PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R126-21

February 2, 2022

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

AUTHORITY: §§ 1, 4, 6, 7, 9-11, 13-16 and 19, NRS 439.200, 652.123, 652.125 and 652.130; §§ 2, 3, 8 and 12, NRS 439.200, 652.123 and 652.130; § 5, NRS 439.200, 652.123, 652.125 and 652.130 and section 1 of Assembly Bill No. 330, Chapter 360, Statutes of Nevada 2021, at page 2156 (NRS 622.087); § 17, NRS 439.200, 652.123, 652.125, 652.127 and 652.130; § 18, NRS 439.150, 439.200 and 652.100.

A REGULATION relating to medical laboratories; exempting a licensed laboratory only for the collection of specimens that meets certain requirements from provisions governing laboratories; prescribing and revising the qualifications and duties of certain laboratory personnel; prescribing documentation necessary to verify the completion of certain training programs for the purpose of receiving equivalent credit toward the qualifications for the issuance of certain licenses and certificates; authorizing a medical officer of the Armed Forces of the United States to provide clinical laboratory services in a hospital under certain circumstances; revising requirements governing the supervision of certain licensed laboratories; prescribing certain fees relating to licensure as a licensed laboratory only for the collection of specimens; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the operator of a medical laboratory to obtain a license from the Division of Public and Behavioral Health of the Department of Health and Human Services. (NRS 652.080) **Section 2** of this regulation defines the term "licensed laboratory only for the collection of specimens" to mean a licensed laboratory at which the only task performed is the collection of tissues, secretions or excretions of the human body for certain examinations by another licensed laboratory. **Section 6** of this regulation makes a conforming change to indicate the placement of **section 2** in the Nevada Administrative Code. **Sections 3 and 7** of this regulation provide that a licensed laboratory only for the collection of specimens that meets certain requirements related to the operation of the laboratory is otherwise exempt from most regulations governing medical laboratories. **Section 11** of this regulation prescribes the required qualifications of a director of a licensed laboratory only for the collection of specimens. **Section 18** of this regulation prescribes the fees for the issuance, renewal and reinstatement of a licensed laboratory only for the collection of specimens.

Existing law requires the State Board of Health to adopt regulations for the certification and licensure of laboratory directors and laboratory personnel who perform technical duties other than the collection of blood. (NRS 652.125) Existing regulations prescribe the qualifications and duties of a general supervisor of a licensed laboratory. (NAC 652.410) **Section 4** of this regulation prescribes: (1) the qualifications of a general supervisor in a specialty; and (2) the duties of a general supervisor in a specialty, which consist of overseeing the technical and administrative functions of the laboratory relating to that specialty. **Sections 9-11 and 13-17** of this regulation revise the required qualifications of certain other laboratory personnel.

Existing law: (1) provides that persons who complete certain training programs for occupational, vocational, career, trade or technical education are eligible to receive equivalent credit towards related professional and occupational licenses and certifications; and (2) provides for the appeal of a denial of such equivalent credit. (Section 1 of Assembly Bill No. 330, chapter 360, Statutes of Nevada 2021, at page 2156 (NRS 622.087)) For the personnel of a medical laboratory, **section 5** of this regulation prescribes the documents required to verify completion of such a program for the purpose of receiving equivalent credit toward a license or certificate. Existing law and regulations: (1) authorize the Division to deny the issuance of a license or certificate if the denial of equivalent credit for a training program results in the applicant failing to possess the required qualifications for the issuance of the license or certificate; and (2) establish a process for a person aggrieved by the denial of a license or certificate under those circumstances to appeal. (NRS 652.220; NAC 439.300-439.395, 652.491, 652.493)

Existing law authorizes a hospital to enter into an agreement with the Armed Forces of the United States to allow a medical officer who is not licensed or certified in this State but meets certain other requirements to provide care in the hospital as part of a training or educational program designed to further the employment of the medical officer. (NRS 449.2455) **Section 7** authorizes such a medical officer who is not licensed or certified in this State to provide clinical laboratory services in a hospital pursuant to such an agreement.

