RULES AND REGULATIONS FOR THE

LICENSURE OF

CLINICAL LABORATORY

SCIENCE PRACTITIONERS

(R23-16.3-CLS)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health

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INTRODUCTION

These *Rules and Regulations for the Licensure of Clinical Laboratory Science Practitioners* (R23-16.3-CLS) are promulgated pursuant to the authority conferred under section 23-16.3 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting prevailing standards for the licensure of clinical laboratory science practitioners in this state.

Pursuant to the provisions of section 42-35-3 (c) of the General Laws of Rhode Island, as amended, consideration was given in arriving at the regulations to: (1) alternative approaches to the regulations; and (2) duplication or overlap with state regulations. No known overlap, duplication, or alternative approach was identified.

These rules and regulations shall supersede any previous rules and regulations pertaining to the licensure of clinical laboratory science practitioners promulgated by the Department of Health and filed with the Secretary of State.

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PART I ***Definitions and Licensure Requirements***
(R23-16.3-CLS)

Section 1.0 ***Definitions***

Wherever used in these rules and regulations, the terms listed below shall be construed as follows:

1.1 ***"Accredited clinical laboratory program"*** means a program planned to provide a predetermined amount of instruction and experience in clinical laboratory science that has been accredited by one (1) of the accrediting agencies recognized by the United States Department of Education.

1.2 ***"Act"*** refers to Chapter 23-16.3 of the General Laws of Rhode Island, as amended, entitled, "Clinical Laboratory Science Practice Act."

1.3 ***"Board"*** means the Clinical Laboratory Science Board appointed by the Director of Health.

1.4 ***"Clinical laboratory"*** or *"laboratory"* means any facility or office in which clinical laboratory tests are performed.

1.5 ***"Clinical laboratory science practitioner"*** or "one who engages in the practice of clinical laboratory science" means a health care professional who performs clinical laboratory tests or who is engaged in management, education, consulting or research in clinical laboratory science, and includes laboratory directors, supervisors, clinical laboratory scientists (technologists), specialists, and technicians working in a laboratory, but does not include persons employed by a clinical laboratory to perform supportive functions not related to direct performance of laboratory tests and does not include clinical laboratory trainees. Provided, however, nothing contained in the Act shall apply to a clinical perfusionist engaged in the testing of human laboratory specimens for extracorporeal functions, which shall include those functions necessary for the support, treatment, measurement or supplementation of the cardiopulmonary or circulatory system of a patient.

1.6 ***"Clinical laboratory scientist"*** and/or *"technologist"* means a person who performs tests pursuant to established and approved protocols requiring the exercise of independent judgment and responsibility, maintains equipment and records, performs quality assurance activities related to test performance, and may supervise and teach within a clinical laboratory setting.

1.7 ***"Clinical laboratory technician"*** means a person who performs laboratory tests pursuant to established and approved protocols which require limited exercise of independent judgment and which are performed under the personal and direct supervision of a clinical laboratory scientist (technologist), laboratory supervisor, or laboratory director.

1.8 ***"Clinical laboratory test"*** or *"laboratory test"* means a cytogenetic, microbiological, serological, chemical, hematological, radiobioassay, cytological, immunological or other pathological examination which is performed on material derived from the human body, or any other test or procedure conducted by a clinical laboratory or facility which provides

information for the diagnosis, prevention or treatment of a disease or assessment of a medical condition.

1.9 ***"Cytotechnologist"*** means a health care professional specializing in cancer detection. She/he is responsible for diagnostic testing and may also be involved in management, education and research.

1.10 ***"Department"*** means the Rhode Island Department of Health.

1.11 ***"Director"*** means Director of the Rhode Island Department of Health.

1.12 ***"Direct supervision"*** means the clinical laboratory scientist (technologist), laboratory supervisor, or laboratory director personally authorizes the procedure(s), duty(ies), and/or tests, to be performed and remains in the laboratory while the procedure(s), duty(ies), and/or tests are being performed and reviews the results.

1.13 ***"Histologic technician"*** means a person who is concerned with the preparation of surgical, autopsy or research tissue for microscopic examination pursuant to established and approved protocols which require limited exercise of independent judgment and responsibility.

1.14 ***"Independent judgment"*** means procedure(s), duty(ies), and/or tests are not subject to review, upon completion, by a supervisor.

1.15 "***Limited function test"*** means those tests listed in the Federal Register as waived tests. Such listing shall be made available through the Department upon request.

1.16 "***MOHS technician***", as used herein, means a person who works under the supervision of a MOHS micrographic surgeon performing MOHS micrographic surgery. Duties of a MOHS technician may include: the preparation of tissue by freezing, cutting, staining, and mounting of the tissue specimen according to routine and specialized techniques.

1.17 ***"Quarter unit"*** and ***"semester unit"*** mean~~s~~ the hours of instruction offered by an accredited academic institution which are credited by that institution as a quarter unit and semester unit, respectively. One quarter unit = 10 contact hours; 1 semester unit = 15 contact hours.

