ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R149-15

Effective June 21, 2017

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§1-4, 6-9, 15-23 and 25, NRS 439.200, 652.123, 652.125 and 652.130; §§5 and 10, NRS 439.200, 652.090 and 652.130; §§11 and 12, NRS 439.200, 652.125 and 652.130; §§13 and 14, NRS 439.200, 652.123, 652.130 and 652.260; §24, NRS 439.150, 439.200, 652.100 and 652.125.

A REGULATION relating to medical laboratories; prescribing requirements for certain laboratory personnel; establishing provisions concerning the performance of certain tests for the detection of the human immunodeficiency virus; revising certain requirements relating to the licensure and certification of laboratory personnel and the operation of laboratories; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Under existing law, medical laboratories and their personnel are subject to both state and federal regulation. (42 U.S.C. § 263a; 42 C.F.R. Part 493; chapter 652 of NRS) The State Board of Health is responsible for adopting regulations governing medical laboratories and their personnel. (NRS 652.090, 652.123, 652.125, 652.127, 652.130, 652.135, 652.215, 652.225) The Division of Public and Behavioral Health of the Department of Health and Human Services is responsible for the enforcement of the applicable laws and regulations. (NRS 652.120)

Federal regulations classify laboratory tests into three categories: (1) simple tests with a low risk for an incorrect result, which are classified as waived tests; (2) tests of moderate complexity, which include certain tests categorized as provider-performed microscopy procedures; and (3) tests of high complexity. (42 C.F.R. § 493.5) **Section 2** of this regulation defines the term "exempt laboratory" as a laboratory in which, with certain exceptions, the only tests performed are: (1) waived tests; and (2) provider-performed microscopy procedures. **Section 6** of this regulation establishes the qualifications to serve as a director of an exempt laboratory.

Assembly Bill No. 243 of the 2015 Legislative Session made various changes concerning the performance of laboratory tests for the detection of the human immunodeficiency virus that are classified as waived tests under federal regulations. (Chapter 176, Statutes of Nevada 2015, at pages 847-49) **Sections 4 and 7-9** of this regulation make additional changes in connection with the performance of such tests. **Section 4** defines a laboratory in which the only test performed is

a test for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to federal regulations as an "HIV testing laboratory." **Section 7** establishes the qualifications to serve as a director of an HIV testing laboratory. **Section 8** provides that, with certain exceptions, the provisions of chapter 652 of NAC do not apply to the director of an HIV testing laboratory. **Section 9** provides that, with the exception of the requirements for licensure and the payment of fees, the provisions of chapter 652 of NAC do not apply to an HIV testing laboratory. **Section 9** also provides that none of the provisions of chapter 652 of NAC apply to a person who performs tests for the detection of the human immunodeficiency virus that are classified as waived tests under federal regulations if the person meets certain statutory requirements to perform such tests that were established in A.B. 243.

Under existing regulations, a laboratory that wishes to perform tests at a temporary location must apply to the Division for a permit and pay a fee. (NAC 652.170) **Sections 5 and 10** of this regulation provide that: (1) only a licensed laboratory may obtain such a permit; and (2) such a permit expires 90 days after its effective date.

Section 11 of this regulation eliminates a provision of existing regulations which provides that the fee which accompanies an application for licensure as a laboratory director is not refundable.

Under existing law, the Medical Laboratory Advisory Committee advises the State Board of Health on matters of policy concerning medical laboratories, qualifications of laboratory directors and personnel and other matters. (NRS 652.160) **Section 12** of this regulation eliminates a provision of existing regulations, which requires the Division, if it cannot determine the qualifications of an applicant for a license as a director of a licensed laboratory, to submit the application to the Committee for its recommendation before making a determination. **Section 21** of this regulation eliminates a similar requirement that the Division refer to the Committee for its recommendation an application for certification to work in a laboratory at any technical level if the application is incomplete or requires further review.

Existing federal regulations require laboratories to participate in a program of proficiency testing. (42 C.F.R. § 493.801) Under existing regulations, the director of a laboratory that fails to perform a particular procedure satisfactorily in two out of any three proficiency testing events for the procedure must ensure that the laboratory ceases to perform the procedure until the laboratory corrects the violation. (NAC 652.284) **Section 13** of this regulation revises the pattern of test failures that triggers a director's duty to ensure that the laboratory ceases performing the procedure.

Section 14 of this regulation revises certain provisions of existing regulations concerning the provision by the Division of a statement of violations to a laboratory following an inspection and the submission to the Division of a plan of correction.

