Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XLV. Medical Professions
Subpart 2. Licensure and Certification
Chapter 35. Clinical Laboratory Personnel
Subchapter A. Scope and Definitions

§3501. Scope and Purpose of Chapter

A. Scope of Chapter. The rules of this Chapter provide for and govern the licensure and certification of clinical laboratory personnel to practice clinical laboratory science in the state of Louisiana.

B. Declaration of Purpose. The purpose of these rules and the law they implement is to protect the public health, safety, and welfare of the people of Louisiana from improper performance of laboratory tests by clinical laboratory personnel. Clinical laboratories provide essential services to health care practitioners by furnishing information vital to determination of the nature, cause, and extent of the condition involved. Licensure of laboratory personnel protects against the improper performance of laboratory tests by establishing and enforcing minimum requirements for safe practice.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1284 (November 1994).

§3503. Definitions

A. As used in this Chapter, the following terms are given the following meanings.

Approved Nationally Recognized Certification Examination—an examination prepared and administered by a certifying organization approved by the board as satisfying the minimum examination qualifications for licensure or certification for each of the classifications of clinical laboratory personnel for which successful completion of a certifying examination is required as provided by the law and these rules.

Approved Professional Organizations—an organization approved by the board to offer continuing education and/or training programs, and includes the following organizations:

a. American Society for Clinical Laboratory Science;

b. American Medical Technologists;

c. International Society for Clinical Laboratory Technology;

d. American Society of Clinical Pathologists;

e. American Society of Cytology;

f. American Society for Microbiology;

g. American Association of Blood Banks;

h. American Association of Clinical Chemistry;

i. Clinical Laboratory Management Association;

j. Association of Territorial and Public Health Laboratory Directors;

k. Centers for Disease Control;

l. National Accrediting Agency for Clinical Laboratory Sciences;

m. Gamma Biologicals Referred Immunohematology Self Evaluation System and Tutorial Program for Continuing Education of Blood Bankers;

n. affiliates of an organization identified by the board, upon recommendation of the committee, as an approved professional organization;

o. accredited colleges and universities;

p. American Society for Cytotechnology;

q. American Academy of Forensic Sciences;

r. Society of Forensic Testing; and

s. other organizations as may be approved by the board upon recommendation of the committee.

Approved School or *Training Program*—a school or training program accredited by the Council on Medical Education of the American Medical Association, the National Accrediting Agency for Clinical Laboratory Sciences, or the Council on Allied Health Education Programs and approved by the committee and the board.

Board—the Louisiana State Board of Medical Examiners.

CLIA—the Clinical Laboratory Improvement Amendments of 1988, Public Law Number 100-578,

and the rules and regulations promulgated pursuant thereto.

Clinical Cytotechnology—the microscopic study or examination of body fluids, tissues, or cells desquamated from a body surface or lesion for the practice of clinical laboratory science including, but not limited to, detecting malignancy and microbiologic changes and the measurement of hormonal levels.

Clinical Laboratory—any building, place, or facility in which an operation and procedure for the biological, microbiological, serological, immunological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examinations of materials derived from the human body is performed to provide information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of, the health of human beings, or for forensic testing.

Clinical Laboratory Personnel—any and all individuals engaged in the practice of clinical laboratory science.

Clinical Laboratory Scientist-Generalist or *CLS-G*—an individual who performs clinical laboratory tests and procedures in all specialty areas of a clinical laboratory which require the exercise of independent judgment and responsibility, including but not limited to, the performance of all laboratory tests as stated in CLIA. The clinical laboratory scientist-generalist may perform the functions of all categories of all clinical laboratory personnel licensed or certified in accordance with the law, except those of the cytotechnologist, without additional licensure or certification.

Clinical Laboratory Scientist-Specialist or *CLS-S*—an individual performing clinical laboratory science in one or more laboratory specialties and who performs functions directly related to such particular laboratory specialty or specialties. A clinical laboratory scientist-specialist may perform the functions of the laboratory assistant and the phlebotomist without additional licensure or certification.

Clinical Laboratory Scientist-Technician or *CLS-T*—an individual who performs medical laboratory tests and procedures of high and moderate complexity as defined in 42 Code of Federal Regulations, Part 493, within any area of clinical laboratory science, which do not require the exercise of independent judgment or responsibility. The clinical laboratory scientist-technician shall perform tests and procedures of high complexity under supervision as defined in CLIA. The clinical laboratory scientist-technician may perform the functions of the laboratory assistant and the phlebotomist without additional licensure or certification.

Committee—the Clinical Laboratory Personnel Committee to the Louisiana State Board of Medical Examiners, as established and constituted under R.S. 37:1314.

Cytotechnologist—an individual engaged in the practice of clinical cytotechnology which requires the exercise of independent judgment and responsibility.