Section 2.0 ***Licensure Requirements***

2.1 No person shall practice clinical laboratory science or hold himself out as a clinical laboratory science practitioner in this state unless he or she is licensed pursuant to the Act.

Section 3.0 ***Exemptions***

3.1 Notwithstanding the provisions of section 2.1 above, excluded from these regulations are the following individuals:

3.1.1 Any person performing clinical laboratory tests within the scope of his or her practice and for which he or she is licensed pursuant to any other provisions of the General Laws.

3.1.2 Clinical laboratory science practitioners employed by the United States government or any bureau, division or agency thereof while in the discharge of the employee's official duties.

3.1.3 Clinical laboratory science practitioners engaged in teaching or research, provided that the results of any examination performed are not used in health maintenance, diagnosis or treatment of disease.

3.1.4 Students or trainees enrolled in a clinical laboratory science education program provided that these activities constitute a part of a planned course in the program, that the persons are designated by title such as intern, trainee, or student, and the persons work directly under the supervision of an individual licensed by this state to practice clinical laboratory science.

3.1.5 Any person performing limited function tests as defined in section 1.15.

3.1.6 Any person performing the duties of a MOHS technician.

Section 4.0 ***Qualifications for Licensure***

All applicants for licensure under these rules and regulations must meet the following requirements:

4.1 ***Clinical Laboratory Scientist (Technologist):***

The Department shall issue a clinical laboratory scientist (technologist) license to an individual who completes the application required in section 5.0 and who meets the following qualifications:

Option #1

4.1.1 A) a baccalaureate degree in clinical laboratory science (medical technology) from an accredited college or university whose curriculum included a twelve (12) month clinical training program approved by the United States Department of Education; ***or***

B) a baccalaureate degree in biological, chemical or physical science from an accredited college or university, and subsequent to graduation (after receipt of the degree specified) at least twelve (12) months of appropriate clinical education in an accredited clinical laboratory science program; ***or***

C) a baccalaureate degree which includes a minimum of thirty-six (36) semester (or equivalent) hours in the biological, chemical and physical sciences from an accredited college or university plus two (2) years of full-time (minimum of thirty-five (35) hours per week) work experience including a minimum of four (4) months in each of the four (4) major disciplines of laboratory practice (clinical chemistry, clinical microbiology, hematology, immunology/immunohematology); ***or***

D) a baccalaureate degree consisting of ninety (90) semester (or equivalent) hours, thirty-six (36) of which must be in the biological, chemical or physical sciences, from an accredited university, and a twelve (12) month clinical training program approved by the United States Department of Education;

And,

E) successful completion of a nationally recognized certification examination for a clinical laboratory scientist (technologist), or other examination as may be approved by the Board, such as the National Credentialing Agency (NCA) examination, the American Medical Technologists (AMT) examination, the American Society of Clinical Pathologists (ASCP) examination, the American Association of Bioanalysts Board of Registry (AAB) examination, or the state civil service examination;

Or,

Option #2

4.1.2 A clinical laboratory scientist (technologist) who previously qualified under federal regulatory requirements such as 493.1433 of the March 14, 1990 *Federal Register* as follows:

A) possession of a license as a laboratory technologist issued by the state, if such licensing existed;

and

B) a) a bachelor's degree in medical technology from an accredited university;

or,

b) successful completion of three (3) years of academic study (a minimum of ninety (90) semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and successful completion of a course of training of at least twelve (12) months in such a school;

or,

c) a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, at least one (1) year of pertinent full-time laboratory experience or training, or both, in the specialty or sub-specialty in which the individual performs tests;

or,

d) successful completion of three (3) years (90 semester hours or equivalent) in

an accredited college or university with the following distribution of courses:

i) for those whose training was completed before 15 September 1963, at least twenty-four (24) semester hours in chemistry and biology courses including:

I) at least six (6) semester hours in inorganic chemistry and at least three (3) semester hours in other chemistry courses; ***and***

II) at least twelve (12) semester hours in biology courses pertinent to the medical sciences;

or,

ii) for those whose training was completed after 14 September 1963:

I) sixteen (16) semester hours in chemistry courses that included at least six (6) semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;

II) sixteen (16) semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; ***and***

III) three (3) semester hours of mathematics;

and,

iii) experience, training or both, covering several fields of medical laboratory work of at least one (1) year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in section 4.1.2(B)(a);

or,

C) for those individuals who first qualified before 1 July 1971:

i) performance of the duties of a laboratory technologist at any time between 1 July 1961 and 1 January 1968, ***and***

ii) at least ten (10) years of pertinent laboratory experience prior to 1 January 1968. A minimum of thirty (30) semester hours of credit from an approved school of medical technology, or toward a bachelor's degree from an accredited institution with a chemical, physical or biological science as the major subject is considered equivalent to two (2) years of experience. Additional education is equated at the rate of fifteen (15) semester hours of credit for one (1) year of experience;

and

D) successful completion of a nationally recognized certification examination for a clinical

laboratory scientist (technologist), or other examination as may be approved by the Board, such as the National Credentialing Agency (NCA) examination, the American Medical Technologists (AMT) examination, the American Society of Clinical Pathologists (ASCP) examination, the American Association of Bioanalysts Board of Registry (AAB) examination, or the state civil service examination;

or,

Option #3

4.1.3 Achievement of a satisfactory grade in a proficiency examination approved by the Department of Health and Human Services (DHHS).