Existing law requires the Board to adopt regulations concerning the licensure of laboratory directors and authorizes the Board to establish the qualifications required for such licensure. (NRS 652.125, 652.130) Existing regulations identify certain professional credentialing institutions whose certifications the Board may accept in determining whether a person has the qualifications for a license as a director of certain licensed laboratories or a registered laboratory.

(NAC 652.380, 652.395) **Sections 15 and 17** of this regulation identify certain additional institutions whose certifications the Board may accept for those purposes. Under existing regulations, only a licensed physician certified in the subspecialty of pulmonary disease by the American Board of Internal Medicine is qualified for a license as a director of a licensed laboratory testing for pulmonary conditions. (NAC 652.385) **Section 16** of this regulation provides that certification by any other nationally recognized board of internal medicine acceptable to the Division is also sufficient for this purpose.

Existing regulations establish various alternative avenues to qualify for a certificate as a clinical laboratory technologist. One such avenue allows a person to qualify for such a certificate if the person: (1) has a bachelor's degree in one of the chemical, physical or biological sciences; (2) has passed an approved national examination for certification; and (3) has at least 1 year of additional full-time experience or training in the specialty or subspecialty in which the person performs tests. (NAC 652.420) **Section 18** of this regulation requires that the experience or training be obtained in a licensed laboratory or a laboratory of a hospital, health department or university. Under existing regulations, a technologist who wishes to be certified by the Division in a specialty must, in addition to other requirements, obtain 1 year of experience working in a licensed laboratory or a laboratory of a hospital, health department or university and must submit with his or her application a letter from the director of the laboratory in which the applicant obtained his or her experience which verifies that the applicant has the experience required. (NAC 652.480) **Section 22** of this regulation requires that the experience be full-time, but allows it to also consist of training. **Section 22** also requires that the letter from the laboratory director be signed and dated.

Section 19 of this regulation: (1) updates the name of the entity that certifies a program of histotechnology whose completion is an acceptable qualification for a certificate as a histologic technician; and (2) revises the qualifications for a certificate as a histologic technician to specify that an associate degree is a valid qualification only if the degree is in chemistry, biology or a physical science.

Section 20 of this regulation clarifies that the provisions of existing regulations concerning the requirement to complete a certain number of hours of continuing education as a condition to reinstate an inactive or delinquent license or certificate do not apply to a person certified as an office laboratory assistant or to such a certificate.

Under existing regulations, a person who has submitted an application for certification may be granted temporary employment for up to 6 months while the application is being processed. A person who has been issued a provisional certificate may also be granted temporary employment for up to 6 months. (NAC 652.470) **Section 21** of this regulation extends the period of temporary employment to up to 12 months for persons whose applications are being processed. **Section 21** also provides that temporary employment may be granted to a person who has been issued a provisional certificate until the expiration of the provisional certificate.

Under existing regulations, the Division will issue a provisional certification to a technologist or technician who is required to pass a national examination for certification if he or she has been accepted as a candidate for testing. A provisional certificate expires 180 days after issuance and

is not renewable. (NAC 652.486) **Section 23** of this regulation revises the circumstances under which a provisional certificate may be issued and provides that such a certificate expires 18 months after issuance.

Existing regulations set forth the various fees that the Division is authorized to charge and collect. (NAC 652.488) **Section 24** of this regulation: (1) establishes the fee for the licensure of an HIV testing laboratory; (2) clarifies that the inspection fee for a laboratory that files an application to perform additional specialty tests is assessed on the application as a whole regardless of the number of tests included in the application; and (3) exempts an HIV testing laboratory from otherwise applicable fees for changing the location, director or name of the laboratory. **Section 24** also provides that a person will be deemed to have paid any fee otherwise charged and collected by the Division in connection with a medical laboratory if the person is, or is employed by, a person, governmental entity or fire-fighting agency that holds and has paid the fee for a permit issued by a health authority to operate an ambulance or air ambulance service or to provide certain emergency medical services.

Under existing regulations, a program of training intended to prepare a person for certification as a technician must be approved by the Board. (NAC 652.600) **Section 25** of this regulation requires such programs to be approved instead by the Division.

Section 1. Chapter 652 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 8, inclusive, of this regulation.

Sec. 2. ***1. Except as otherwise provided in this section and NAC 652.175, "exempt laboratory" means a laboratory in which each test performed is:***

(a) Classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; or

(b) Categorized as a provider-performed microscopy procedure pursuant to 42 C.F.R. § 493.19.

