

PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

LCB File No. R149-15

These regulations are being proposed in accordance with NRS 652.125 and 652.090.

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

Chapter 652 of NAC is hereby amended by adding thereto the provisions set forth as sections 1 to 20, inclusive, of this regulation.

Section 1 *“Temporary Location” defined. “Temporary Location” means a location established by a licensed laboratory that is located outside of the licensed laboratory and is established for no more than 90 days from the effective date of licensure.*

Section 2 *“Exempt Laboratory” defined. Except as otherwise provided in NAC 652.175, “exempt laboratory” means a laboratory in which the only laboratory tests performed are:*

- 1. Classified as waived tests pursuant to 42 CFR Part 493, Subpart A; or*
- 2. Categorized as provider-performed microscopy procedures pursuant to 42 CFR § 493.19.*

Section 3 *“Form” defined. “Form” means a paper form or electronic form including an online application as required by the Division.*

Section 4 *1. Except as otherwise provided in this section and NRS 652.071, the provisions of this chapter do not apply to a laboratory in which the only test performed is for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to the provisions of Part 496 of Title 42 of the Code of Federal Regulations.*

2. The provisions of this section do not relieve a laboratory in which the only test performed is for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to the provisions of Part 496 of Title 42 of the Code of Federal Regulations from the requirement to submit an application in a format prescribed by the Division and pay the applicable fees as set forth in NAC 652.488.

3. The laboratory director of a laboratory pursuant to this section does not have to meet any qualifications except those as provided in NRS 652.180.

Section 5 NAC 652.155 is hereby amended to read as follows:

1. Except as otherwise provided in this section and NRS 652.230, 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 which is registered 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 pursuant to NAC 652.291; or

~~(b)~~*(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 categorized pursuant to 42 C.F.R. § 493.19.

5. Except as otherwise provided in subsection 3 of Section 4, to serve as the laboratory director of an exempt laboratory an individual must be a licensed physician, an advanced practice registered nurse licensed pursuant to Chapter 632 of NRS, a physician assistant licensed pursuant to chapter 630 or 633 of NRS, a general supervisor of a licensed laboratory licensed pursuant to Chapter 652 of NRS, or a clinical laboratory technologist licensed pursuant to Chapter 652 of NRS.

6. Except as otherwise provided in subsection 3 of Section 4, to serve as the laboratory director of an exempt laboratory that only performs one waived test classified as a waived test pursuant to the provisions of Part 493 of Title 42 of the Code of Federal Regulations an individual must be one of the individuals listed in subsection 5 of this section, a nurse licensed pursuant to Chapter 632 of NRS, a pharmacist licensed pursuant to Chapter 639 of NRS or any laboratory personnel licensed or certified pursuant to Chapter 652 of NRS except that a certified office laboratory assistant, blood gas assistant or laboratory assistant would not be able to serve as a laboratory director.

~~[5-]~~ 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.

Section 6 NAC 652.200 is hereby amended to read as follows:

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.]~~

Section 7 NAC 652.210 is hereby amended to read as follows:

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.]~~ The Division shall notify the applicant of the status of the application within 30 days after receipt of the application.

Section 8 NAC 652.284 is hereby amended to read as follows:

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 then has one or more subsequent failures after the two failures noted in this section*, the laboratory *shall* cease[s] 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.

Section 9 NAC 652.320 is hereby amended to read as follows:

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 the director, *or the director's designee* a statement of violations, which must include the severity level for the violation as determined by the Division, and a ~~form~~ *mechanism* 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~~ **calendar** 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.

Section 10 NAC 652.380 is hereby amended to read as follows:

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 National Registry of Certified Chemists;*

~~[(5)]~~ **(6) The American Board of Forensic Toxicology; or**

~~[(6)]~~ **(7) The American Board of Medical Genetics *and Genomics;* or**

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

(9) *Any other board approved pursuant to 42 CFR § 493.1443 (b) (3).*

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

Section 11 NAC 652.385 is hereby amended to read as follows:

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

1. Be a physician certified by the American Board of Internal Medicine in the subspecialty of pulmonary disease **or certified by the American Osteopathic Board of Internal Medicine in the subspecialty of pulmonary disease;** or

2. In a geographical area which does not have a person who meets the qualifications set forth

in subsection 1, be a physician licensed to practice in this State, whose experience is acceptable to the Division.