Or

Option #4

4.1.4 A doctoral degree in a clinical laboratory science from an accredited institution ***and***

A) successful completion of a national certification examination, as approved by the Board, and as may be offered by the American Board of Medical Microbiology (ABMM), the American Board of Clinical Chemistry (ABCC), the American Board of Bioanalysis (ABB), the American Board of Medical Laboratory Immunology (ABMLI), the American Board of Medical Genetics (ABMG) or others as may be approved by the Board.

4.2 ***Clinical Laboratory Scientist (Technologist)/Cytogenetics***

4.2.1 The Department of Health shall issue a clinical laboratory scientist (technologist)/cytogenetics license to an individual who completes the application requirements in section 5.0 and who meets the following qualifications:

A) a baccalaureate degree from an accredited college or university majoring in a scientific discipline and two (2) years of supervised training in clinical cytogenetics; ***and***

B) successful completion of a nationally recognized certification examination for a clinical laboratory scientist (technologist)/cytogeneticist, or other examination as may be approved by the Board, such as the National Credentialing Agency (NCA) examination, the American Board of Medical Genetics (ABMG) examination in clinical cytogenetics, or the state civil service examination; ***or***

C) a doctoral degree in a biological or clinical laboratory science, genetics, or cytogenetics from an accredited institution ***and***

D) successful completion of a national certification examination in clinical cytogenetics, as approved by the Board, and as may be offered by the American Board of Medical Genetics (ABMG) or others as may be approved by the Board.

4.3 ***Cytotechnologist:***

The Department of Health shall issue a cytotechnologist license to an individual who completes the application required in section 4.0 and who meets the following qualifications:

Option #1

4.3.1 A) a baccalaureate degree from an accredited college or university with twenty (20) semester hours (30 quarter hours) of biological science, eight (8) semester hours (12 quarter hours) of chemistry and three (3) semester hours (4 quarter hours) of mathematics and successful completion of twelve (12) month cytotechnology program; ***or***,

B) a baccalaureate degree from an accredited college or university with twenty (20) semester hours (30 quarter hours) of biological science, eight (8) semester hours (12 quarter hours) of chemistry and three (3) semester hours (4 quarter hours) of mathematics and five (5) years full time acceptable clinical laboratory experience including cytopreparatory techniques, microscopic analysis and evaluation of the body systems within the last ten (10) years. At least two (2) of these years must be subsequent to the completion of the academic component and at least two (2) years must be under the supervision of a licensed physician who is a pathologist, certified, or eligible for certification, by the American Board of Pathology (ABP) in Anatomic Pathology or has other suitable qualifications acceptable to the Board;

And,

C) successful completion of a nationally recognized certification examination for a cytotechnologist, or other examination as may be approved by the Board, such as the American Society of Clinical Pathologists (ASCP) examination or the state civil service examination;

Or,

Option #2

4.3.2 A cytotechnologist who previously qualified under federal regulatory requirements such as 493.1433 of the March 14, 1990 *Federal Register* as follows:

A) possession of a current license as a cytotechnologist issued by the state, if such licensing exists;

and,

B)i) successful completion of two (2) years in an accredited college or university with at least twelve (12) semester hours in science, eight (8) semester hours of which are in biology; ***and,***

a) twelve (12) months of training in a school of cytotechnology accredited by an accrediting agency approved by the DHHS; ***or***

b) six (6) months of formal training in a school of cytotechnology accredited by an accrediting agency approved by the Secretary and six (6) months of full time

experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal six (6) months of training;

or

ii) before January 1, 1969, had:

a) a high school diploma (or equivalent);

b) completion of six (6) months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology; ***and***

c) completion of two (2) years of full-time supervised experience in cytotechnology;

and

C) successful completion of a nationally recognized certification examination for a cytotechnologist, or other examination as may be approved by the Board, such as the American Society of Clinical Pathologists (ASCP) examination or the state civil service examination;

or

Option #3

4.3.3 Achievement of a satisfactory grade in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists.

4.4 ***Clinical Laboratory Scientist (Technologist)/Electron Microscopy*:**

4.4.1 The Department of Health shall issue a clinical laboratory scientist (technologist)/electron microscopy license to an individual who completes the application required in section 5.0 and who meets the following qualifications:

A) two (2) years (60 semester hours) or equivalent education, including at least two (2) semesters (6 semester hours) of laboratory courses in each of the following subjects: chemistry, physics, biology, and transmission electron microscopy (TEM) and one semester (3 semester hours) of mathematics; ***or***

B) one (1) year (30 semester hours) or equivalent, including at least two semesters (six [6] semester hours) of laboratory courses each in chemistry and physics and one (1) year (within the five [5] years prior to application) of full-time work (at least thirty-five [35] hours per week) experience doing biological TEM; ***or***

C) a high school diploma or equivalent and two (2) years (within the five years prior to application) of full time (at least thirty-five (35) hours per week) work experience doing biological TEM; ***or***

D) three (3) years (within the five [5] years prior to application) of full time (at least

thirty-five [35] hours per week) work experience doing biological TEM;

And,

E) successful completion of the certification examination of the Electron Microscopy Society of America (EMSA) or an equivalent examination, as may be approved by the Board.