2. The term does not include an HIV testing laboratory.

Sec. 3. ***"Form" includes, without limitation, a printed form, an electronic form or an online or interactive process provided via the Internet.***

Sec. 4. ***"HIV testing laboratory" means a laboratory in which the only test performed is a test for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A.***

Sec. 5. *1. A licensed laboratory that wishes to collect specimens or perform tests, or both, at a location other than the location set forth in its license must obtain a permit to operate a laboratory at a temporary location.*

2. An application for a permit to operate a laboratory at a temporary location must be:

(a) Made on a form provided by the Division;

(b) Submitted to the Division in the manner set forth in NAC 652.170; and

(c) Accompanied by the fee set forth in NAC 652.488.

3. The Division shall notify an applicant of the disposition of an application within 30 days after receipt of a completed application.

4. A permit to operate a laboratory at a temporary location issued pursuant to this section expires 90 days after the effective date of the permit.

Sec. 6. *1. Except as otherwise provided in subsection 2 and NAC 652.395, to qualify to serve as a director of an exempt laboratory, a person must be:*

(a) A licensed physician;

(b) Qualified for a license as a director of a licensed laboratory pursuant to NAC 652.380;

(c) Qualified for a license as a director of a registered laboratory pursuant to NAC 652.395;

(d) An advanced practice registered nurse licensed pursuant to chapter 632 of NRS;

(e) A physician assistant licensed pursuant to chapter 630 or 633 of NRS;

(f) A general supervisor of a licensed laboratory certified in accordance with NAC 652.410; or

(g) A clinical laboratory technologist certified in accordance with NAC 652.420.

2. To qualify to serve as a director of an exempt laboratory in which the only tests performed are glucose tests that are classified as waived tests pursuant to 42 C.F.R. Part 493, Subpart A, a person must be:

(a) A person identified in subsection 1;

(b) A nurse licensed pursuant to chapter 632 of NRS;

(c) A pharmacist registered pursuant to chapter 639 of NRS; or

(d) A person licensed or certified pursuant to chapter 652 of NRS, other than a certified blood-gas assistant, certified laboratory assistant or certified office laboratory assistant.

3. As used in this section, "licensed physician" includes:

(a) A physician licensed as a doctor of medicine pursuant to chapter 630 of NRS;

(b) A physician licensed as a doctor of osteopathic medicine pursuant to chapter 633 of NRS;

(c) A chiropractic physician licensed pursuant to chapter 634 of NRS; and

(d) A podiatric physician licensed pursuant to chapter 635 of NRS.

Sec. 7. *To qualify to serve as a director of an HIV testing laboratory, a person must:*

1. Possess the technical and managerial skills necessary to perform the duties of a laboratory director set forth in NRS 652.180; and

2. Satisfy the requirements set forth in NRS 652.186 to perform a test for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A.

Sec. 8. *Except as otherwise provided in section 7 of this regulation, the provisions of this chapter, including, without limitation, any requirement to perform duties other than those prescribed in NRS 652.180, do not apply to the director of an HIV testing laboratory.*

Sec. 9. NAC 652.155 is hereby amended to read as follows:

652.155 1. Except as otherwise provided in this section and NRS ~~[652.230,]~~ ***652.071,*** the provisions of this chapter:

(a) Apply to:

(1) A laboratory which is licensed pursuant to NRS 652.080 and which provides services to the public; and

(2) A nonexempt laboratory which is registered pursuant to NAC 652.175; and

(b) Do not apply to ~~[an exempt laboratory]~~ :

(1) ***An exempt laboratory which:***

(I) Is licensed pursuant to chapter 652 of NRS; and

(II) Pays the applicable fees required by NAC 652.488;

(2) An HIV testing laboratory which:

(I) Is licensed pursuant to chapter 652 of NRS; and

(II) Pays the applicable fees required by NAC 652.488; or

(3) A laboratory which is registered ***as exempt*** pursuant to NAC 652.175.

2. Except as otherwise provided in subsection 3, a person who is employed by a laboratory that is licensed by or registered with the Division pursuant to chapter 652 of NRS may perform a test without complying with the provisions of this chapter if:

(a) The test has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; and

(b) The director, a designee of the director or a licensed physician at the laboratory at which the test is performed:

(1) Verifies that the person is competent to perform the test;

(2) Ensures that the test is performed in accordance with instructions of the manufacturer of the test; and

(3) Validates and verifies the manner in which the test is performed by using controls which ensure that the results of the test will be accurate and reliable.

