient, date and time of specimen collection, units of measurement, test location and identity of the analyst performing the test. Such records must be readily retrievable for inspection.

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

6. Written policies and procedures, as approved by the Medical Laboratory Director, shall be available in the laboratory and at all locations where point of care laboratory testing is performed. Such procedures shall be appropriate to the personnel and location performing the testing.

(d) Approval to perform point of care laboratory testing may be granted annually provided all minimum guidelines are met. The criteria for withdrawal of approval to perform such testing shall include but not be limited to:

1. Performance of testing by unauthorized personnel.

2. Failure to comply with the above stated guidelines

3. Unsatisfactory performance on two (2) consecutive or two (2) of three (3) consecutive proficiency test surveys.

4. Failure to comply with other State or Federal guidelines.

5. Deficiencies without an acceptable plan of correction cited by the Tennessee Medical Laboratory Board surveyors upon and on-site inspection of the laboratory.

(2) Physician's Office Laboratories - Physician Office Laboratories (POLs) are exempt from licensure requirements of the Medical Laboratory Act

~~(a) To be eligible for this exemption, the following conditions must be met:~~

(Rule 1200-06-03-.16, continued)

~~1. The laboratory collects, accepts and tests only specimens from the private and personal patients of the physician who owns the practice or from the private and personal patients of any physician who is a member of a medical/physician group practice that owns and operates the laboratory regardless of the distance of any member physician's practice location from the group practice's laboratory or the number of specimens collected, accepted and/or tested; and~~

~~2. The laboratory must be operated by the physician who owns the practice or through his own employees. In a medical/physician group practice, one (1) of the group's physicians must be designated to operate the laboratory. The designated physician is responsible for actual supervision and direct responsibility for the performance of the laboratory and its personnel which includes, but is not limited to, actual supervision and direct responsibility for quality assurance, quality control, and test management; and~~

~~3. The tests performed in the laboratory are used only for diagnosis and/or treatment of patients of the individual or group practice and are maintained in the practice's medical records for the patients for whom the test were performed.~~

(a) To be eligible for this exemption, the following conditions must be met:

1. The laboratory collects, accepts, and tests only specimens from the private and personal patients of the physician who operates the practice or from the private and personal patients of any physician who is a member of a medical/physician group practice that operates the laboratory regardless of the distance of any member physician's practice location from the group practice's laboratory or the number of specimens collected, accepted, and/or tested; and

2. The laboratory must be operated by the physician or through the employees of the physician. In a medical/physician group practice, one (1) of the group's physicians must be designated to operate the laboratory. The designated physician is responsible for actual supervision and direct responsibility for the performance of the laboratory and its personnel which includes, but is not limited to, actual supervision and direct responsibility for quality assurance, quality control, and test management; and

3. The tests performed in the laboratory are used only for diagnosis and/or treatment of patients of the individual or group practice and are maintained in the practice's medical records for the patients for whom the tests were performed.

(b) In the case of a medical/physician group practice, proof of affiliation with the group practice must be maintained at all offices in which the laboratory is not physically located and produced upon request by an authorized agent of the Department.

(c) Industrial or company physician practices, student health services and other arrangements in which a licensed physician is responsible for the continuing care of a group of patients on an ongoing basis will be designated to be POLs.

(3) Screening Programs – Screening programs are offerings of specified medical laboratory tests to the general public, the purpose of which is educational rather than for diagnosis of disease, and the results of which are immediately available on the site of the program to the person being tested except for those tests which for methodological reasons must be submitted to a medical laboratory in which case they shall be sent to a Tennessee licensed medical laboratory.

(Rule 1200-06-03-.16, continued)

(a) Screening programs conducted by for-profit hospitals or nonprofit organizations are exempt from the licensure requirements of the Medical Laboratory Act, pursuant to T.C.A. § 68-29-104(6), when the following conditions are met:

(b) The screening program must be under the direct supervision of a physician licensed in Tennessee. Direct supervision means that a physician will be responsible for quality assurance of the testing performed and review of the results of such testing. The physician is not required to be on site for the screening program event.

(c) The results of the screening program testing must be submitted to the personal physician of the individual being screened or reviewed by the physician responsible for the screening program. During the screening process, the individual being screened must be afforded reasonable privacy and, when required, on-site confidential counseling about the results of the testing.

(d) A written notification to conduct a screening program must be submitted to the Administrative Office for the Medical Laboratory Board, indicating compliance with these rules and providing the following information:

1. Location of testing.

2. Date of testing.

3. Type of tests to be performed and methodology to be used.

4. Name of the licensed physician supervising the screening.

5. Name and address of the for-profit hospital or nonprofit organization conducting the screening.

6. Statement indicating that the testing staff has appropriate training and competency to conduct the testing.

7. Assurance that the for-profit hospital or nonprofit organization is in compliance with Rule 1200-06-03-.11 regarding the handling of infectious and hazardous waste.

(e) A copy of the written notification submitted to the Administrative office must be retained by the for-profit hospital or nonprofit organization conducting the screening program and must be available for inspection at the site of the screening program.

(f) Notification of screening is not required when the for-profit hospital or nonprofit organization is a licensed medical laboratory, provided the laboratory has complied with Rules 1200-06-03-.17 regarding the performance of waived testing and 1200-06-03-.16 regarding point of care testing.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-29-104, and 68-29-105.* ***Administrative History:*** *Original rule filed February 14, 2000; effective April 29, 2000. Amendment filed December 1, 2000; effective February 14, 2001. Repeal and new rule filed June 18, 2002; effective September 1, 2002. Amendment filed May 23, 2003; effective August 6, 2003. Amendment filed February 15, 2006; effective May 1, 2006. Amendment filed March 14, 2006; effective May 28, 2006. Amendment filed July 10, 2006; effective September 23, 2006. Amendment filed December 27, 2006; effective March 12, 2007.*

1200-06-03-.17 WAIVED TESTING.