Health Care Provider—any person licensed, certified, or registered by a department, board, commission, or other agency of the state of Louisiana to provide preventive, diagnostic, or therapeutic health care services.

Independent Judgment—the performance or conduct of clinical laboratory tests and assumption of responsibility for determination of the validity and interpretation of clinical laboratory test results without intervention by or the supervision of another health care provider authorized by law to assume responsibility for the conduct and validity of clinical laboratory tests. As respects clinical laboratory personnel, the authorized exercise of independent judgment shall not be deemed to include or permit the exercise of independent medical judgment in the diagnosis of or treatment of, or reporting of clinical laboratory test results or their interpretation to, patients except as authorized in accordance with CLIA.

Laboratory Assistant or *LA*—an individual who performs medical laboratory tests and procedures under supervision by a licensed health care provider or laboratory director as defined in 42 Code of Federal Regulations, Part 493. Laboratory tests and procedures performed by the laboratory assistant do not require the exercise of independent judgment or responsibility within any area of clinical laboratory science. The laboratory assistant may perform high complexity tests under supervision as stated in CLIA.

Laboratory Specialty—any category or subcategory recognized as a specialty by a certifying agency for the category of clinical laboratory scientist-specialist, including, but not limited to, the categories of hematology, microbiology, chemistry and blood bank, and the subcategories thereunder.

Louisiana Clinical Laboratory Personnel Law or *the Law*—R.S. 37:1311-1329, as the same may be amended hereafter.

Phlebotomist—an individual performing invasive procedures to withdraw blood samples from the human body for the practice of clinical laboratory

science, including but not limited to, clinical laboratory testing for analysis and typing and cross-matching of blood for medical examination and human transfusion. A phlebotomist may perform and report results of any waived tests.

Practice of Clinical Laboratory Science—the performance by any individual, other than a physician licensed by the board, of laboratory testing, analysis, or examination of human specimens.

Temporary License or *Temporary Certificate*—a license or certificate issued to an individual that qualifies by education, experience, or training that will allow that individual to engage in the practice of clinical laboratory science at the appropriate level (CLS-G, CLS-S, CLS-T, laboratory assistant, cytotechnologist, or phlebotomist).

Trainee—an individual who has not fulfilled the educational requirements to take an approved nationally recognized certification examination or who needs to obtain full-time comprehensive experience under supervision.

Waived Test—those routine technical procedures performed under or eligible for a certificate of waiver under CLIA. An illustrative list of such routine technical procedures includes:

a. dipstick or tablet reagent urinalysis (nonautomated) for the following determination levels: bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, or urobilinogen;

b. fecal occult blood;

c. ovulation tests-visual color tests for human luteinizing hormone;

d. urine pregnancy tests-visual color comparison tests;

e. erythrocyte sedimentation rate, nonautomated;

f. hemoglobin-copper sulfate, nonautomated;

g. blood glucose as determined by monitoring device approved by the Federal Drug Administration specifically for home use;

h. spun microhematocrit;

i. hemoglobin by single analyte instrument with self-contained or component features to perform specimen/reagent interaction providing direct measurement or readout.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1284 (November 1994).

Subchapter B. Licensure and Certification Requirements

§3505. Licensure or Certification Generally

A. On and after January 1, 1995, no individual shall act as, or perform the duties of a clinical laboratory scientist-generalist, clinical laboratory scientist-specialist, clinical laboratory scientist-technician, laboratory assistant, cytotechnologist, or phlebotomist unless such individual possesses a current license or certification issued by the board pursuant to this Chapter or is exempt from such licensure or certification as provided by §3507.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1285 (November 1994).

§3507. Exceptions to Licensure or Certification Requirements

A. The licensure and certification requirements of this Chapter shall not apply to:

1. clinical laboratory personnel practicing exclusively in, and in the course and scope of their employment by, a clinical laboratory operated by the United States government;

2. clinical laboratory personnel practicing exclusively in, and in the course and scope of their employment by, a nonprofit laboratory operated and maintained exclusively for instruction or research involving no individual patient or public health care service, provided the results of any examination performed in such laboratory are not used directly in the diagnosis, evaluation, or treatment of human disease or disorder;

3. any physician licensed by the board to practice medicine;

4. any individual working under the direction and supervision of a physician licensed by the board in an operating room, theater, emergency room, or intensive care unit;

5. any pulmonary function technician acting within the scope of performance of the practice of respiratory therapy;

6. any clinical perfusionist acting within the scope of practice of perfusion in the support, treatment, measurement, or supplementation of the

cardiopulmonary and circulatory system of an individual patient;

7. any health care provider when acting within the scope of practice authorized by his or her licensure, certification, or registration;

8. any individual whose duties include only the performance of waived tests, whether performed in a physician's office laboratory, a hospital clinical laboratory, or at the point of care, and which do not require the exercise of independent judgment;

9. any individual performing phlebotomy or acting as a phlebotomist employed by or acting under the direction and supervision of a physician licensed by the board, a clinic operated by a health care provider authorized by license to perform clinical laboratory testing, a hospital, a nursing home, or other licensed health care facility authorized by licensure to perform clinical laboratory testing;

10. any individual whose duties may include demonstrating or instructing, or both, the use of any automated or digital instrument, device, machine, or similar mechanical equipment and related procedures utilized to assist in the practice of clinical laboratory science, provided the results furnished by such equipment during demonstration or instruction are not used in the diagnosis, evaluation, or treatment of human disease or disorder; or

11. individuals performing forensic testing and examinations of body fluids, tissues, cells, or blood solely for the purpose of law enforcement and the state's criminal justice system.