3. Except as otherwise provided in subsection 4, the provisions of subsection 2 do not relieve a person who performs a test from the requirement to:

(a) Comply with the policies and procedures that the director of the laboratory at which the test is performed has established pursuant to NAC 652.280; ~~[or]~~

(b) ***Comply with the laboratory safety guidelines adopted by the laboratory pursuant to NAC 652.291; or***

(c) Obtain certification pursuant to NAC 652.470 and pay the applicable fees as set forth in NAC 652.488.

4. An advanced practice registered nurse as defined in NRS 632.012 or a physician assistant as defined in NRS 630.015 who is employed by a laboratory that is licensed by or registered with the Division pursuant to chapter 652 of NRS and who has not received certification pursuant to NAC 652.470 may perform a test without complying with the provisions of this chapter if the test:

(a) Has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; or

(b) Is a provider-performed microscopy ***procedure*** categorized pursuant to 42 C.F.R. § 493.19.

5. ***Except as otherwise provided in this subsection, a person may perform a test for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A, without complying with the provisions of this chapter if he or***

she complies with NRS 652.186. This subsection does not apply to a person who holds a license or certification issued pursuant to this chapter or a license or certification described in NRS 652.210.

6. As used in this section, "licensed physician" includes:

(a) A physician licensed as a doctor of medicine pursuant to chapter 630 of NRS;

(b) A physician licensed as a doctor of osteopathic medicine pursuant to chapter 633 of NRS;

(c) A chiropractic physician licensed pursuant to chapter 634 of NRS; and

(d) A podiatric physician licensed pursuant to chapter 635 of NRS.

Sec. 10. NAC 652.170 is hereby amended to read as follows:

652.170 1. An application for a license or registration for a laboratory must be made on a form provided by the Division. Upon receipt of a completed application, the Division shall conduct an inspection of the facility which may include an examination of the policies and procedures of the laboratory to determine whether the laboratory is in substantial compliance with this chapter for the procedures for testing that the laboratory desires to provide.

2. The Division shall notify the applicant of the disposition of the application within 30 days after receipt of the application.

3. ~~[A laboratory seeking to perform tests at a temporary location must submit to the Division an application on the form provided by the Division and the fees required by NAC 652.488.~~

~~4.]~~ The laboratory director shall include at least one of the following forms of proof of identity with the application:

(a) An electronic signature;

(b) A notarized statement;

(c) A copy of a form of government-issued identification, which may include, without limitation, a driver's license, passport, identification card issued by the Department of Motor Vehicles or other government-issued identification acceptable to the Division; or

(d) Other proof of identity acceptable to the Division.

~~[5.]~~ ***4.*** As used in this section, "electronic signature" means a user name attached to or logically associated with a record and executed or adopted by an applicant with the intent to sign an electronic application or other document.

Sec. 11. NAC 652.200 is hereby amended to read as follows:

652.200 An application for a license as a director must be on a form provided by the Division, giving complete information as indicated, including educational background, experience and the identity of the laboratory to be directed. ~~[The fee for licensure is not refundable.]~~

Sec. 12. NAC 652.210 is hereby amended to read as follows:

652.210 A license as a director may be issued by the Division on behalf of the Board for those applicants who qualify for licensure under NAC 652.380 ~~[or 652.383. If the Division cannot determine the qualifications of an applicant, the Division shall submit the application to the Committee for its recommendation before making a determination.]~~ ***to 652.395, inclusive.*** The Division shall notify the applicant of the status of the application within 30 days after receipt of ~~[the]~~ ***a completed*** application.

Sec. 13. NAC 652.284 is hereby amended to read as follows:

652.284 A director shall ensure that:

1. The laboratory is enrolled in a program for proficiency testing regarding all the testing performed by the laboratory.

2. All procedures of the program are followed, including:

(a) The testing of samples as required; and

(b) The return of results within the required time.

3. Corrective action, which is approved by the Division, is performed if any results are found to be unacceptable or unsatisfactory.

4. The maintenance of documentation to verify that all reports received regarding the program are reviewed by appropriate members of the staff for evaluation of the performance of the laboratory and identification of any problems requiring corrective action.

5. If the laboratory fails to perform satisfactorily in two ***consecutive testing events or two*** out of ~~[any]~~ three testing events for a procedure, ***and thereafter fails to perform that procedure satisfactorily in one or more subsequent testing events,*** the laboratory ceases to perform that procedure until it demonstrates to the satisfaction of the Division that the violations of the laboratory have been corrected in such a manner as to ensure that they will not recur.