Existing regulations require the Division to inspect periodically the premises and operation of each medical laboratory. (NAC 652.320) **Section 8** of this regulation authorizes: (1) an authorized employee or contractor of the Division to enter and inspect any building or premises to secure compliance with statutes and regulations governing medical laboratories; and (2) the Division to request records from certain licensed health care facilities or a licensed laboratory that may have information pertinent to a complaint which is within the authority of the Division to investigate. **Section 19** of this regulation makes a conforming change to revise an internal reference to a provision amended by **section 8**.

Existing regulations require the general supervisor of a licensed laboratory to be on the premises during all hours in which routine tests are being performed. (NAC 652.400) **Section 12** of this regulation authorizes the general supervisor of a licensed laboratory in a hospital to also oversee a licensed laboratory in a freestanding emergency room operated by the hospital if: (1) the licensed laboratory in the freestanding emergency room only performs point-of-care tests; (2) the general supervisor is on the premises of the licensed laboratory in the freestanding emergency room at least monthly; and (3) certain other requirements are met.

Section 1. Chapter 652 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 5, inclusive, of this regulation.

Sec. 2. ***"Licensed laboratory only for the collection of specimens" means a licensed laboratory at which the only task performed is the collection of tissues, secretions or excretions of the human body for microbiological, serological, immunohematological, cytological, histological, chemical, hematological, biophysical or toxicological examinations by another licensed laboratory.***

Sec. 3. ***1. A licensed laboratory only for the collection of specimens that elects pursuant to subparagraph (3) of paragraph (b) of subsection 1 of NAC 652.155 not to comply with the provisions of this chapter, other than those listed in subsection 3, must:***

(a) Have physical premises and environmental conditions that:

(1) Are appropriate for the collection of specimens, including, without limitation, the maintenance of an appropriate temperature for the collection and maintenance of specimens for the purpose of the analyses for which the specimens are collected; and

(2) Provide a safe environment in which personnel of the laboratory are protected from biological, physical and chemical hazards;

(b) Be adequately ventilated; and

(c) Have one or more showers and eyewashes where necessary for safety.

2. A person who is employed by a licensed laboratory only for the collection of specimens described in subsection 1 may collect a specimen if:

(a) The employee is competent to collect specimens; and

(b) Each specimen is:

(1) Collected in accordance with the policies of the licensed laboratory to which the specimen will be sent for analysis; and

(2) Labeled with the name of the patient and a unique identifier for the patient.

3. A licensed laboratory only for the collection of specimens described in subsection 1 shall comply with the provisions of:

(a) NAC 652.291;

(b) Subparagraphs (1) and (2) of paragraph (b) of subsection 2 of NAC 652.310; and

(c) Subsections 1 and 2 of NAC 652.350.

4. The director, a designee of the director or a licensed physician at a licensed laboratory for the collection of specimens described in subsection 1 shall regularly verify compliance with the requirements of subsections 1, 2 and 3.

Sec. 4. *1. To qualify for a certificate as a general supervisor in a specialty, a person must be:*

(a) A person who:

(1) Is a technologist certified in a specialty pursuant to NAC 652.478; and

(2) Has at least 3 years of experience as a full-time employee working at least 30 hours per week in a licensed laboratory or a laboratory of a college, university or school in the specialty in which he or she is certified, with at least 2 of those years spent working as a technologist under the supervision of a director who holds a doctoral degree;

(b) A person who:

(1) Holds a doctoral degree from an accredited institution in a chemical, physical or biological science, clinical laboratory science or medical technology; and

(2) Has at least 1 year of clinical experience as a full-time employee working at least 30 hours per week as a technologist in a licensed laboratory or a laboratory of a college, university or school under the supervision of a person who:

(I) Holds a doctoral degree; or

(II) Possesses the qualifications necessary for certification as a general supervisor of a licensed laboratory prescribed by NAC 652.410; or

(c) A person who:

(1) Holds a master's degree from an accredited institution in a chemical, physical or biological science, clinical laboratory science or medical technology; and

(2) Has at least 2 years of clinical experience as a full-time employee working at least 30 hours per week as a technologist in a licensed laboratory or a laboratory of a college, university or school under the supervision of a person who:

(I) Holds a doctoral degree; or

(II) Possesses the qualifications necessary for certification as a general supervisor of a licensed laboratory prescribed by NAC 652.410.

