

**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) General Requirements for All Programs
- (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 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

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

- (b) The Certificate of Approval shall be for one (1) year and shall expire on December 31st 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'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 provided under other sections of these regulations.
 - (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;

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

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 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.
- (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. 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,

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

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.

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 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.
- (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-

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

- (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 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 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. Amendments filed October 3, 2014; effective January 1, 2015.

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
 - (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) 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.
 - (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.

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

- (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, 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 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. 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.

(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:

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

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.
- (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.
 - (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. Amendments filed October 3, 2014; effective January 1, 2015.

**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 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. 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. Amendment filed October 3, 2014; effective January 1, 2015.

**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:

(Rule 1200-06-02-.04 continued)

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.

1200-06-02-.05 MEDICAL LABORATORY TECHNOLOGIST TRAINING PROGRAM MINIMUM REQUIREMENTS.

- (1) Minimum Curriculum Requirements:
- (a) The program must provide a structured curriculum that documents the clinical education with clearly written program goals and a course syllabus which includes both individual course objectives and competency levels to be achieved. The curriculum shall include all the major subject areas commonly offered in the modern clinical laboratory. Objectives which address the cognitive, psychomotor, and affective domains must be provided for didactic and clinical aspects of the program and must include clinical significance. These course objectives shall show progression to the level consistent with entry into the profession. The curriculum shall include:
 1. Principles and methodologies for all major areas commonly practiced by a modern clinical laboratory,
 2. Clinical significance of laboratory procedures in diagnosis and treatment;
 3. Principles and practices of quality assurance;
 4. Principles of laboratory management, supervision, safety, and problem solving;
 5. Educational methodology; and
 6. Computer application in the clinical laboratory sciences.
 - (b) Educational programs for medical laboratory technologists shall be conducted by accredited colleges and universities, hospitals, or other institutions that have been approved in advance by the Board.
- (2) Minimum Prerequisites for Admission of Students:

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

- (a) The educational prerequisites for admission to schools for medical laboratory technologists shall be three (3) years of academic study plus one (1) year of a training program (3+1) with graduation (or equivalent) from high school and successful completion of 90 semester hours (135 quarter hours) of academic credit in a college or university accredited by the Southern Association of Colleges and Secondary Schools or an equivalent thereto. The 90 semester hours (135 quarter hours) shall be acceptable as the first three (3) years of a baccalaureate program. During the three (3) years of collegiate education, the following courses shall be required:
 1. Chemistry: A minimum of 16 semester hours (24 quarter hours) credit is required. Organic chemistry or biological chemistry must be included. Quantitative analysis and physical chemistry are recommended.
 2. Biological Science: A minimum of 16 semester hours (24 quarter hours) credit is required. Microbiology (bacteriology) and immunology must be included in the curriculum. Genetics, anatomy, and physiology are recommended.
 3. Mathematics: Three (3) semester hours (four and one half (4.5) quarter hours) credit in pre-science mathematics is required. Minimum requirements are met by course recognized as prerequisites for admissions to physics courses, except that the content of chemistry, biological sciences, and mathematics courses, shall be acceptable toward a major in those subjects of study. Survey courses do not qualify as fulfillment of chemistry, biological sciences, and mathematical prerequisites.
 - (b) The educational prerequisites for admission to a medical laboratory technologist integrated program (based in a college or university) shall be graduation from high school or equivalent and successful completion of a minimum of 60 semester hours (90 quarter hours) of academic credit in a college or university accredited by Southern Association of Colleges and Secondary Schools (or equivalent). The total program must include the courses mentioned in part (2)(a), subparts 1., 2., and 3. above.
- (3) Additional Administrative Requirements:
- (a) Unless a student is given equivalent credit by examination, the curriculum shall consist of a minimum of 12 months of structured educational experience.
 - (b) Clinical laboratory experience acceptable to the Board shall be included in the college or university-based programs.
 - (c) Reasonable vacation or sick leave may be granted at the discretion of the director. General rules regarding this should be in the programs brochure/student handbook.
 - (d) Students shall be oriented in medical ethics and institutional functions or regulations at the beginning of their clinical experience.
 - (e) The curriculum shall be comprised of all the major subjects commonly involved in the modern clinical laboratory. The curriculum must also include but not be limited to:
 1. Principles of representative procedures and instruments: clinical significance of laboratory procedures in diagnosis and treatment including normal values; principles and practices of quality control and problem solving;
 2. Principles of laboratory organization, management, and supervision;
 3. Uses of laboratory data by physicians in patient management; and

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

4. Such other topics which may be of value in laboratory medicine.
- (f) A complete outline of the curriculum must be submitted to the Board with the application form for approval to operate. It must include:
1. Expected capability of the graduates (what they should be able to do and at what level of competence);
 2. Outline of learning experience, including:
 - (i) Lecture outlines;
 - (ii) Demonstrations; and
 - (iii) Laboratory rotational plan;
 3. Description of procedures to be used in evaluation of knowledge, performance, professional attitude, and competence. Criteria for pass/fail decisions should be established and failing performance must be documented; and
 4. A grievance process for student objections.

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 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. Amendment filed October 2, 2014; effective January 1, 2015.

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;

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

- (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

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

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

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

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.

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

9. Institutional Requirements

- (i) A specialty program may be conducted in one of the following ways:
 - (II) 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.
 - (III) 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.
- (i) 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;

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

- (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.
 - (iii) 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

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

- (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);

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

- (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. **Administrative History:** Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997. Repeal and new rule filed October 3, 2014; effective January 1, 2015.

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.