4.5 ***Clinical Laboratory Scientist (Technologist)/Chemistry***:

4.5.1 As of the effective date of these regulations, the Department of Health shall issue a clinical laboratory scientist (technologist)/chemistry license to an individual who completes the application required in section 5.0 and who meets the following qualifications:

A) a baccalaureate degree from an accredited college or university that includes thirty-six (36) semester hours (or fifty-four [54] quarter hours) in the biological, chemical, and physical sciences and the equivalent of six (6) months of full-time clinical laboratory supervised training in chemistry within the last ten (10) years; ***and***

B) successful completion of a nationally-recognized certification examination or other examination as may be approved by the Board, such as the National Registry in Clinical Chemistry (NRCC) examination, the National Credentialing Agency (NCA) examination, the American Society of Clinical Pathologists (ASCP) examination, or the state civil service examination; ***or***

C) a doctoral degree in a chemical or clinical laboratory science from an accredited institution ***and***

D) successful completion of a national certification examination, as approved by the Board, and as may be offered by the American Board of Clinical Chemistry (ABCC), the American Board of Bioanalysis (ABB) or others as may be approved by the Board.

4.6 ***Clinical Laboratory Scientist (Technologist)/Microbiology***:

4.6.1 As of the effective date of these regulations, the Department of Health shall issue a clinical laboratory scientist (technologist)/microbiology license to an individual who completes the application required in section 5.0 and who meets the following qualifications:

A) a baccalaureate degree from an accredited college or university that includes thirty-six (36) semester hours (or fifty-four [54] quarter hours) in the biological, chemical, and physical sciences and the equivalent of six (6) months of full-time clinical laboratory supervised training in microbiology within the last ten (10) years; ***and***

B) successful completion of a nationally-recognized certification examination or other examination as may be approved by the Board, such as the National Credentialing Agency (NCA) examination, the American Society of Clinical Pathologists (ASCP) examination, the American Society for Microbiologists (ASM) examination, or the state civil service examination; ***or***

C) a doctoral degree in a biological or clinical laboratory science from an accredited institution ***and***

D) successful completion of a national certification examination, as approved by the Board, and as may be offered by the American Board of Medical Microbiology (ABMM), the American Board of Bioanalysis (ABB) or others as may be approved by the Board.

4.7 ***Clinical Laboratory Scientist (Technologist)/Hematology***:

4.7.1 As of the effective date of these regulations, the Department of Health shall issue a clinical laboratory scientist (technologist)/hematology license to an individual who completes the application required in section 5.0 and who meets the following qualifications:

A) a baccalaureate degree from an accredited college or university that includes thirty-six (36) semester hours (or fifty-four [54] quarter hours) in the biological and physical sciences and the equivalent of six (6) months of full-time clinical laboratory supervised training in hematology within the last ten (10) years; ***and***

B) successful completion of a nationally-recognized certification examination or other examination as may be approved by the Board, such as the National Credentialing Agency (NCA) examination, the American Society of Clinical Pathologists (ASCP) examination, or the state civil service examination; ***or***

C) a doctoral degree in a biological or clinical laboratory science from an accredited institution ***and***

D) successful completion of a national certification examination, as approved by the Board, and as may be offered by the American Board of Bioanalysis (ABB), the American Society for Hematology (ASH), or others as may be approved by the Board.

4.8 ***Clinical Laboratory Scientist (Technologist)/Immunohematology***:

4.8.1 As of the effective date of these regulations, the Department of Health shall issue a clinical laboratory scientist (technologist)/immunohematology license to an individual who completes the application required in section 5.0 and who meets the following qualifications:

A) a baccalaureate degree from an accredited college or university that includes thirty-six (36) semester hours (or fifty-four [54] quarter hours) in the biological and physical sciences and the equivalent of six (6) months of full-time clinical laboratory supervised training in immunohematology within the last ten (10) years; ***and***

B) successful completion of a nationally-recognized certification examination or other examination as may be approved by the Board, such as the National Credentialing Agency (NCA) examination, the American Society of Clinical Pathologists (ASCP), or the state civil service examination; ***or***

C) a doctoral degree in a chemical, biological or clinical laboratory science from an accredited institution ***and***

D) successful completion of a national certification examination, as approved by the Board, and as may be offered by the American Board of Bioanalysis (ABB), the American Board of Medical Laboratory Immunology (ABMLI) or others as may be approved by the Board.