B. Any individual who is exempt from the requirement of licensure or certification under this Chapter, but who meets the qualifications for licensure or certification under this Chapter, including any individual performing clinical procedures for analysis of nonhuman specimens, shall be considered actively engaged in the practice of clinical laboratory science and may apply for licensure or certification as provided in this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1286 (November 1994).

§3509. Qualifications for Licensure and Certification

A. Clinical Laboratory Scientist-Generalist. To be eligible for licensure as a clinical laboratory scientist-generalist an applicant, in addition to satisfaction of the procedural requirements for licensure under this Chapter, shall have successfully completed an approved nationally recognized certification examination for such clinical laboratory personnel classification as developed and administered by one of the following organizations or their successor organizations:

1. American Society of Clinical Pathologists (ASCP);

2. American Medical Technologists (AMT); or

3. American Association of Bioanalysts (AAB)

provided, however, that an applicant for licensure as a CLS-G who has, prior to January 1, 1995, successfully completed the certification examination for such clinical laboratory personnel classification developed and administered by the United States Department of Health, Education, and Welfare (HEW) (predecessor to the Department of Health and Human Services) shall also be eligible for licensure as a clinical laboratory scientist-generalist.

B. Clinical Laboratory Scientist-Specialist. To be eligible for licensure as a clinical laboratory scientist-specialist, an applicant, in addition to satisfaction of the procedural requirements for licensure under this Chapter, shall:

1. possess a baccalaureate or more advanced degree from an accredited college or university with a major in one of the chemical, physical, or biological sciences; and

2. have successfully completed an approved nationally recognized certification examination for such clinical laboratory personnel classification, as developed and administered by one of the following organizations:

a. American Society of Clinical Pathologists (ASCP);

b. National Certification Agency (NCA);

c. American Society of Microbiology (ASM);

d. American Association of Clinical Chemistry (AACC);

e. American Board of Immunology (ABI);

f. American Board of Bioanalysts (ABB); or

g. American Board of Forensic Toxicology (ABFT).

C. Clinical Laboratory Scientist-Technician. To be eligible for licensure as a clinical laboratory scientist-technician, an applicant, in addition to satisfaction of the procedural requirements for licensure under this Chapter, shall have successfully completed an approved nationally recognized certification

examination for such clinical laboratory personnel classification, as developed and administered by one of the following organizations or their successor organizations:

1. American Society of Clinical Pathologists (ASCP);

2. American Medical Technologists (AMT); or

3. American Association of Bioanalysts (AAB).

D. Cytotechnologist. To be eligible for licensure as a cytotechnologist, an applicant, in addition to satisfaction of the procedural requirements for licensure under this Chapter, shall:

1. possess a baccalaureate degree from an accredited college or university, fulfill the educational requirements necessary to enroll in a school of cytotechnology, complete one full year of full-time cytotechnology experience or its equivalent in an approved school of cytotechnology, and successfully complete an approved nationally recognized certification examination for such clinical laboratory personnel classification, as developed and administered by one of the following organizations:

a. American Society of Clinical Pathologists (ASCP); or

b. International Academy of Cytology (IAC);

2. have successfully completed an approved nationally recognized certification examination for such clinical laboratory personnel classification, as developed and administered by one of the following organizations:

a. American Society of Clinical Pathologists (ASCP); or

b. International Academy of Cytology (IAC).

E. Laboratory Assistant. To be eligible for licensure as a laboratory assistant, an applicant, in addition to satisfaction of the procedural requirements for licensure under this Chapter, shall:

1. possess a high school diploma or its equivalent;

2. document to the board, in a form sufficient to and upon the recommendation of the committee, training as evidence of competency in the basic practice of clinical laboratory science. For this purpose, successful completion of the certification examinations for laboratory assistants offered by the International Society of Clinical Laboratory Technology and the American Society of Clinical Pathologists shall be deemed a conclusive, but not the exclusive, means of documenting competency in the basic practice of clinical laboratory science;

3. prior to the performance of moderate complexity testing as provided in 42 CFR Part 493, have provided to the applicant's employer or laboratory director documentation of training appropriate for the testing performed. Such documentation shall ensure that the applicant has all of the following:

a. the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;

b. the skills required for implementing all standard laboratory procedures;

c. the skills required for performing each test method and for proper instrument use;

d. the skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

e. a working knowledge of reagent stability and storage;

f. the skills required to implement the quality control policies and procedures of the laboratory;

g. an awareness of the factors that influence test results; and

h. the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results; and

4. have provided to the committee or board, upon good cause shown, the documentation of training appropriate for the moderate complexity testing to be performed as provided in §3509.E.3.