Sec. 14. NAC 652.320 is hereby amended to read as follows:

652.320 1. Except as otherwise provided in this subsection, the Division shall inspect periodically the premises and operation of each laboratory, including, without limitation, the premises of an outpatient center of the laboratory, if any. A laboratory that is subject to inspection by an accrediting organization approved by the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services pursuant to 42 C.F.R. §§ 493.551 to 493.575, inclusive, is not required to be inspected periodically by the Division if the reports of the inspections are available to the Division.

2. Upon receipt of a complaint against a laboratory or its personnel, except for a complaint concerning the cost of services, the Division may conduct an investigation into the premises,

qualifications of personnel, methods of operation, policies, procedures and records of that laboratory or any other laboratory which may have information pertinent to the complaint.

3. The Division shall report violations noted at the time of each inspection by ~~[forwarding to]~~ ***providing*** the director ***, or the director's designee, with*** a statement of violations, which must include the severity level for the violation as determined by the Division, and a form for the director to submit a plan of correction. Any violation for which a severity level is not specified in the statement of violations is presumed to be a violation of severity level one. The director shall ~~[return the form]~~ ***submit the plan of correction*** to the Division, containing thereon the plan of correction for each of the violations, within ~~[10 working]~~ ***14*** days after receiving the form. The plan must indicate the date by which each violation will be corrected.

4. Failure to submit the plan of correction timely pursuant to subsection 3 to the Division constitutes a separate violation subject to monetary penalties with a severity level rated at the same level as the highest violation identified on the statement of violations.

Sec. 15. NAC 652.380 is hereby amended to read as follows:

652.380 Except as otherwise provided in NAC 652.383, to qualify for a license as a director of a licensed laboratory, a person must meet one of the following qualifications:

1. Be a physician who is licensed to practice medicine in this State and:

(a) Be certified in anatomical and clinical pathology, or in clinical pathology, by:

(1) The American Board of Pathology; or

(2) The American Osteopathic Board of Pathology;

(b) Possess qualifications which are equivalent to those required for certification by either of the institutions listed in paragraph (a);

(c) Within the 10 years immediately preceding application for a license, have successfully completed a 4-year program accredited by the National Accrediting Agency for Clinical Laboratory Sciences;

(d) Be certified, in accordance with NAC 652.410, as a general supervisor; or

(e) Have at least 4 years of experience as a technologist:

(1) In a licensed laboratory or a laboratory of a hospital, health department or university;

(2) As a full-time employee working at least 30 hours per week; and

(3) Under the supervision of a director who possesses a doctoral degree.

2. Hold an earned doctoral degree from an accredited institution, with a chemical, physical, biological or clinical laboratory science as the major, and:

(a) Be certified by:

(1) The American Board of Medical Microbiology;

(2) The American Board of Clinical Chemistry;

(3) The American Board of Bioanalysis;

(4) The American Board of Medical Laboratory Immunology;

(5) The American Board of Forensic Toxicology; ~~[or]~~

(6) The American Board of Medical Genetics ~~[,]~~ ***and Genomics;***

(7) The National Registry of Certified Chemists;

(8) The American Board of Histocompatibility and Immunogenetics; or

(9) Any other institution approved by the United States Department of Health and Human Services in accordance with 42 C.F.R § 493.1443(b)(3); or

(b) Possess qualifications which are equivalent to those required for certification by any of the institutions listed in paragraph (a).

Sec. 16. NAC 652.385 is hereby amended to read as follows:

652.385 ***1.*** To qualify for a license as a director of a licensed laboratory testing for pulmonary conditions, a person must:

~~[1.]~~ ***(a)*** Be a physician certified ~~[by the American Board of Internal Medicine]~~ in the subspecialty of pulmonary disease ~~[,]~~ ***by the:***

(1) American Board of Internal Medicine; or

(2) Any other nationally recognized board of internal medicine acceptable to the Division; or

~~[2.]~~ ***(b)*** In a geographical area which does not have a person who meets the qualifications set forth in ~~[subsection 1,]~~ ***paragraph (a),*** be a physician licensed to practice in this State, whose experience is acceptable to the Division.