2. A general supervisor in a specialty may be certified in any specialty in which a technologist may be certified pursuant to subsection 1 of NAC 652.478.

3. The general supervisor in a specialty shall oversee the technical and administrative functions of the laboratory relating to that specialty and may supervise other personnel, as assigned by the director. A general supervisor in a specialty shall not perform or supervise technical or administrative functions relating to another specialty.

Sec. 5. *A person who wishes to receive equivalent credit pursuant to section 1 of Assembly Bill No. 330, chapter 360, Statutes of Nevada 2021, at page 2156 (NRS 622.087), towards the satisfaction of requirements for the issuance of a license or certificate pursuant to this chapter or chapter 652 of NRS for a training program for occupational, vocational, career, trade or technical education approved by the State Board of Education must submit, as part of the application for the license or certificate:*

1. Transcripts or other documents substantiating the courses completed as part of the training program; and

2. A copy of the certificate issued for the completion of the training program.

Sec. 6. NAC 652.010 is hereby amended to read as follows:

652.010 As used in this chapter, unless the context otherwise requires, the words and terms defined in NAC 652.020 to 652.151, inclusive, ***and section 2 of this regulation,*** have the meanings ascribed to them in those sections.

Sec. 7. NAC 652.155 is hereby amended to read as follows:

652.155 1. Except as otherwise provided in this section ***and section 3 of this regulation*** and NRS 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:

(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 licensed laboratory only for the collection of specimens which:***

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

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

(III) Has a director who possesses the qualifications prescribed by NAC 652.397; and

(IV) Complies with the requirements of section 3 of this regulation; or

(4) 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;

(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. ***A medical officer employed by the Armed Forces of the United States to provide clinical laboratory services who is not licensed or certified pursuant to this chapter may provide clinical laboratory services in a hospital as part of a training or educational program pursuant to an agreement entered into in accordance with the provisions of NRS 449.2455.***

7. 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. 8. 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. ***An authorized employee or contractor of the Division may enter and inspect any building or premises to secure compliance with or prevent a violation of any provision of this chapter or chapter 652 of NRS.***

3. 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.]~~ ***4. The Division may request records from any facility licensed pursuant to chapter 449 of NRS, including, without limitation, any facility which is required by the regulations adopted by the Board pursuant to NRS 449.0303 to be licensed, or any laboratory licensed pursuant to chapter 652 of NRS that may have information pertinent to a complaint which is within the authority of the Division to investigate.***

5. The Division shall report violations noted at the time of each inspection by 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 submit the plan of correction to the Division, containing thereon the plan of correction for each of the violations, within 14 days after receiving the form. The plan must indicate the date by which each violation will be corrected.

~~[4.]~~ ***6.*** Failure to submit the plan of correction timely pursuant to subsection ~~[3]~~ ***5*** 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. 9. 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 ***have at least 1 year of experience performing tests at the level of a technologist in a clinical laboratory and*** 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;

(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. 10. 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 ~~[:]~~ ***have at least 1 year of experience performing tests at the level of a technologist in a clinical laboratory and:***

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;

(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. 11. NAC 652.397 is hereby amended to read as follows:

652.397 1. Except as otherwise provided in subsection 2 and NAC 652.395, to qualify to serve as a director of an exempt laboratory ~~[,]~~ ***or a licensed laboratory only for the collection of specimens,*** 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 ~~[.]~~ ***; or***

(h) A dentist licensed pursuant to chapter 631 of NRS.