F. Phlebotomist. To be eligible for certification as a phlebotomist, an applicant, in addition to satisfaction of the procedural requirements for certification under this Chapter, shall:

1. have successfully completed a certification examination approved or written and administered by the board and the committee following completion of a training program for phlebotomists satisfactory to the board, upon recommendation of the committee, consisting of a minimum of 20 lecture hours or adequate practical hours to ensure that the applicant possesses:

a. the skills required for proper specimen collection, including patient identification and

preparation, labeling, handling, preservation, processing, transportation, and storage of specimens;

b. the skills required for selecting the appropriate type of tube to collect for each test;

c. the skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

d. a working knowledge of reagent stability and storage;

e. the skills required to perform quality control procedures;

f. an awareness of the factors that influence test results;

g. a working knowledge of the actions of various anticoagulants;

h. a working knowledge of the anatomy and physiology of blood vessels and the circulatory system and blood;

i. a working knowledge of the components and functions of those components of blood to include, RBC, WBC, platelets, and plasma or serum;

j. a working knowledge of primary hemostasis;

k. a working knowledge of laboratory safety to include OSHA standards for handling bloodborne pathogens;

l. a working knowledge of the various isolation procedures and infection control;

m. a working knowledge of various medical terms and laboratory tests;

n. a working knowledge of the requirements of special laboratory tests;

o. a working knowledge of the clinical laboratory;

p. a working knowledge of the major tests performed in the clinical laboratory and specimen requirements;

q. a working knowledge of aseptic techniques and methods of sterilization; and

r. completion of 100 successful venipunctures and 25 successful capillary collections; or

2. have successfully completed an approved nationally recognized certification examination for such clinical laboratory personnel classification, as developed and administered by one of the following organizations:

a. American Society of Clinical Pathologists (ASCP);

b. National Certification Agency (NCA);

c. American Society of Phlebotomy Technicians (ASPT);

d. National Phlebotomy Association (NPA);

e. American Medical Technologists (AMT);

f. American Association of Blood Banks;

g. National Allied Health Test Registry (NAHTR); or

h. International Academy of Phlebotomy Science (IAPS).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and R.S. 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1286 (November 1994), amended, LR 37:597 (February 2011), LR 37:2401 (August 2011), LR 38: 1026 (April 2012).

§3511. Licensure or Certification without Examination

A. Notwithstanding the examination requirements prescribed and required by §3509, provided that application is made within 12 months of the effective date of these rules, any individual who desires to be licensed as a CLS-G, CLS-S, CLS-T, cytotechnologist, or laboratory assistant may qualify for licensure and shall be issued the appropriate license without having to successfully complete an approved nationally recognized certification examination, upon application on a form provided by the board, payment of the required license fee, and submission of evidence of competency, which may include but does not require successful completion of an approved nationally recognized certifying examination, prior to the effective date of this Chapter, satisfactory to the committee and the board that the applicant:

1. has been actively engaged in the category for which the license is requested for at least two full years within the three years immediately prior to the effective date of these rules;

2. has ceased to engage in the practice of clinical laboratory science, but was actively engaged in such practice in the category for which license is requested for at least two full years immediately prior to inactivity, provided the applicant has not been inactive more than five years; or

3. was eligible for licensure without examination in accordance with either §3511.A.1 or 2 on the effective date of these rules and at that time was in the military forces of the United States.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1288 (November 1994).

§3513. Reciprocity

A. The board, upon recommendation of the committee, shall license, without examination, and upon payment of the prescribed license fee, an applicant for licensure who is duly licensed in the same or comparable category for which he or she is applying for licensure in this state under the laws of another state, territory, commonwealth, or the District of Columbia, if the qualifications for licensure of such applicant in such category are at least equal to the qualifications provided in this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1288 (November 1994).

§3515. Trainee License

A. Generally. A trainee who engages in the practice of clinical laboratory science in any category for which a license is required shall be required to apply for and obtain a trainee license in the category corresponding to the work performed. All work performed by a trainee under a trainee license shall be under the direct supervision of clinical laboratory personnel licensed as either CLS-G, CLS-S, or cytotechnologist.

B. Exception. §3515.A shall not apply to a trainee who engages in the practice of clinical laboratory science exclusively through an approved school or training program.