4.9 ***Clinical Laboratory Scientist (Technologist)/Immunology***:

4.9.1 As of the effective date of these regulations, the Department of Health shall issue a clinical laboratory scientist (technologist)/immunology license to an individual who completes the application required in section 5.0 and who meets the following qualifications:

A) a baccalaureate degree from an accredited college or university that includes thirty-six (36) semester hours (or fifty-four [54] quarter hours) in the biological and physical sciences and the equivalent of six (6) months of full-time clinical laboratory supervised training in immunology within the last ten (10) years; ***and***

B) successful completion of a nationally-recognized certification examination or other examination as may be approved by the Board, such as the American Society of Clinical Pathologists (ASCP) examination, the National Credentialing Agency (NCA) examination, or the state civil service examination; ***or***

C) a doctoral degree in a chemical, biological or clinical laboratory science from an accredited institution ***and***

D) successful completion of a national certification examination, as approved by the Board, and as may be offered by the American Board of Bioanalysis (ABB), the American Board of Medical Laboratory Immunology (ABMLI) or others as may be approved by the Board.

4.10 ***Clinical Laboratory Scientist (Technologist)/Molecular Diagnostics:***

As of the effective date of these regulations, the Department shall issue a clinical laboratory scientist (technologist)/molecular diagnostics license to an individual who completes the application required in section 5.0 and who meets the following qualifications:

A) a) Successful completion of a National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) accredited baccalaureate or a post-baccalaureate molecular diagnostic or molecular biotechnology education program; ***or***

b) Successful completion of a baccalaureate degree or a post-baccalaureate certificate molecular biology education program sponsored by an accredited college or university that includes the equivalent of six (6) months of full-time experience in a full-service molecular biology laboratory; ***or***

c) Successful completion of a National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) approved baccalaureate-level education program in a clinical laboratory science (clinical laboratory sciences, medical technology, cytogenetics); and successful completion of the equivalent of six (6) months of full-time experience gained within the last year prior to application for licensure in a full-service molecular biology laboratory; ***or***

d) Successful completion of a baccalaureate degree in the biological, chemical and/or medical sciences from an accredited college or university and completion of the equivalent of one (1) year of full-time work experience within the last (2) years prior to application for licensure in a full-service molecular biology laboratory; ***or***

e) Be certified as a clinical laboratory scientist (CLS) or equivalent, or a clinical laboratory specialist in cytogenetics {CLSp(CG)}; and successfully complete the equivalent of six (6) months of full-time work experience gained within the last year prior to application for licensure in a full-service molecular biology laboratory; ***or***

f) Successful completion of a post-baccalaureate degree in a chemical, biological or clinical laboratory science from an accredited institution, including sixteen (16) semester hours of formal coursework in genetics, and either molecular biology or biochemistry and twelve (12) months acceptable clinical laboratory experience in molecular diagnostics in the past five (5) years prior to application for licensure; ***or***

g) Successful completion of a baccalaureate degree from an accredited college or university and completion of thirty-six (36) semester hours in the biological, chemical and/or medical sciences in addition to or as part of the baccalaureate degree and has completed the equivalent of one (1) year of full-time work experience gained within the last two (2) years prior to application for licensure in a full-service molecular biology laboratory. **The provisions of this subsection (g) shall expire on July 1, 2009.**

and

B) successful completion of a nationally-recognized certification examination in molecular diagnostics or other examination as may be approved by the Board, such as the American Society of Clinical Pathologists (ASCP) examination, the National Credentialing Agency (NCA) examination, or the state civil service examination.

4.11 ***Clinical Laboratory Technician*:**

The Department shall issue a clinical laboratory technician license to an individual who completes the application required in section 5.0 and who meets the following qualifications:

Option #1

4.11.1 A) an associate degree or completion of sixty (60) semester (or equivalent) hours from a clinical laboratory technician program (MLT or equivalent) accredited by an agency recognized by the United States Department of Education that included a structured curriculum in clinical laboratory techniques; ***or***

B) a high school diploma (or equivalent) ***and*** completion of twelve (12) months in a technician training program such as a clinical laboratory assistant (CLA) program or a medical laboratory technician certificants (MLT-C) program in an accredited school approved by the Board; ***or***

C) successful completion of an official military medical laboratory procedure course of at least fifty (50) weeks duration and has held the military enlisted occupational specialty of Medical Laboratory Specialist (laboratory technician);

And,

D) successful completion of a nationally recognized certification examination for a clinical laboratory technician or other examination as may be approved by the Board, such as the National Credentialing Agency (NCA) examination, the American Society of Clinical Pathologists (ASCP) examination, the American Medical Technologists (AMT) examination, the American Association of Bioanalysts Board of Registry (AAB) examination, or the state civil service examination;

Or,

Option #2

4.11.2 A clinical laboratory technician who previously qualified under federal regulatory requirements such as 493.1433 of the March 14, 1990 *Federal Register* as follows:

A) possession of a current license as a technician, issued by the state if such licensing exists; ***and***

a) successful completion of sixty (60) semester hours of academic credit including chemistry and biology as well as a structured curriculum in medical laboratory techniques at an accredited institution or an associate degree based on a course of study including those subjects from an accredited institution; or prior to September 1, 1997*:*

(i) a high school diploma or equivalent and completion of at least one (1) year in a technician training program in a school accredited by an accrediting agency approved by the DHHS; ***or***

(ii) a high school diploma or equivalent and two (2) years of pertinent full-time laboratory experience as a technician trainee in a laboratory; ***or***

(iii) a high school diploma or equivalent and successful completion of an official military medical laboratory procedures course of at least fifty (50) weeks duration and has held the military enlisted occupational

specialty of Medical Laboratory Specialist (Laboratory Technician); ***or***

(iv) for those technicians not meeting the training and experience requirements defined in paragraph 4.10.2 of this section, performance of the duties of a clinical laboratory technician any time between 1 July 1961 and 1 January 1968 and at least five (5) years of pertinent laboratory experience prior to 1 January 1968. (This required experience may be met by the substitution of education for experience);

and

b) successful completion of a nationally recognized certification examination for a clinical laboratory technician or other examination as may be approved by the Board, such as the National Credentialing Agency (NCA) examination, the American Society of Clinical Pathologists (ASCP) examination, the American Medical Technologists (AMT) examination, the American Association of Bioanalysts Board of Registry (AAB) examination, or the state civil service examination;

or

B) achievement of a satisfactory grade in a proficiency examination approved by the DHHS. However, after 31 December 1977, initial certification as a technician must be in accordance with paragraph 4.10.2 of this section.

4.12 ***Clinical Histologic Technician:***

4.12.1 The Department of Health shall issue a clinical histologic technician license to an individual who completes the application required in section 5.0 and who meets the following qualifications:

A) associate degree or at least sixty (60) semester hours (or equivalent) from an accredited college/university to include a combination of mathematics and at least twelve (12) semester hours of biology and chemistry and successful completion of an accredited program in histologic technique or one (1) full year of training in histologic technique under the supervision of certified histotechnologist or an appropriately certified histopathology supervisor with at least three (3) years experience; ***or***

B) a high school diploma (or equivalent) and two (2) years full time acceptable experience under the supervision of a certified/licensed clinical histologic technician at a licensed clinical laboratory in histologic technique;

And,

C) successful completion of a nationally recognized certification examination for a clinical histologic technician or other examination as may be approved by the Board, such as the National Credentialing Agency (NCA) examination, the American Society of Clinical Pathologists (ASCP) examination, or the state civil service examination.

Section 5.0 ***Application for Licensure and Fees***

5.1 Application for licensure shall be made on forms provided by the Department and shall be completed, notarized and submitted to the Department by applicants seeking licensure not less than thirty (30) days prior to the scheduled date of the Board meeting.

5.2 Such application shall be accompanied by the following documents and fee:

5.2.1 ***Good Moral Character***: signed statement on application;

5.2.2 ***Photographs****:* a recent identification photograph of the applicant, head and shoulder front view approximately 2 x 3 inches in size;

5.2.3 ***Resume****:* a chronological resume of experience;

5.2.4 ***Job description****:* where required, a notarized copy of your job description signed by the laboratory director or physician;

5.2.5 ***Verification*** *(applicants licensed in another state):* the Board of Clinical Laboratory Science Practitioners in each state in which the applicant has held or holds licensure shall submit directly to the Department, a statement attesting to the licensure status of the applicant during the time period the applicant held licensure in said state;

5.2.6 ***Transcripts:*** supporting certified transcript(s) of educational credentials as required in the appropriate section of 4.0 herein, signed by the dean or registrar of the college, university or accredited clinical laboratory science program, verifying the dates of attendance and completion of the appropriate program. Such documentation must be sent directly from the school to the Department and must consist of original statements and/or photocopies bearing the signature of the dean or registrar and the imprint of the school seal. Verification of high school graduation or equivalent may be an original signed statement from the high school or equivalent program or a notarized photocopy of the original document;

5.2.7 ***Examinations****:* the results of any required examination under section 4.0 must be submitted directly to the Department;

5.2.8 ***Fees:***

A) for Clinical Laboratory Scientist (Technologist), Clinical Laboratory Scientist (Technologist)/Cytogenetics, Clinical Laboratory Scientist (Technologist)/Electron Microscopy, Clinical Laboratory Scientist (Technologist)/Chemistry, Clinical Laboratory Scientist (Technologist)/Microbiology, Clinical Laboratory Scientist (Technologist)/Hematology, Clinical Laboratory Scientist (Technologist)/Immunohematology., Clinical Laboratory Scientist (Technologist)/Immunology, Clinical Laboratory Scientist (Technologist)/Molecular Diagnostics, and Cytotechnologist, the application fee as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health;*

B) for Clinical Histologic Technician and Clinical Laboratory Technician the application fee as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health;*

5.2.9 ***Other:*** such other information as may be deemed necessary and appropriate by the Board.