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. 12. NAC 652.400 is hereby amended to read as follows:

652.400 1. The general supervisor of a licensed laboratory shall oversee the technical and administrative functions of the laboratory and may supervise other personnel, as assigned by the director.

2. ~~[The]~~ ***Except as otherwise provided in this section, the*** general supervisor shall be on the premises during all hours in which routine tests are being performed. The presence of the supervisor is not required during the performance of emergency testing procedures after scheduled work hours, but he or she shall review these procedures during his or her next period of duty.

3. A general supervisor of a licensed laboratory who works in a hospital that operates a freestanding emergency room may oversee the technical and administrative functions of a licensed laboratory in the freestanding emergency room if:

(a) The freestanding emergency room is covered by the license of the hospital issued by the Division pursuant to chapter 449 of NRS or, if applicable, the certification of the hospital to participate in Medicare, made as provided in 42 C.F.R. Parts 482 to 498, inclusive;

(b) The licensed laboratory in the freestanding emergency room only performs point-of-care tests;

(c) The general supervisor is on the premises of the licensed laboratory in the freestanding emergency room at least monthly to ensure that tests are performed in accordance with the instructions of the manufacturer of the tests and all applicable federal and state laws and regulations;

(d) Persons performing tests in the licensed laboratory in the freestanding emergency room are authorized to do so under the provisions of this chapter and NRS 652.210; and

(e) The licensed laboratory in the freestanding emergency room is in compliance with all other federal and state laws and regulations.

4. A general supervisor who oversees the technical and administrative functions of a licensed laboratory in a freestanding emergency room pursuant to subsection 3 shall be deemed to be the general supervisor of that licensed laboratory for all purposes.

Sec. 13. NAC 652.410 is hereby amended to read as follows:

652.410 1. To qualify for a certificate as a general supervisor of a licensed laboratory, a person must, except as otherwise provided in this section, be:

(a) A qualified physician serving on behalf of the director; or

(b) A clinical laboratory technologist who has had at least 3 years of experience in a laboratory as a full-time employee working at least 30 hours per week, of which at least 2 years have been spent working ~~[:]~~ ***at the level of a technologist:***

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

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

2. A technologist certified by the Board in a specialty who has had at least 3 years of experience in a laboratory as a full-time employee working at least 30 hours per week, of which at least 2 years have been spent working ~~[:]~~ ***at the level of a technologist:***

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

(b) Under the supervision of a director who possesses a doctoral degree,

➥ qualifies for a certificate as a general supervisor of a licensed laboratory if the tests performed in the laboratory are solely in his or her specialty.

3. A person who possesses a doctoral degree from an accredited institution with a major in chemical, physical or biological science ***, clinical laboratory science or medical technology*** and who has had at least 1 year of ***clinical*** experience ***at the level of a technologist*** in a licensed laboratory or a laboratory of a hospital, university or health department as a full-time employee working for at least 30 hours per week under the supervision of a director who possesses a doctoral degree qualifies for a certificate as a general supervisor of a licensed laboratory.

4. A person who possesses a master's degree from an accredited institution with a major in chemical, physical or biological science ***, clinical laboratory science or medical technology*** and who has had at least 2 years of ***clinical*** experience ***at the level of a technologist*** in a licensed laboratory or a laboratory of a hospital, university or health department as a full-time employee working at least 30 hours per week under the supervision of a director who possesses a doctoral degree qualifies for a certificate as a general supervisor of a licensed laboratory.