C. Licensure Period; Renewal. A trainee license issued in accordance with these regulations shall be effective for the calendar year beginning January 1 and ending December 31 in which it is issued, and may be renewed for up to three additional years provided the trainee remains enrolled in an approved school or training program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1288 (November 1994).

§3517. Returning Practitioners

A. Generally. An applicant who has been certified in the practice of clinical laboratory science by passing an approved nationally recognized certification examination, but who has not engaged in the practice of clinical laboratory science within the 10 years preceding application and who has not fulfilled the continuing education requirements of this Chapter, shall be granted a trainee license in the category for which the applicant is otherwise qualified.

B. Eligibility for Full Licensure. A returning practitioner who has been granted a trainee license in accordance with §3517.A shall be eligible and may apply for full licensure upon completion of 12 continuing education hours as provided in §3533 of these rules and documentation of competency by the director of the retraining facility or his or her designee. Supervised retraining must be under the direct supervision of clinical laboratory personnel licensed as either CLS-G, CLS-S, or cytotechnologist.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1288 (November 1994).

§3519. Temporary License or Certificate

A. Generally. Applicants that qualify by education, experience, or training but have not taken or passed an approved nationally recognized certification examination may be granted a temporary license or temporary certificate that will allow that individual to engage in the practice of clinical laboratory science at the appropriate level (CLS-G, CLS-S, CLS-T, cytotechnologist, or phlebotomist). The temporary license or certificate will be valid for three months.

B. Failure to Pass Examination; Renewal. A temporary license or temporary certificate issued pursuant to this Section may be renewed one time upon failure to pass an approved nationally recognized certification examination. Such renewal shall be effective for three months. Applicants who fail to pass the appropriate approved nationally recognized certification examination a second time may not renew their temporary license or temporary certificate. Such applicants shall:

1. refrain from the practice of clinical laboratory science until successful completion of an appropriate approved nationally recognized certification examination;

2. complete a supervised retraining program and, upon submitting evidence satisfactory to the board of completion of such program, apply for a new

temporary license or temporary certificate in the same category; or

3. apply for a temporary license or temporary certificate for the practice of clinical laboratory science at a lower level of complexity.

C. Failure to Appear. Applicants who do not appear to take an approved nationally recognized certification examination for which they are registered shall not receive a second temporary license or temporary certificate and the temporary license or temporary certificate held shall be invalid as of that date (unless extension is approved by the board, upon recommendation of the committee, due to mitigating circumstances). Such applicants may, however:

1. reapply for full licensure upon successful completion of an approved nationally recognized certification examination; or

2. apply for a temporary license or temporary certificate for the practice of clinical laboratory science at a lower level of complexity.

D. Foreign-Trained Applicants. An applicant basing eligibility for a temporary license or temporary certificate upon a degree from a foreign university must have his or her transcript validated and evaluated by an acceptable foreign transcript evaluation agency listed as an Appendix to this Chapter (§3545). That evaluation must be submitted to the national certifying agency offering the approved nationally recognized certification examination for which the applicant wishes to sit. The committee will not evaluate or validate foreign transcripts. Upon notification of acceptance to sit for such examination, the applicant may apply for a temporary license or temporary certificate in the corresponding category. A copy of the letter stating that the applicant is eligible to sit for an approved nationally recognized certification examination must accompany the application for temporary license or temporary certificate. Agencies approved by and acceptable to the board and the committee for purposes of validating and evaluating transcripts from foreign universities are listed in an Appendix to these rules (§3545).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1289 (November 1994), amended LR 42:752 (May 2016).

§3521. Reinstatement of Lapsed License or Certificate

A. An individual whose license has lapsed and who has not been actively engaged in the practice of clinical laboratory science during the preceding period of not more than seven years may have his or her license or certificate reinstated upon payment of the renewal fee and the delinquent fee provided in §3529 and submission of evidence satisfactory to the board that during the lapsed period he or she fulfilled the continuing education requirements of this Chapter. An individual whose license has lapsed and who has not been actively engaged in the practice of clinical laboratory science for a period of more than seven years, but not more than 10 years, shall be subject to the provisions in §3517 provided that any such individual may petition the committee, for good cause shown, for a reduction or waiver of the continuing education and/or supervised retraining requirements of §3517.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1289 (November 1994).

Subchapter C. Procedures for Obtaining Licensure or Certification

§3523. Issuance

A. If an applicant meets the qualification requirements of this Chapter for the category in which the license or certificate is requested and otherwise complies with the requirements of this Chapter, the board shall issue the applicant a license or certificate for the practice of clinical laboratory science within the specific category of licensure or certification for which the applicant qualifies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1289 (November 1994).

§3525. Application

A. General Requirements. Application for licensure or certification under this Chapter shall be made on a form supplied by the committee. Such form, and any supporting documentation required to be submitted therewith, shall provide information sufficient to assure the applicant satisfies the minimum qualifications for the category of licensure or certification applied for.