(Rule 1200-06-02-.08, continued)

- (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 scheduled publication whichever is later whether or not the services are actually rendered or completed within that time.
- (4) Advertising Content. The following acts or omissions in the context of advertisement by any licensee shall constitute unethical conduct, and subject the licensee to disciplinary action pursuant to T.C.A. § 68-29-127(9) and (10).
- (a) Claims that the education offered is professionally superior to that which is ordinarily offered, or that convey the message that one licensee is better than another when superiority of services, personnel, materials or equipment cannot be substantiated.
 - (b) The misleading use of an unearned or non-health degree in any advertisement.
 - (c) Promotion of professional services which the licensee knows or should know is beyond the licensee's ability to perform.
 - (d) Techniques of communication which intimidate, exert undue pressure or undue influence over a prospective client.
 - (e) Any appeals to an individual's anxiety in an excessive or unfair manner.
 - (f) The use of any personal testimonial attesting to a quality of competency of a service or treatment offered by a licensee that is not reasonably verifiable.

(Rule 1200-06-02-.08, continued)

- (g) Utilization of any statistical data or other information based on past performances for prediction of future services, which creates an unjustified expectation about results that the licensee can achieve.
- (h) The communication of personal identifiable facts, data, or information about a patient without first obtaining patient consent.
- (i) Any misrepresentation of a material fact.
- (j) The knowing suppression, omission or concealment of any material fact or law without which the advertisement would be deceptive or misleading.
- (k) Statements concerning the benefits or other attributes of medical procedures or products that involve significant risks without including:
 - 1. A realistic assessment of the safety and efficiency of those procedures or products; and
 - 2. The availability of alternatives; and
 - 3. Where necessary to avoid deception, descriptions or assessment of the benefits or other attributes of those alternatives.
- (l) Any communication which creates an unjustified expectation concerning the potential results of any treatment.
- (m) Failure to comply with the rules governing advertisement of fees and services, or advertising records.
- (n) Misrepresentation of a licensee's credentials, training, experience, or ability.
- (o) Failure to include the corporation, partnership or individual licensee's name, address, and telephone number in any advertisement. Any corporation, partnership or association which advertises by use of a trade name or otherwise fails to list all licensees practicing at a particular location shall:
 - 1. Upon request provide a list of all licensees practicing at that location; and
 - 2. Maintain and conspicuously display at the licensee's office, a directory listing all licensees practicing at that location.
- (p) Failure to disclose the fact of giving compensation or anything of value to representative of the press, radio, television or other communicative medium in anticipation of or in return for any advertisement (for example, newspaper article) unless the nature, format or medium of such advertisement make the fact of compensation apparent.
- (q) After thirty (30) days of a personnel departure, the use of the name of any medical laboratory personnel formerly practicing at or associated with any advertised location or on office signs or buildings. This rule shall not apply in the case of a retired or deceased former associate who practiced in association with one or more of the present occupants if the status of the former associate is disclosed in any advertisement or sign.

(Rule 1200-06-02-.08, continued)

- (r) Stating or implying that a certain licensee provides all services when any such services are performed by another licensee.
 - (s) Directly or indirectly offering, giving, receiving, or agreeing to receive any fee or other consideration to or from a third party for the referral of a patient in connection with the performance of professional services.
- (5) Advertising Records and Responsibility
- (a) Each licensee who is a principal partner, or officer of a firm or entity identified in any advertisement, is jointly and severally responsible for the form and content of any advertisement. This provision shall also include any licensed professional employees acting as an agent of such firm or entity.
 - (b) Any and all advertisement are presumed to have been approved by the licensee named therein.
 - (c) A recording of every advertisement communicated by electronic media, and a copy of every advertisement communicated by print media, and a copy of any other form of advertisement shall be retained by the licensee for a period of two (2) years from the last date of broadcast or publication and be made available for review upon request by the Board or its designee.
 - (d) At the time any type of advertisement is placed, the licensee must possess and rely upon information which, when produced, would substantiate the truthfulness of any assertion, omission or representation of material fact set forth in the advertisement or public information.
- (6) Use of Titles in Advertisements. Any medical laboratory training program licensed by the Board which includes in its advertisements the names of its laboratory personnel must, in every "advertisement" [as that term is defined in rule 1200-06-02-.08(2)(a)] it publishes, use an appropriate personnel title for each such licensee as authorized by rule 1200-06-01-.03(3) of this rule. Failure to do so may constitute an omission of a material fact which makes the advertisement misleading and deceptive and subjects the medical laboratory training program to disciplinary action pursuant to T.C.A. § 68-29-126(9), 68-29-126(11), 68-29-126(13), 68-29-127(9), 68-29-127(9), 68-29-127(10), and/or 68-29-129(8).
- (7) Severability. It is hereby declared that the sections, clauses, sentences and part of these rules are severable, are not matters of mutual essential inducement, and any of them shall be rescinded if these rules would otherwise be unconstitutional or ineffective. If any one or more sections, clauses, sentences or parts shall for any reason be questioned in court, and shall be adjudged unconstitutional or invalid, such judgment shall not affect, impair or invalidate the remaining provisions thereof, but shall be confined in its operation to the specific provision or provisions so held unconstitutional or invalid, and the inapplicability or invalidity of any section, clause, sentence or part in any one or more instance shall not be taken to affect or prejudice in any way its applicability or validity in any other instance.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-1-145, 63-1-146, 68-29-105, 68-29-110, 68-29-126, 68-29-127 and 68-29-129. **Administrative History:** Original rule filed March 16, effective May 30, 2007. Amendment filed April 22, 2010; effective July 21, 2010.