

**Department of State**  
**Division of Publications**  
 312 Rosa L. Parks, 8th Floor Snodgrass/TN Tower  
 Nashville, TN 37243  
 Phone: 615.741.2650  
 Fax: 615.741.5133  
 Email: register.information@tn.gov

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# Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

<b>Agency/Board/Commission:</b>	Department of Health
<b>Division:</b>	Tennessee Medical Laboratory Board
<b>Contact Person:</b>	Diona E. Layden
<b>Address:</b>	665 Mainstream Drive, Nashville, TN 37243
<b>Phone:</b>	(615) 741-1611
<b>Email:</b>	Diona.Layden@tn.gov

Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

<b>ADA Contact:</b>	ADA Coordinator
<b>Address:</b>	710 James Robertson Parkway, Andrew Johnson Building, 5 <sup>th</sup> Floor, Nashville, Tennessee 37243
<b>Phone:</b>	(615) 741-6350
<b>Email:</b>	Tina.M.Harris2@tn.gov

**Hearing Location(s)** (for additional locations, copy and paste table)

Address 1:	Metro Center
Address 2:	665 Mainstream Drive, Iris Room
City:	Nashville, Tennessee
Zip:	37228
Hearing Date :	10/17/13
Hearing Time:	9:00 am
	<input checked="" type="checkbox"/> CST/CDT <input type="checkbox"/> EST/EDT

**Additional Hearing Information:**

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**Revision Type (check all that apply):**

- Amendment
- New
- Repeal

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

Chapter Number	Chapter Title
1200-06-01	General Rules Governing Medical Laboratory Personnel
Rule Number	Rule Title
1200-06-01-.12	Continuing Education
1200-06-01-.21	Qualifications and Duties of the Medical Laboratory Supervisor

1200-06-01-.22	Qualifications, Responsibilities and Duties of Testing Personnel
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<b>Chapter Number</b>	<b>Chapter Title</b>
1200-06-02	Training Programs for Medical Laboratory Personnel
<b>Rule Number</b>	<b>Rule Title</b>
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

<b>Chapter Number</b>	<b>Chapter Title</b>
1200-06-03	General Rules Governing Medical Laboratories
<b>Rule Number</b>	<b>Rule Title</b>
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 1200-06-01  
General Rules Governing Medical Laboratory Personnel  
Amendments

Rule 1200-06-01-.12 Continuing Education is amended by deleting subparagraphs (6)(a), (6)(c), and (6)(e) in their entirety, and substituting instead the following language, so that, as amended the new subparagraphs (6)(a), (6)(c), and (6)(e) shall read:

(6) (a) Reactivation of Retired License

1. An individual whose license has been retired for two (2) years or less will be required to fulfill continuing education requirements as outlined in this rule.
2. An individual whose license has been retired for more than two (2) years will be required to fulfill continuing education requirements as outlined in this rule. However, the individual shall not be required to complete more than thirty-six (36) hours of continuing education.

(c) Reinstatement of Expired Licensure – No person whose license has expired may be reinstated without submitting evidence of continuing education. The continuing education hours documented at the time of reinstatement must equal the hours required, had the license remained in an active status, and must have begun and been successfully completed before the date of reinstatement. However, the person shall not be required to complete more than thirty-six (36) hours of continuing education.

(e) Unless the licensee has actively practiced in another state while the licensee's Tennessee license has been retired, revoked, or expired, then no more than one-half of the required continuing medical education for licensure reinstatement or reactivation shall be taken via the Internet, in multi-media and/or electronic formats as provided in subparagraph (4)(a). For the purpose of this subparagraph (e), "actively practiced" means practiced at any time within the two (2) years prior to applying for reinstatement of the Tennessee license.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-119.

1200-06-01-.21 Qualifications and Duties of the Medical Laboratory Supervisor is amended by deleting parts (1)(b)1 through 4 and substituting instead the following language, so that as amended, the new parts (1)(b)1 through 4 shall read:

1. Be a physician licensed in Tennessee or hold a doctoral degree from an accredited college/university in a chemical, physical, biological, or clinical laboratory science. Subsequent to obtaining a doctoral degree the applicant must have at least two (2) years of full time clinical laboratory work experience as defined in Rule 1200-06-01-.22 (1)(h) in the area they wish to supervise.
2. Hold a valid general medical laboratory technologist license in Tennessee or meet one (1) of the requirements under Rule 1200-06-01-.22(1)(a)1. through 5. and provide all required documentation in support of that qualification and have at least four (4) years of full time clinical laboratory work experience as defined in Rule 1200-06-01-.22(1)(h) in the area they wish to supervise.
3. Hold a valid general medical laboratory technologist license in Tennessee limited to one of the categories of chemistry, hematology, immunohematology, or microbiology and meet the requirements under Rule 1200-06-01-.22(1)(c) and provide all required documentation in support of that qualification and have at least four (4) years of full time clinical laboratory work experience as defined in Rule 1200-06-01-.22(1)(h) subsequent

to qualifying as a technologist. The license shall be limited to the category for which the applicant is qualified.