B. Applicant for Licensure as CLS-G, CLS-S, CLS-T, or Cytotechnologist. Each application for licensure as a CLS-G, CLS-S, CLS-T, or cytotechnologist shall be accompanied by all of the following:

1. a recent photograph for identification;

2. the appropriate fee;

3. a copy of the registration or certification card indicating successful completion of an approved nationally recognized certification examination;

4. for non-U.S. citizen applicants, proof of lawful entry into the country; and

5. if the requested licensure or certification is based on reciprocity as provided in §3513, a statement from the licensing authority of the other state attesting to the licensure status of the applicant in the other state. Such statement shall be issued directly to the committee from the licensing authority of the other state.

C. Application for Licensure as a Laboratory Assistant. Each application for licensure as a laboratory assistant shall be accompanied by all of the following:

1. a recent photograph for identification;

2. the appropriate fee;

3. evidence of completion of a satisfactory training program;

4. copy of a high school diploma or equivalent; and

5. if moderate complexity testing is to be performed, documentation of competency in the area of testing to be performed.

D. Application for Certification as a Phlebotomist. Each application for certification as a phlebotomist shall be accompanied by all of the following:

1. a recent photograph for identification;

2. the appropriate fee; and

3. evidence of completion of a satisfactory training program and successful completion of a board-approved or administered certifying examination or successful completion of an approved nationally recognized certification examination.

E. Multiple Licensure. An applicant may be licensed or certified in each category for which he or she is qualified.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1289 (November 1994).

§3527. Expiration and Renewal of Licenses and Certificates

A. Expiration. Every license or certificate issued by the board under this Chapter, the expiration date of which is not stated thereon or otherwise provided by these rules, shall expire, and thereby become null, void, and to no effect, on the last day of the year in which such license or certificate was issued.

B. Continuation Pending Renewal. The timely submission of a properly completed application for renewal of a license or certificate, as provided by §3527.C, shall operate to continue the expiring license or certificate in full force and effect pending the board's issuance or refusal to issue the renewal license or certificate. The committee may recommend and the board may continue a license or certificate in effect, without application for renewal or payment of the renewal fee for any clinical laboratory personnel licensed or certified under this Chapter while the individual is in active military service of the United States or any of its allies, upon notification by the licensee to the committee of such service.

C. Renewal. Every license and certificate issued by the board under this Chapter shall be renewed annually on or before the date of its expiration by submitting to the board a properly completed application for renewal, upon forms supplied by the board, together with the renewal fee prescribed by §3529 of this Chapter. An application for renewal of license or certificate form shall be mailed by the board to each person holding a license or certificate issued under this Chapter on or before November 15 of each year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1290 (November 1994).

§3529. Fees

A. General Provisions. Except as provided in §3529.B, the fee for obtaining or renewing a license or certificate as provided in this Chapter shall be as follows.

1. clinical laboratory scientist (all categories) $65

2. cytotechnologist $65

3. laboratory assistant $40

4. phlebotomist $40

B. Exceptions

1. Delinquent Fee. In addition to the fee prescribed by §3529.A, any individual who fails to renew his or her license or certificate by January 1 shall be charged a delinquent fee of $50.

2. Duplicate Fee. The fee for obtaining a duplicate license or certificate shall be $10.

3. Temporary License or Certificate. The fee for obtaining a temporary license or temporary certificate shall be the amount of the fee prescribed by §3529.A for the category for which such license or certificate is to be issued.

4. Trainee License. If an individual is required to obtain or renew a trainee license in accordance with this Chapter, the fees for obtaining or renewing such trainee license shall be the fee prescribed by §3529.A for the category under which such trainee license is issued.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1290 (November 1994), amended LR 35:2182 (October 2009).

Subchapter D. Continuing Education

§3531. General Requirement

A. All clinical laboratory personnel licensed or certified under this Chapter shall satisfy the continuing education requirements of this Subchapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1290 (November 1994).

§3533. Minimum Hours

A. Effective January 1, 1995, every person licensed or certified under this Chapter shall complete a minimum of 12 contact hours of continuing education (1.2 Continuing Education Units, or CEUs) each calendar year. No carryover credit shall be allowed for excess credit earned in one calendar year to the next calendar year. One CEU equals 10 contact hours of participation in an organized education experience, under responsible sponsorship, capable direction, and qualified instruction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1291 (November 1994).

§3535. Credit Hours Awarded

A. Except as otherwise provided, one hour of continuing education credit shall be awarded for the first contact hour of a continuing education program. Thereafter, for programs lasting longer than one hour, one continuing education hour shall be awarded for every 50 contact minutes. No credit shall be awarded for partial completion of a program (i.e., no credit shall be awarded for one hour attendance at a three-hour continuing education program).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1291 (November 1994).