2. As used in this section, "physician" means a physician licensed pursuant to chapter 630 or 633 of NRS.

Sec. 17. NAC 652.395 is hereby amended to read as follows:

652.395 To qualify for a license as a director of a registered laboratory, a person must:

1. Be a physician licensed to practice in this State and have:

(a) At least 1 year of experience directing or supervising laboratory testing in a laboratory which meets the requirements of NAC 652.170 to 652.600, inclusive;

(b) Credit for at least 20 hours of continuing medical education in laboratory practice regarding the responsibilities of a director; or

(c) Laboratory training, obtained during medical residency, equivalent to the training required by paragraph (b); or

2. Hold an earned doctoral degree from an accredited institution, with a major in chemical, physical, biological or clinical laboratory science, and:

(a) Have at least 1 year of experience directing or supervising laboratory testing in a laboratory which meets the requirements of NAC 652.170 to 652.600, inclusive;

(b) Be certified by:

(1) The American Board of Medical Microbiology;

(2) The American Board of Bioanalysis;

(3) The American Board of Medical Laboratory Immunology;

(4) The American Board of Clinical Chemistry;

(5) The American Board of Forensic Toxicology; ~~[or]~~

(6) The American Board of Medical Genetics ~~[,]~~ ***and Genomics;***

(7) The National Registry of Certified Chemists;

(8) The American Board of Histocompatibility and Immunogenetics; or

(9) Any other institution approved by the United States Department of Health and Human Services in accordance with 42 C.F.R § 493.1443(b)(3); or

(c) Possess qualifications which are equivalent to those required for certification by any of the institutions listed in paragraph (b).

Sec. 18. NAC 652.420 is hereby amended to read as follows:

652.420 1. A clinical laboratory technologist may:

(a) Perform tests which require the exercise of independent judgment, under minimum supervision or review by the director or general supervisor, in those specialties for which the technologist has had adequate education, training and experience and in which he or she has demonstrated a proficiency; and

(b) Supervise, if necessary, the work of the medical technicians and laboratory assistants.

2. To qualify for a certificate as a clinical laboratory technologist, a person must:

(a) Successfully complete a full course of study which meets all academic requirements for a bachelor's degree in medical technology from an accredited college or university, and pass a national examination for certification approved by the Board;

(b) Successfully complete a course of study for a bachelor's degree in one of the chemical, physical or biological sciences at an accredited college or university, have at least 1 year of additional full-time experience or training in ***a licensed laboratory, or laboratory of a hospital, health department or university in*** the specialty or subspecialty in which the person performs tests, and pass a national examination for certification approved by the Board; or

(c) Pass the examination for clinical laboratory technologists given by the United States Department of Health and Human Services.

Sec. 19. NAC 652.437 is hereby amended to read as follows:

652.437 1. To qualify for a certificate as a histologic technician, a person must:

(a) Successfully complete a program in histotechnology certified by the ~~[Committee]~~ ***Commission*** on ***Accreditation of*** Allied Health Education ~~[and Accreditation;]~~ ***Programs;***

(b) Have an associate degree ***in chemistry, biology or a physical science*** or successfully complete at least 60 semester hours or the equivalent of academic credit from an accredited college or university with at least 12 semester hours in science, of which 6 hours are in chemistry and 6 hours are in biology, and have 1 year of full-time experience in histotechnology in a histology laboratory under the supervision of a pathologist certified in anatomic pathology by the American Board of Pathology Incorporated or a pathologist eligible for certification in anatomic pathology; or

(c) Be a high school graduate or the equivalent and have 2 years of full-time experience in histotechnology, within the preceding 5 years, in a histology laboratory under the supervision of a pathologist certified in anatomic pathology by the American Board of Pathology Incorporated or a pathologist eligible for certification in anatomic pathology.

2. A histologic technician may only perform histologic procedures under the supervision of a histotechnologist or the director and may only perform cytologic procedures under the direction of a cytotechnologist, a histotechnologist or the director.

Sec. 20. NAC 652.461 is hereby amended to read as follows:

652.461 1. Except as otherwise provided in subsection 2 ~~[, any]~~ ***:***

(a) Any person desiring to have an inactive or a delinquent license or certificate reinstated shall submit evidence to the Division that he or she has completed 1 unit of continuing education within the 2 years immediately preceding the application for reinstatement of the license or certificate.

~~[2.]~~ ***(b)*** An inactive or delinquent license or certificate may be conditionally reinstated without the evidence required by ~~[subsection 1]~~ ***paragraph (a)*** if the applicant completes one unit of continuing education within a period established by the Division. Any failure to complete the continuing education or satisfy any other condition established by the Division is a ground for revocation of the license or certificate.

2. This section does not apply to a person certified as an office laboratory assistant or to such a certificate.

Sec. 21. NAC 652.470 is hereby amended to read as follows:

652.470 1. Before working in a laboratory at any technical level:

(a) An application for certification must be made on a form provided by the Division giving information on the applicant's educational background;

(b) Substantiating documents such as college or other academic transcripts or copies of certificates of registration should accompany the application, but must be submitted within 6 months after the date of the application;

(c) The form must indicate the level and title for which certification is desired; and

(d) The fee prescribed in NAC 652.488 must accompany the application.