Sec. 14. 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 ***, clinical laboratory science or medical technology*** at an accredited college or university, have at least 1 year of additional full-time ***clinical*** experience or training ***at the level of a technologist*** 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. 15. NAC 652.454 is hereby amended to read as follows:

652.454 ***1.*** To qualify for a certificate as a point-of-care test analyst, a person must:

~~[1.]~~ ***(a)*** Be a:

~~[(a)]~~ ***(1)*** Registered nurse as defined in NRS 632.019;

~~[(b)]~~ ***(2)*** Advanced practice registered nurse as defined in NRS 632.012;

~~[(c)]~~ ***(3)*** Licensed practical nurse as defined in NRS 632.016;

~~[(d)]~~ ***(4)*** Practitioner of respiratory care as defined in NRS 630.023;

~~[(e)]~~ ***(5)*** Physician assistant as defined in NRS 630.015;

~~[(f)]~~ ***(6)*** Registered pharmacist as defined in NRS 639.015 who has participated in the development of written guidelines and protocols as described in ~~[subsection 8 of]~~ NRS 639.0124 ~~[; or~~

~~(g)]~~ ***, as amended by section 1 of Senate Bill No. 229, chapter 290, Statutes of Nevada 2021, at page 1660, section 2 of Senate Bill No. 325, chapter 492, Statutes of Nevada 2021, at page 3201, and section 5 of Senate Bill No. 190, chapter 504, Statutes of Nevada 2021, at page 3270;***

(7) Certified laboratory assistant who has successfully completed training approved by a director in performing point-of-care tests;

(8) Certified nursing assistant, as defined in NRS 632.0166; or

(9) Student enrolled in an accredited school of professional nursing or graduate of such a school pending the results of the first licensing examination scheduled by the State Board of Nursing following graduation; and

~~[2.]~~ ***(b)*** Provide verification from a director that the person has successfully completed training approved by a director in performing the preanalytic, analytic and postanalytic phases of point-of-care tests.

2. A certified nursing assistant who is certified as a point-of-care test analyst may only perform glucose testing classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A.

Sec. 16. 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 ***clinical*** experience or training ***at the level of a technologist*** 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. 17. NAC 652.4855 is hereby amended to read as follows:

652.4855 To qualify for certification as a laboratory assistant, an applicant must submit with the application proof that the applicant has a high school diploma or a general equivalency diploma and has:

1. Completed at least 6 months of training approved by the Division and demonstrated an ability to perform laboratory procedures in the laboratory where he or she has received such training;

2. Obtained a certification in phlebotomy from an organization approved by the Division, including, without limitation:

(a) The American Medical Technologists;

(b) The American Society for Clinical Pathology;

(c) The American Certification Agency for Healthcare Professionals;

(d) The National Center for Competency Testing;

(e) The National Healthcareer Association; and

(f) The National Phlebotomy Association; or

3. Worked at least 30 hours per week for at least 3 years during the immediately preceding 5 years in ~~[a]~~ ***:***

(a) A laboratory certified pursuant to the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a ~~[, or a]~~ ***;***

(b) A laboratory that is licensed by a federal or state governmental agency in any state or territory of the United States ~~[.]~~ ***;***

(c) A clinical laboratory in another country accredited by:

(1) The Joint Commission International, or its successor organization, or

(2) The College of American Pathologists, or its successor organization;

(d) A clinical laboratory in another country accredited pursuant to ISO 15189 of the International Organization for Standardization issued by an appropriate organization that accredits medical laboratories in that country; or

(e) A clinical laboratory licensed or certified by an appropriate governmental entity in that country and approved by an International Advisory Board appointed by the Board of Certification of the American Society of Clinical Pathology, or its successor organization.

Sec. 18. NAC 652.488 is hereby amended to read as follows:

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

(a) Licensure of laboratory not described in paragraph (b) ~~[or]~~ ***,*** (c) ***or (d)***

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

(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

(c) ***Licensure of laboratory only for the collection of specimens***

Initial $500

Biennial renewal 300

Reinstatement 500

(d) Licensure of HIV testing laboratory

Initial $150

Biennial renewal 150

~~[(d)]~~ ***(e)*** 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

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

Initial $1,500

Biennial renewal 900

Reinstatement 1,500

~~[(f)]~~ ***(g)*** Registration of laboratory operated pursuant to NRS 652.072

which is exempt pursuant to NAC 652.155

Initial $500

Biennial renewal 300

~~[(g)]~~ ***(h)*** 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

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

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

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

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

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

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

~~[(n)]~~ ***(o)*** Inspection following receipt of an application to perform additional tests at a laboratory (per application) $300