4. Hold a valid special analyst license limited to one (1) subspecialty or meet one (1) of the requirements under Rule 1200-06-01-.22(1)(d) and provide all required documentation in support of that qualification and have at least four (4) years of full time clinical laboratory work experience as defined in Rule 1200-06-01-.22(1)(h) subsequent to qualifying as a special analyst. The license shall be limited to the subspecialty for which the applicant is qualified.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, 68-29-105, 68-29-116, and 68-29-118.

Rule 1200-06-01-.22 Qualifications, Responsibilities and Duties of Testing Personnel is amended by deleting part (1)(a)1 in its entirety including its subparts, subpart (1)(a)2(i), part (1)(c)1, part (1)(e)2, part (1)(g)4, and substituting instead the following language, so that, as amended the new parts shall read:

- (1) (a) To become licensed as a medical laboratory technologist an applicant must:
  1. Submit satisfactory evidence of the following:
    - (i) Successfully completing and passing a national certifying examination within the three (3) years preceding the application and being nationally certified at the technologist level by either the ASCP, NCA, NRCC, NRM, ABB, AMT or any other national certifying agency recognized by the Board (Successful completion of the Health and Human Services proficiency examination in clinical laboratory science does not meet this criteria for licensure); or
    - (ii) National certification and proof of having relevant work experience in the medical laboratory field, as approved by the Board, for at least six (6) months within the three (3) years preceding the application; or
    - (iii) Submit proof of successfully completing thirty-six (36) hours of approved continuing education pertaining to laboratory technology or laboratory management; and
  2. (i) A baccalaureate degree in medical technology or in one of the biological, chemical or physical sciences with completion of science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g), and completion of a medical laboratory technologist training program that was, at the time of graduation, either
- (c) To become licensed as a medical laboratory technician an applicant must:
  1. Submit satisfactory evidence of the following:
    - (i) Successful completion and passing of a national certifying examination within the three (3) years preceding the application and being nationally certified at the technician level; or
    - (ii) Proof of national certification and proof of having relevant work experience in the medical laboratory field, as approved by the Board, for at least six (6) months within the three (3) years preceding the application; or
    - (iii) Submit proof of successfully completing thirty-six (36) hours of approved continuing education pertaining to laboratory technology or laboratory management.
  - (e) 2. In the absence of national certification, the individual must possess at least a baccalaureate degree from an accredited college/university relevant to the subspecialty in which licensure is being sought and proof of relevant work experience, as approved by the Board, within the three (3) years preceding the application. The Board shall approve all individuals qualifying in this manner. Individuals must obtain national certification at

such time as it becomes available and must request that proof of said national certification be sent directly to the Board's administrative office from the certifying agency in order to continue licensure. Failure to obtain national certification shall result in revocation of the license.

- (g) 4. The college courses must be acceptable toward a major in those fields of study. Survey, audit, remedial, college level examination program, advanced placement, and clinical courses and courses obtained via on-line, distance or Internet learning do not qualify as fulfillment of the chemistry, biology, or mathematics requirements.

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

## 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 shall read:

- (d) The Special Analyst Program

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 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.

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

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

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 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.

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 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.

Rule 1200-06-02-.01 General Requirements for All Programs is amended by adding a new paragraph (10) by adding the following language, so that the new paragraph 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 a 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 by deleting subparagraph (c) in its entirety, so that as amended, the new parts and 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 of the regulation governing the Tennessee Medical Laboratory Act. The program he/she directs must be related to his/her training. Special analyst training programs must comply with this rule.

Rule 1200-06-02-.02 Faculty Requirements for Medical Laboratory Training Programs is amended by deleting parts (2)(a)1 and (2)(a)2 and (2)(c)1 and only subpart (2)(a)1.(iv) in their entirety and substituting instead the following language, and by adding a new subpart (2)(c)2.(iv) and new subparagraph (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. Duties of the program director. 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, 68-29-10, 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 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 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.

#### New Rule

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 of the regulations governing the Tennessee Medical Laboratory Act. 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; 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. Site Consortium Education Coordinator (when required, one at each participating entity in a consortium or joint venture)
- (i) The 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 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 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 of the regulations governing the Tennessee Medical Laboratory Act. 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 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. Site Program Coordinator (required for consortia or multi-location only; one at each participating site)
- (i) The 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 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.

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 test were performed.

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

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

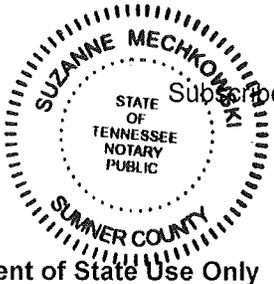
Date: August 22, 2013

Signature: DEJ

Name of Officer: Diona E. Layden

Deputy General Counsel

Title of Officer: Department of Health



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Subscribed and sworn to before me on: August 22, 2013

Notary Public Signature: Suzanne Mechkowski

My commission expires on: \_\_\_\_\_

MY COMMISSION EXPIRES  
APRIL 19, 2017

Filed with the Department of State on: 8/22/13

Tre Hargett

Tre Hargett  
Secretary of State

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