

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 6, 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 Laboratories that perform only HIV tests classified as a waived test

1. Except as otherwise provided in this section and NRS 652.230, the provisions of this chapter do not apply to a laboratory pursuant to Section 2.

2. Except as otherwise provided in subsection 3, a person who is employed by a laboratory pursuant to Section 2 may perform a laboratory test for the detection of the human immunodeficiency virus that is classified as a waived test pursuant to the provisions of Part 493 of Title 42 of the Code of Federal Regulations without complying with the provisions of this chapter if the director or a designee of the director 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;*
- (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;*
- (4) Conducts the tests in accordance with NRS 652.185; and*
- (5) Adopts the laboratory safety guidelines pursuant to NAC 652.291.*

3. The provisions of subsection 2 do not relieve a person who performs a laboratory test 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:

- (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) Submit an application in a format prescribed by the Division, comply with NAC 652.157 and pay the applicable fees as set forth in NAC 652.488.*

4. The laboratory director of a medical laboratory pursuant to Section 2 must ensure the laboratory is in compliance with NRS 652.185 and carry out the duties of a laboratory director in accordance with NRS 652.180.

5. The laboratory director of a medical laboratory pursuant to Section 2 does not have to meet any qualifications except those as provided in NRS 652.185.

Section 3 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; ~~for~~

(b) Comply with the Laboratory Safety Guidelines pursuant to NAC 652.291; or

~~for~~ *(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. 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. 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 or laboratory assistant would not be able to serve as a laboratory director.

~~15.1~~ 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 4 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)~~ ***(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***

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

Section 5 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; or
 - (c) Possess qualifications which are equivalent to those required for certification by any of the institutions listed in paragraph (b).

Section 6 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 2

Initial.....	\$150
Biennial Renewal.....	\$150

~~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 2...</i>	\$300
{11} 12. Change of director of laboratory <i>except a laboratory pursuant to Section 2...</i>	\$300
{12} 13. Change of name of laboratory <i>except a laboratory pursuant to Section 2...</i>	\$300
{13} 14. Inspection for additional {specialties and subspecialties in which} tests <i>which</i> will be performed at <i>a</i> 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 medical 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 not be required to pay a fee in accordance with this section.</i>	
<i>18. Medical laboratory personnel certified pursuant to NRS and NAC of Chapter 652 who work in a medical laboratory which is also permitted in accordance with NRS 450B.100 shall not be required to pay a fee in accordance with this section.</i>	
<i>19. The Division's Emergency Medical Services program shall administer the provisions of NRS Chapter 652 and NAC Chapter 652 for agencies permitted in accordance with NAC 450B.505.</i>	
<i>20. The Division's Emergency Medical Services program may enter into an agreement with the Southern Nevada Health District which would allow the Southern Nevada Health District to determine compliance with NAC Chapter 652 for permitted emergency medical services and fire-fighting agencies permitted by Southern Nevada Health District. The Division would be</i>	

able to use the determination of compliance by the Southern Nevada Health District to issue a medical laboratory license and certify personnel in accordance with this section. There would be no additional fees or charges collected by the Southern Nevada Health District to carry out the provisions of this section.

Section 7 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 an *analyte 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 *analyte 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.