Section 12 NAC 652.395 is hereby amended to read as follows:

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 National Registry of Certified Chemists;*
 - ~~[(5)]~~ (6) The American Board of Forensic Toxicology; or
 - ~~[(6)]~~ (7) The American Board of Medical Genetics *and Genomics;* or
 - (8) *The American Board of Histocompatibility and Immunogenetics;* or
 - (9) *Any other board approved pursuant to 42 CFR § 493.1443 (b) (3).*
 - (c) Possess qualifications which are equivalent to those required for certification by any of the institutions listed in paragraph (b).

Section 13 NAC 652.420 is hereby amended to read as follows:

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 *if the technologist does not have the 1 year of experience he or she must work under the supervision of a director who possesses a doctoral degree for the first 12 months of employment, in the chosen specialty. If there is a break in employment the time not working does not count towards the 12 months* or training 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.

Section 14 NAC 652.437 is hereby amended to read as follows:

1. To qualify for a certificate as a histologic technician, a person must:
 - (a) Successfully complete a program in histotechnology certified by the Committee on Allied Health Education and Accreditation;
 - (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.

Section 15 NAC 652.461 is hereby amended to read as follows:

1. Except as otherwise provided in subsection 2, any person, *except an office laboratory assistant*, 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. An inactive or delinquent license or certificate may be conditionally reinstated without the evidence required by subsection 1 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.

Section 16 NAC 652.470 is hereby amended to read as follows:

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~~ 12 months, may be granted while the application is being processed, or when the applicant has been issued a provisional certificate *for the length of time that the provisional certificate is active*.
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](#).

Section 17 NAC 652.480 is hereby amended to read as follows:

- 1) 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 1 year of experience working 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 or if the technologist does not have the 1 year of experience he or she must work under the supervision of a director who possesses a doctoral degree for the first 12 months of employment, in the chosen specialty. If there is a break in employment the time not working does not count towards the 12 months.*
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 letter from the director of the laboratory in which the applicant obtained experience which verifies that the applicant has the experience required by subsection 1 ~~];~~ *or*
3. *A signed and dated letter from the director of the laboratory in which the applicant is hired stating he or she will supervise the applicant pursuant to subsection 1.*
4. ~~[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.

Section 18 NAC 652.486 is hereby amended to read as follows:

1. The Division shall, upon request by a technologist or technician who is required to pass a national examination for certification and who has been accepted as a candidate for testing, issue him or her a provisional certificate. ~~The provisional certificate expires 180 days 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.
2. *The provisional certification shall be valid for 18 months from the time of issuance. The provisional certification cannot be renewed.*

Section 19 NAC 652.488 is hereby amended to read as follows:

The following fees will be charged:

1. Licensure of laboratory not described in subsection 2
 - 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. 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. 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. Registration of laboratory operated pursuant to NRS 652.235 which is nonexempt pursuant to NAC 652.155
 - Initial..... \$1,500
 - Biennial renewal..... 900
 - Reinstatement..... 1,500

5. Registration of laboratory operated pursuant to NRS 652.235 which is exempt pursuant to NAC 652.155
 - Initial..... \$500
 - Biennial renewal..... 300

6. *Registration of a laboratory pursuant to Section 4*

<i>Initial</i>	<i>\$150</i>
<i>Biennial Renewal</i>	<i>\$150</i>
6 7. 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 8. Placement of license or certificate in inactive status.....	\$50
8 9. Issuance of original duplicate license or certificate.....	\$50
9 10. Permit to operate laboratory at temporary location.....	\$300
10 11. Change of location of laboratory <i>except a laboratory pursuant to Section 4</i>	\$300
11 12. Change of director of laboratory <i>except a laboratory pursuant to Section 4</i>	\$300
12 13. Change of name of laboratory <i>except a laboratory pursuant to Section 4</i>	\$300
13 14. Inspection for additional [specialties and subspecialties in which] tests <i>which</i> will be performed at a laboratory.....	\$300
<i>The fee will cover all additional tests listed in one application for the addition of tests. [Plus \$50 for each additional specialty or subspecialty]</i>	
14 15. Inspection of an outpatient center of a laboratory (per site)	
Initial inspection.....	\$300
Inspection at time of biennial renewal.....	150
15 16. 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.	
<i>17. A laboratory licensed pursuant to NRS and NAC of Chapter 652 which is located within an agency which is also permitted in accordance with NRS 450B.100 shall be deemed to have met payment of the fee required in accordance with this section.</i>	

18. Laboratory personnel certified pursuant to NRS and NAC of Chapter 652 who work in a laboratory which is also permitted in accordance with NRS 450B.100 shall be deemed to have met payment of the fee required in accordance with this section.

Section 20 NAC 652.600 is hereby amended to read as follows:

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 by a mechanism 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.