2. Temporary employment ~~[, for a period not exceeding 6 months,]~~ may be granted ***:***

(a) For a period not exceeding 12 months while the application is being processed ***;*** ~~[,]~~ or ~~[when]~~

(b) If the applicant has been issued a provisional certificate ~~[.]~~ ***, until the expiration of the provisional certificate.***

3. The Division shall issue the appropriate certificate on behalf of the Board when it is determined that all requirements for certification are satisfied. ~~[Applications which are incomplete or require further review must be referred to the Committee for its recommendation.]~~

4. A person may upgrade his or her certificate after completing the appropriate additional experience, training or academic requirements, or any combination thereof, by applying to the Division pursuant to subsection 1.

5. A person whose certification has lapsed for more than 5 years may reapply for certification by submitting an original application to the Division accompanied by the fee prescribed in NAC 652.488.

6. A person whose certification has lapsed for 5 years or less may reapply for certification by submitting an application for reinstatement to the Division accompanied by the fee prescribed in NAC 652.488.

7. A certificate will be placed in an inactive status upon the approval of the Division and payment of the fee prescribed in NAC 652.488.

Sec. 22. NAC 652.480 is hereby amended to read as follows:

652.480 1. Except as otherwise provided in NAC 652.483, to be certified by the Division in a specialty, a technologist must pass a national examination for certification in the specialty and must have successfully completed a course of study for a bachelor's degree in one of the chemical, physical or biological sciences at an accredited college or university, and have ***at least*** 1 year of ***additional full-time*** experience ~~[working]~~ ***or training*** in a licensed laboratory, or a laboratory of a hospital, health department or university, in the chosen specialty under the supervision of a director who possesses a doctoral degree.

2. Each applicant for certification in a specialty must designate on the application the specialty in which he or she desires to be certified. The applicant must submit with the application:

(a) Verification of successful completion of the course of study required by subsection 1; and

(b) A ***signed and dated*** letter from the director of the laboratory in which the applicant obtained ***his or her*** experience ***,*** which verifies that the applicant has the experience required by subsection 1.

3. Each certificate will designate the holder by:

(a) The title of "Technologist" in a specialty; or

(b) An equivalent title and will show his or her area of specialty by a subtitle.

Sec. 23. NAC 652.486 is hereby amended to read as follows:

652.486 ***1.*** The Division shall ~~[, upon request by]~~ ***issue a provisional certificate to*** a technologist or technician who is ***otherwise qualified for a certificate if he or she has not yet:***

(a) Passed a required ~~[to pass a]~~ national examination for certification ~~[and who]~~ ***, but*** has been accepted as a candidate for testing ~~[, issue him or her a provisional certificate. The]~~ ***; or***

(b) Accumulated the amount of experience or training required for certification.

2. A technologist or technician must apply for a provisional certificate on a form provided by the Division and pay the fee for initial certification of personnel set forth in NAC 652.488.

3. A provisional certificate ***issued pursuant to this section*** expires ~~[180 days]~~ ***18 months*** after the date of issue and is not renewable. ~~[No technologist or technician may request more than three provisional certificates pursuant to this section. The fee for a provisional certificate is the same as the fee set forth in NAC 652.488 for the certification of personnel.]~~

Sec. 24. NAC 652.488 is hereby amended to read as follows:

652.488 ~~[The]~~

1. Except as otherwise provided in this section, the following fees will be charged:

~~[1.]~~ ***(a)*** Licensure of laboratory not described in ~~[subsection 2]~~ ***paragraph (b) or (c)***

Initial:

Annual test volume less than 25,000 ..... $1,100

Annual test volume at least 25,000 but less than 100,000 3,000

Annual test volume 100,000 or more 4,000

Biennial renewal:

Annual test volume less than 25,000 800

Annual test volume at least 25,000 but less than 100,000 2,500

Annual test volume 100,000 or more 3,500

Reinstatement:

Annual test volume less than 25,000.....1,100

Annual test volume at least 25,000 but less than 100,000.....3,000

Annual test volume 100,000 or more 4,000

~~[2.]~~ ***(b)*** Licensure of laboratory operated by health district, district board of health, county board of health or city or town board of health, or the State Public Health Laboratory

Initial:

Annual test volume less than 25,000.....$550

Annual test volume at least 25,000 but less than 100,000.....800

Annual test volume 100,000 or more 1,150

Biennial renewal:

Annual test volume less than 25,000.....400

Annual test volume at least 25,000 but less than 100,000.....600

Annual test volume 100,000 or more 800

Reinstatement:

Annual test volume less than 25,000.....550

Annual test volume at least 25,000 but less than 100,000.....800

Annual test volume 100,000 or more 1,150

~~[3.]~~ ***(c) Licensure of HIV testing laboratory***

Initial.....$150

Biennial renewal.....150

(d) Licensure of director pursuant to paragraph (b) of subsection 3 of NAC 652.175 or NAC 652.380 to 652.395, inclusive

Initial $500

Biennial renewal 300

Reinstatement 500

~~[4.]~~ ***(e)*** Registration of laboratory operated pursuant to NRS ~~[652.235]~~ ***652.072*** which is nonexempt pursuant to NAC 652.155

Initial $1,500

Biennial renewal 900

Reinstatement 1,500

~~[5.]~~ ***(f)*** Registration of laboratory operated pursuant to NRS ~~[652.235]~~ ***652.072*** which is exempt pursuant to NAC 652.155

Initial $500

Biennial renewal 300

~~[6.]~~ ***(g)*** Certification of personnel

Initial:

General supervisor $225

Technologist 113

Technician 113

Pathologist's assistant 113

Point-of-care test analyst 75

Laboratory, blood-gas or office laboratory assistant 60

Biennial renewal:

General supervisor.....150

Technologist.....75

Technician.....75

Pathologist's assistant.....75

Point-of-care test analyst.....60

Laboratory, blood-gas or office laboratory assistant.....45

Reinstatement:

General supervisor.....225

Technologist.....113

Technician.....113

Pathologist's assistant.....113

Point-of-care test analyst.....75

Laboratory, blood-gas or office laboratory assistant.....60

~~[7.]~~ ***(h)*** Placement of license or certificate in inactive status.....$50

~~[8.]~~ ***(i)*** Issuance of original duplicate license or certificate.....$50

~~[9.]~~ ***(j)*** Permit to operate laboratory at temporary location.....$300

~~[10.]~~ ***(k)*** Change of location of laboratory.....$300

~~[11.]~~ ***(l)*** Change of director of laboratory.....$300

~~[12.]~~ ***(m)*** Change of name of laboratory.....$300

~~[13.]~~ ***(n)*** Inspection ~~[for]~~ ***following receipt of an application to perform*** additional ~~[specialties and subspecialties in which]~~ tests ~~[will be performed]~~ at ***a*** laboratory ***(per application)*** $300

~~[Plus $50 for each additional~~

~~specialty or subspecialty~~

~~14.~~ *(o)* Inspection of an outpatient center of a laboratory (per site)

Initial inspection.....$300

Inspection at time of biennial renewal 150

~~15.~~ *2.* If the Division conducts an inspection of a laboratory that is located outside of this State, the Division shall assess the expenses that the Division incurs as a result of the inspection to the laboratory. The laboratory shall reimburse the Division for the expenses assessed pursuant to this subsection.

3. The Division shall not charge or collect a fee set forth in paragraph (k), (l) or (m) of subsection 1 to an HIV testing laboratory.

4. The holder of or an applicant for a license or certificate issued pursuant to chapter 652 of NRS, or an applicant for a permit to operate a laboratory at a temporary location issued pursuant to section 5 of this regulation, shall be deemed to have paid any fee otherwise required pursuant to subsection 1 if the holder or applicant:

(a) Is, or is employed by, a medical laboratory that is operated by a person, governmental entity or fire-fighting agency that holds a permit issued by a health authority pursuant to NRS 450B.200; and

(b) Has paid the fee for the permit established by a board pursuant to NRS 450B.200.

5. As used in this section:

(a) "Board" has the meaning ascribed to it in NRS 450B.060.

(b) "Health authority" has the meaning ascribed to it in NRS 450B.077.

(c) "Permit" has the meaning ascribed to it in NRS 450B.100.

Sec. 25. NAC 652.600 is hereby amended to read as follows:

652.600 1. Any program of training intended to prepare a person for certification as a technician must be approved by the ~~[Board.]~~ ***Division.*** Application for approval must be submitted ~~[in writing]~~ to the ~~[Board.]~~ ***Division in the manner prescribed by the Division.*** The application must include:

(a) A description of the goals of the program;

(b) A description of the methods of instruction;

(c) A description of the contents of the courses;

(d) A description of the qualifications of the instructors;

(e) A description of the methods of evaluating the performance of the trainee; and

(f) The name of the director who is responsible for the program.

2. The director shall certify in writing to the Division each trainee who has successfully completed the program.