Section 6.0 ***Application for Licensure by Endorsement***

6.1 A license to practice under any category of licensure described in section 4.0 may be issued to an applicant who holds a valid license or its equivalent, in that category, issued by another state provided:

6.1.1 The Board of Licensure in each state in which the applicant has held or holds licensure submits directly to the Department, a statement attesting to the licensure status of the applicant during the time period the applicant held licensure in said state;

6.1.2 The applicant provides acceptable evidence to the Department that the requirements under which the applicant was originally licensed in another state meet or exceed the standards required in this state.

Section 7.0 ***Issuance and Renewal of License and Fee***

7.1 Upon completion of the aforementioned requirements and at the recommendation of the Board, the Department shall issue a license to those applicants found to have satisfactorily met all the requirements herein. Said license unless sooner suspended or revoked shall expire on the first day of January of each even-numbered year and may be renewed upon submission of the license renewal fee.

7.1.1 for Clinical Laboratory Scientist (Technologist), Clinical Laboratory Scientist (Technologist)/Cytogenetics, Clinical Laboratory Scientist (Technologist)/Electron Microscopy, Clinical Laboratory Scientist (Technologist)/Chemistry, Clinical Laboratory Scientist (Technologist)/Microbiology, Clinical Laboratory Scientist (Technologist)/Hematology, Clinical Laboratory Scientist (Technologist)/Immunohematology, Clinical Laboratory Scientist (Technologist)/Immunology, Clinical Laboratory Scientist (Technologist)/Molecular Diagnostics, and Cytotechnologist the license renewal fee shall be as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health;*

7.1.2 for Clinical Histologic Technician and Clinical Laboratory Technician, the license renewal fee shall be as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.*

7.2 On or before the first day of November of each odd-numbered year, the Department shall mail an application for renewal of license to every person to whom a license has been issued or

renewed during the current licensure period. Every person so licensed who desires to renew his or her license shall file with the Department such renewal application duly executed, together with the renewal fee on or before the thirty-first day of December of each odd numbered year.

7.3 Upon receipt of such application, and payment of said fee, the Department shall grant a renewal license effective the second day of January and expiring on the first day of January of the next even-numbered year.

7.4 ***Continuing Education***

For the period beginning 1 January 1996, each renewal application must be accompanied by one of the following: 1) proof of completion of at least thirty (30) hours continuing education courses, clinics, lectures, training programs, seminars, or other programs related to clinical laboratory practice which are approved or accepted by the Board; 2) proof of recertification by a national certification organization that mandates an annual minimum of fifteen (15) hours of continuing education, such as a national certification organization for medical laboratory personnel; or 3) proof of a continuing competency recognition program by a national certification organization.

7.4.1 For the period beginning January 1, 1996, each renewal application shall be accompanied by an attestation statement indicating either: 1) completion of at least thirty (30) hours of continuing education courses, clinics, lectures, training programs, seminars, or other programs related to clinical laboratory practice which are approved or accepted by the Board; or 2) successful completion of a continuing competency recognition program by a national certification organization.

7.4.2 An individual holding more than one license under these rules and regulations need earn only thirty (30) continuing education credits every two (2) years.

7.4.3 It shall be the sole responsibility of the individual technologist to obtain documentation from the approved sponsoring organization of his or her participation in a continuing education program and/or activity. This documentation shall be retained by the licensee for a minimum of four (4) years.

7.4.4 Failure to provide on request such evidence shall constitute grounds for revocation, suspension, or refusal to renew such license.

7.5 ***Standards for Continuing Education***

7.5.1 Continuing education offerings approved by the Board shall meet the following standards. The offered programs shall:

A) provide learner objectives stating expected outcomes for the learner.

B) provide appropriate subject matter reflecting the professional educational needs for continuing competency in the laboratory from one or more of the following:

1) clinical laboratory practice areas;
2) legal aspects of clinical laboratory science;
3) management or administration of a clinical laboratory;
4) subjects relating to laboratory practice which are required as part of an approved laboratory training program and which are advanced beyond that completed for current licensure;
5) universal precautions;
6) educational methodologies and instructional technologies.

C) the content of the planned learning experience shall provide expertise and competence in the subject matter taught.

D) provide qualified faculty whose qualifications shall be presented to the Board upon request.

E) provide learning experience and teaching methods which are appropriate to achieve the objectives.

F) provide that time scheduled for each activity is sufficient for the learner to meet the objectives.

G) provide participants an opportunity to evaluate learning experiences, instructional methods, facilities and resources used for the offering.

H) provide offerings which are at least fifty (50) minutes in duration for one (1) contact hour. In calculating the number of contact hours for offerings which are longer than one (1) hour, the time used for refreshment breaks, lunches and other activities not directly part of the instructional experience shall be subtracted from the total number of hours in the offering.