~~[(o)]~~ ***(p)*** Inspection of an outpatient center of a laboratory (per site)

Initial inspection $300

Inspection at time of biennial renewal 150

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) ***or (n)*** 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 NAC 652.195, 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. 19. NAC 652.550 is hereby amended to read as follows:

652.550 1. In determining the amount of a monetary penalty, the Division:

(a) For a first violation with a severity level of four, shall impose a monetary penalty of $1,000 per violation.

(b) For a first violation with a severity level of three, shall impose a monetary penalty of $800 per violation.

(c) For a first violation with a severity level of two, may impose a monetary penalty of $100 per violation. The Division may suspend this penalty if the laboratory corrects the violations within the time specified in the plan of correction submitted to the Division pursuant to NAC 652.320.

(d) For a second violation with a severity level of four discovered during any subsequent inspection, shall impose a monetary penalty of $5,000 per violation.

(e) For a second violation with a severity level of three discovered during any subsequent inspection, shall impose a monetary penalty of $1,600 per violation.

(f) For a second violation with a severity level of two discovered during any subsequent inspection, may impose a monetary penalty of $200 regardless of whether a penalty was imposed for the first violation.

(g) For a third or subsequent violation with a severity level of four discovered during any subsequent inspection, shall impose a monetary penalty of $10,000 per violation.

(h) For a third or subsequent violation with a severity level of three discovered during any subsequent inspection, shall impose a monetary penalty of $3,200 per violation.

(i) For a third or subsequent violation with a severity level of two discovered during any subsequent inspection, may impose a monetary penalty of $400 per violation regardless of whether a first or second monetary penalty was imposed.

2. The Division shall not impose a monetary penalty for a violation with a severity level of one.

3. If the same violation that was discovered during the initial inspection is found during a subsequent inspection conducted to evaluate compliance with a plan of correction submitted to the Division pursuant to subsection ~~[3]~~ ***5*** of NAC 652.320, there is a rebuttable presumption that the violation continued through the period between the inspection and the subsequent inspection. The Division may impose an additional monetary penalty for such a violation only if the subsequent inspection is made and the violation is found to be present after the laboratory has been notified of the violation and given an opportunity to correct the violation.

4. A laboratory may, upon approval by the Division, use a monetary penalty that would otherwise be imposed by the Division to correct the violation and to put measures in place to prevent the violation from reoccurring. In such a case, the laboratory must provide proof to the Division that the money was used to correct the violation. If the amount of the monetary penalty

is greater than the cost to correct the violation, the laboratory must pay to the Division the portion of the monetary penalty that was not used to correct the violation.

Errata – LCB File No. R126-21

Black regular font = Existing language in chapter NAC 432A
Blue bold italic = Proposed language found in LCB File No. R135-18RP1
~~[***Red italic in brackets with strikethrough***]~~ = Proposed omitted material found in LCB File No. R135-18RP1
~~***Red italic strikethrough***~~ = New language proposed to be stricken in the Errata
Green italic = New language proposed in Errata

Sec. 9. 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 have at least 1 year of experience performing tests at the level of a technologist in a clinical laboratory and***~~ 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) Have at least 1 year of experience directing, supervising laboratory testing or performing laboratory testing at a technologist level in a laboratory defined pursuant to NAC 652.075 which meets the requirements of NAC 652.170 to 652.600, inclusive;

~~(a)~~ ***(b)*** 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;

(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. 10. 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 ~~[:]~~ :

~~*have at least 1 year of experience performing tests at the level of a technologist in a clinical laboratory and:*~~

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***,*** supervising laboratory testing ***or performing laboratory testing at a technologist level*** in a laboratory ***defined pursuant to NAC 652.075*** 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;

(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).