§3537. Sources of Continuing Education

A. Deemed Approved. The following sources of continuing education shall be deemed approved for purposes of satisfying the continuing education requirements of this Chapter without prior submission to the committee or board:

1. professional meetings sponsored by approved professional organizations;

2. audio conferences sponsored by approved professional organizations;

3. teleconferences and videoconferences sponsored by approved professional organizations;

4. self-study courses sponsored by approved professional organizations;

5. training programs sponsored by medical technology instrument manufacturers;

6. coursework relevant to the practice of clinical laboratory science at an accredited college or university. A completed full-credit course shall qualify for six Category 2 continuing education hours. A course qualifying for less than full-credit shall be pro-rated and continuing education credit awarded appropriately;

7. publication of an article in a professional journal. A published article shall qualify for six continuing education hours;

8. presentation of a poster or program at a local, state, regional, national, or international meeting or program, with a poster presentation qualifying for two continuing education hours and other presentations qualifying for twice the credit for attendees of the

presentation, but without credit for repeat poster sessions or presentations;

9. laboratory sessions such as role playing, buzz sessions, product preparation, or a "wet workshop" that have been approved by the board, upon recommendation of the committee, for continuing education credit, with participants in such sessions credited with one hour of continuing education credit in accordance with §3535; and

10. continuing education programs sponsored and presented by the committee.

B. Other Continuing Education Sources. In addition to the sources of continuing education deemed approved for continuing education credit without prior submission to the committee or board, such other programs or events that satisfy the standards set forth in §3539 and have been submitted to the board for approval in accordance with the procedures provided in §3541 shall, upon recommendation of the committee, be approved for continuing education credit as a continuing education source.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1291 (November 1994).

§3539. Standards for Continuing Education

A. Any continuing education offering submitted to the board for consideration as an approved source of continuing education credit shall meet the following standards:

1. provide a structured learning experience;

2. provide appropriate subject matter reflecting the professional educational needs for continuing competency in the practice of clinical laboratory science from one or more of the following subject areas:

a. clinical laboratory practice areas;

b. legal aspects of laboratory medicine;

c. educational methodology as utilized in the clinical laboratory; or

d. laboratory safety, bloodborne pathogens, and chemical hygiene;

3. have written learning objectives, stated in terms of actions, conditions, and degree related to level of audience (Basic, Intermediate, Advanced);

4. have a set time schedule and be at least one hour in length;

5. have qualified faculty with background and experience necessary to teach the subject. Copies of credentials shall be available to the board upon request;

6. include assessment and evaluation mechanisms to ensure that participants have achieved a specified level of performance and to provide for evaluation of instructional methods, facilities, and resources used;

7. make available a brochure or flyer containing the following information:

a. the program objectives stated in terms of what the participant will learn or be able to do as a result of the program;

b. the program level:

i. basic: entry level; no prior knowledge of subject necessary;

ii. intermediate: refresher course; some basic knowledge required; for the bench technologist with several years of experience;

iii. advanced: highly technical: for those with current skills/ knowledge; for those with at least two years experience in specialty area;

c. program schedule;

d. fee for the program if applicable;

e. number of CEUs or continuing education hours granted;

f. faculty credentials;

g. include the following statement:

"[Provider Name] is approved as a Provider of continuing education programs in the clinical laboratory sciences by the Clinical Laboratory Personnel Committee to the Louisiana State Board of Medical Examiners."

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1291 (November 1994).

§3541. Procedures for Obtaining Approval as a Continuing Education Source

A. Single Program Approval. A program sponsor may be approved for a single program pursuant to the following procedures.

1. Not less than 120 days prior to the scheduled date of the proposed program, the program sponsor shall request approval of the program as a source of continuing education credit from the committee. Such

request shall be submitted on a form recommended by the committee and approved by the board.

2. The committee shall review and evaluate the request for compliance with the standards for continuing education provided in §3539.

3. The committee shall determine whether the proposed program complies with the standards for continuing education in all material respects. If the committee determines that the program does not comply with the standards for continuing education, the program sponsor shall be so notified in writing within 60 days of the committee's receipt of the form requesting approval. If the committee determines that the program complies with the standards for continuing education, then committee shall recommend to the board that the program be approved as a source of continuing education credit.

4. The program sponsor shall be notified in writing of the board's approval or nonapproval of the program as a source of continuing education credit within 60 days of the committee's receipt of the form requesting approval. If the program is not approved, the notice shall include the reason or reasons for nonapproval.

5. Upon approval, the program shall be assigned a program identification number. The program sponsor shall be notified of the identification number and reference such number on all correspondence with the committee or board concerning that program.

6. The program sponsor shall provide each participant in the program with an authenticated certificate or letter of attendance.

7. The program sponsor shall maintain records of the program, including content, faculty, attendance, assessment, and evaluation for a period of not less than two years.

8. The program sponsor shall provide satisfactory proof of any individual's attendance at the program upon the committee's request.