7.5.2 ***Approval of Continuing Education Programs***

A) The following activities are examples of continuing education that satisfy the requirements:

1) approved Continuing Education programs, sponsored by the American Society for Clinical Laboratory Science, Association of Cytogenetic Technologists, American Society of Microbiology, American Society for Clinical Pathologists, College of American Pathologists, American Association for Clinical Chemistry, American Association of Blood Banks, American Society of Hematology, Clinical Laboratory Managers Association, American Association of Bioanalysts, American College of Medical Genetics, American Society of Human Genetics, or programs provided or approved by any national laboratory-related professional organization and/or their constituent groups;

2) programs provided by government agencies;

3) college or university course work. For example, this may include science,

computer science or business management courses, as well as other clinically relevant courses appropriate to the field of clinical laboratory science;

4) cardiopulmonary Resuscitation (CPR) certification approved by the American Red Cross or the American Heart Association;

5) activities which have been approved by the American Medical Association (AMA Category I) or the American Nurses Association (ANA) through the American Nurses Credentialing Center (ANCC) as long as they are relevant to the clinical laboratory sciences;

6) activities related to the development and initial offering of clinical laboratory science or other career related courses or workshops to clinical laboratory personnel, students or allied health professionals. Lectures = 5 contact hours per hour of lecture (this includes 4 hours preparation time); teleconferences = 5 contact hours per hour of lecture. Credit may be obtained only for teaching the same topic once. Documentation includes copy of syllabus, program or letter of recognition that demonstrates content and length of teaching time;

7) credit for papers, publications, books, and exhibits (paper or poster sessions), including publishing a paper in a recognized (indexed) journal or presented before a professional audience; writing a chapter of a clinical laboratory science or medically related book; or developing a technical/scientific exhibit for display at a national scientific meeting. Single or dual authorship = 10 contact hours; first (senior) authorship = 10 contact hours; multiple authorship = 5 contact hours. Documentation includes title page of publication, chapter listing and title page, abstract identifying poster session, or meeting outline identifying presentation.

8) any continuing education activity relevant to the clinical laboratory sciences that meets the standards for continuing education set forth in section 7.5.

Section 8.0 ***Temporary Permit***

8.1 The Department may issue a temporary permit for a period of ninety (90) days from the date on the application fee receipt issued by the Department to individuals who qualify for licensure under section 4.0 of these rules and regulations ***and*:**

8.1.1 have filed an application for licensure in this state; ***and***

8.1.2 have provided acceptable evidence of being currently licensed under the laws of another state ***or,*** in the absence of a licensure law, has successfully completed a nationally recognized certification examination, such as National Credentialing Agency (NCA), American Society of Clinical Pathologists (ASCP), American Medical Technologists (AMT), or others, including appropriate categorical and specialty examinations.

8.1.3 The original privilege to work ninety (90) days from the date on the application fee

receipt shall not be extended or renewed.

Section 9.0 ***Provisional License***

9.1 The Department may issue a provisional license for a period of twelve (12) months to individuals who meet the education and experience requirements for licensure under section 4.0 of these rules and regulations and are awaiting the results of certification examinations or are employees of the state awaiting the results of the civil service examination ***and*** have filed an application that is complete except for the examination scores.

9.1.1 If such an applicant shall fail to take the first available examination following issuance of the provisional license without due cause or fails to pass the examination and be licensed, all aforementioned privileges shall automatically cease.

9.1.2 The provisional license issued under this section may be reissued at least one (1) time at the discretion of the Board with the approval of the Director.

Section 10.0 ***Denial, Suspension, Revocation of License***

10.1 The Board shall recommend to the Director to deny, revoke, or suspend a license, place on probation, censure or reprimand a licensee, or to take such other disciplinary action as the Board may deem appropriate, including the imposition of a civil penalty for conduct that may result from, but not necessarily be limited to:

10.1.1 a material misstatement in furnishing information to the Department of Health;

10.1.2 a violation or negligent or intentional disregard of the Act or of the rules or regulations promulgated thereunder;

10.1.3 a conviction of any crime under the laws of the United States or any state or territory thereof which is a felony or which is a misdemeanor, an essential element of which is dishonesty, or of any crime which is directly related to the practice of the profession;

10.1.4 making any misrepresentation for the purpose of obtaining registration or violating any provision of the Act;

10.1.5 any activity in violation of professional standards of practice at a level consistent with current community and national standards;

10.1.6 engaging in dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public;

10.1.7 providing professional services while mentally incompetent, under the influence of alcohol or a narcotic or a controlled dangerous substance that is in excess of therapeutic amounts or without valid medical indication;

10.1.8 directly or indirectly contracting to perform clinical laboratory tests in a manner

which offers or implies an offer of rebate, fee-splitting inducements or arrangements, or other unlawful remuneration; ***or***

10.1.9 aiding or assisting another person in violating any provision of the Act or any rule adopted thereunder.

Section 11.0 ***Rules Governing Practices and Procedures***

11.1 All hearings and reviews required under the provisions of Chapter 23-16.3 of the General Laws of Rhode Island, as amended, shall be held in accordance with the provisions of the *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP).*

Section 12.0 ***Severability***

12.1 If any provision of the Act or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of the Act which can be given effect without the invalid provision or application, and to this end the provisions of the Act are declared to be severable.

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