B. Multiple Program Approval. A program sponsor may be approved for multiple program offerings. An approved sponsor need not submit each program offered for approval, but each program shall be considered an approved source of continuing education credit. The following procedures shall be applicable for approval of a sponsor as a sponsor or multiple programs for continuing education credit.

1. The sponsor shall request approval as a sponsor of multiple continuing education programs from the committee. Such request shall be submitted on a form recommended by the committee and approved by the board.

2. The sponsor shall certify that each continuing education program offered shall comply with the standards for continuing education provided in §3539.

3. The sponsor shall designate an individual who shall be responsible for continuing education programs for clinical laboratory personnel.

4. The sponsor shall establish a comprehensive plan for ongoing evaluation of the content, faculty, and assessment tools used for each program and for compliance of all continuing education offerings with the standards for continuing education provided in §3539. Such plan shall be submitted to the committee for review with the sponsor's request for approval.

5. The sponsor shall certify that each participant in each program will be provided with an authenticated certificate or letter of attendance.

6. The sponsor shall certify that records of each continuing education program offered, including content, faculty, attendance, assessment, and evaluation shall be maintained for a period of not less than two years.

7. The sponsor shall certify that satisfactory proof of any individual's attendance at a program shall be maintained for not less than two years and shall be available to the committee on request.

8. The committee shall determine whether the sponsor has complied with the requirements for approval as a sponsor of multiple programs for continuing education credit. If the committee determines that the sponsor has not complied with such requirements, the sponsor shall be so notified within 60 days of receipt of the form requesting approval. If the committee determines that the sponsor has complied with such requirements, the committee shall recommend to the board that the sponsor be approved as a sponsor for multiple continuing education programs.

9. The sponsor shall be notified in writing of the board's approval or nonapproval of the sponsor as a sponsor for multiple continuing education programs within 90 days of the committee's receipt of the form requesting approval. If the sponsor is not approved, the written notice shall include the reasons for nonapproval.

10. Upon approval, the sponsor shall be assigned a sponsor identification number. The sponsor shall be notified of the identification number and reference such number on all correspondence with the committee or the board.

11. Approval of a sponsor for multiple continuing education programs may be for a period not to exceed 36 months.

12. Approval of a sponsor for multiple continuing education programs shall be subject to periodic review. At the committee's request, the sponsor shall submit records and materials from its continuing education programs to assure compliance with these requirements. Approval of the sponsor may be withdrawn upon a finding by the committee of noncompliance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1292 (November 1994).

§3543. Proof of Compliance with Continuing Education Requirements

A. Form. Each applicant for renewal of licensure or certification shall certify his or her compliance with the continuing education requirements of this Chapter on a form recommended by the committee and approved by the board. Such form shall provide for submission of documentation supporting the applicant's statement of compliance.

B. Audits. Random audits of applications for license or certificate renewals shall be conducted by the committee or the board, at their discretion, to verify compliance with the continuing education requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1293 (November 1994).

§3545. Appendix—Approved Foreign Transcript Evaluation Agencies

As Approved by the Louisiana State Board of Medical Examiners as of November 20, 1994

Center of Applied Research, Evaluation, and Education, Inc. P.O. Box 20348
Long Beach, CA 90801
Telephone: (310) 430-1105

Education Evaluators International, Inc.
P.O. Box 5397
Los Alamitos, CA 90721
Telephone: (310) 431-2187; Facsimile: (310) 493-5021

Education International
29 Denton Road
Wellesley, MA 02181
Telephone: (617) 235-7425; Facsimile: (617) 235-6831

Educational Credential Evaluators, Inc.
P.O. Box 92970
Milwaukee, WI 53202-0970
Telephone: (414) 289-3400; Facsimile: (414) 289-3411

Foreign Academic Credentials Service, Inc.
P.O. Box 307
Glen Carbon, IL 62034
Telephone: (618) 288-5892

Foundation for International Services, Inc.
3123 Eastlake Avenue East
Seattle, WA 98102-3875
Telephone: (206) 328-0260; Facsimile: (206) 726-0528

International Consultants of Delaware, Inc.
109 Barksdale Professional Center
Newark, DE 19711
Telephone: (302) 737-8715; Facsimile: (302) 737-8756

International Education Research Foundation, Inc.
P.O. Box 66940
Los Angeles, CA 90066
Telephone: (310) 390-6276; Facsimile: (310) 397-7686

Josef Silny and Associates, Inc.
P.O. Box 248233
Coral Gables, FL 33124
Telephone: (305) 666-0233; Facsimile: (305) 666-4133

World Education Services, Inc.
P.O. Box 745
Old Chelsea Station; New York, NY 10013-0745
Telephone: (212) 966-6311; Facsimile: (212) 966-6395

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(5) and 37:1311-1329.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 20:1293 (November 1994).