

**REVISED PROPOSED REGULATION OF
THE STATE BOARD OF HEALTH**

LCB File No. R078-04

May 21, 2004

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

AUTHORITY: §§1, 2, 4 and 8-12, NRS 652.125 and 652.130; §§3 and 5, NRS 652.100, 652.125, 652.130 and 652.235; §§6 and 13, NRS 652.100, 652.125 and 652.130; §7, NRS 652.130; §14, NRS 652.100; §§15 and 16, NRS 652.125.

A REGULATION relating to medical laboratories; providing for the denial, suspension or revocation of a certificate issued pursuant to chapter 652 of NRS; revising provisions regarding laboratories operated by physicians; requiring an application and payment of a fee for a laboratory seeking to perform tests at a temporary location; revising provisions regarding the certification of a director of a licensed or registered laboratory; revising provisions regarding the certification of a supervisor of a licensed laboratory; revising provisions regarding applications for certification after a lapse in certification; establishing fees for the certification of pathologists' assistants; revising fees regarding change of location, director or name of laboratory and inspections of laboratories; repealing certain sections; and providing other matters properly relating thereto.

Section 1. Chapter 652 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 and 3 of this regulation.

Sec. 2. *A certificate may be denied, suspended or revoked if an applicant, person who holds a certificate or a technical employee of the laboratory:*

- 1. Violates any provision of this chapter or chapter 652 of NRS;*
- 2. Makes any misrepresentation in obtaining a certificate;*
- 3. Has been convicted of a felony relating to the position for which the applicant has applied or for which his certificate has been issued pursuant to chapter 652 of NRS;*
- 4. Is guilty of unprofessional conduct; or*

5. *Fails to meet the minimum standards prescribed by the Board.*

Sec. 3. *1. A laboratory operated by a licensed physician pursuant to NRS 652.235 must register with the Health Division as an exempt laboratory or a nonexempt laboratory.*

2. A laboratory operated by a licensed physician pursuant to NRS 652.235 may register with the Health Division as an exempt laboratory if:

(a) The operating physician submits an application for registration as an exempt laboratory on a form provided by the Bureau;

(b) The operating physician pays the applicable fees set forth in NAC 652.488;

(c) Each test performed by personnel other than the physician has been classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A; and

(d) Either:

(1) The operating physician performs tests on his own patients and makes his own readings of the results of the tests; or

(2) Any manipulation of a person for the collection of a specimen is made by an employee of the laboratory who is qualified pursuant to NRS 652.210.

3. A laboratory operated by a licensed physician pursuant to NRS 652.235 may register with the Health Division as a nonexempt laboratory if:

(a) The operating physician submits an application for registration as a nonexempt laboratory on a form provided by the Bureau;

(b) The operating physician pays the applicable fees set forth in NAC 652.488;

(c) At least some tests performed by personnel other than the physician have not been classified as waived tests pursuant to 42 C.F.R. Part 493, Subpart A; and

(d) Either:

(1) The operating physician or an employee of the laboratory performs tests on the patients of the physician and the physician or the employee of the laboratory makes his own readings of the results of the tests; or

(2) Any manipulation of a person for the collection of a specimen is made by an employee of the laboratory who is qualified pursuant to NRS 652.210.

4. As used in this section, “physician” includes:

(a) A licensed chiropractor, as defined in NRS 634.090.

(b) A licensed podiatrist, as defined in NRS 635.050.

Sec. 4. NAC 652.137 is hereby amended to read as follows:

652.137 “Rural area” means any area other than that included in Carson City, *Henderson*, Reno, Sparks, *Las Vegas* or *North* Las Vegas.

Sec. 5. NAC 652.155 is hereby amended to read as follows:

652.155 1. ~~[The] Except as otherwise provided in this section and NRS 652.230, the provisions of this chapter [do not apply to a laboratory operated by a licensed physician pursuant to NRS 652.235 in which the operating physician performs the tests on his own patients and makes his own readings of the results of the tests.] :~~

(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 registered pursuant to section 3 of this regulation; and

(b) Do not apply to an exempt laboratory registered pursuant to section 3 of this regulation.

2. Except as otherwise provided in subsection 3, a person who is employed by a laboratory that is licensed by or registered with the Health Division pursuant to chapter 652 of NRS may perform a test without complying with the provisions of chapter 652 of NAC 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 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; 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. ~~The~~ *Except as otherwise provided in subsection 4, the* provisions of subsection 2 do not relieve a person who performs a test of 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) Obtain certification pursuant to NAC 652.470.

4. An advanced practitioner of nursing 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 Health 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 chapter 652 of NAC 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 pursuant to 42 C.F.R. Part 493.19.*

Sec. 6. NAC 652.170 is hereby amended to read as follows:

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

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

3. A laboratory seeking ~~[exemption from the provisions of this chapter]~~ *to perform tests at a temporary location* must submit to the Bureau an application ~~[for exemption]~~ on the form provided by the Bureau ~~[]~~ *and the fees required by NAC 652.488.*

Sec. 7. NAC 652.320 is hereby amended to read as follows:

652.320 1. Except as otherwise provided in this subsection, the Bureau 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 ~~[Health Care Financing Administration]~~ *Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services* pursuant to 42 C.F.R. §§ ~~[493.501 to 493.521,]~~ *493.551 to 493.575*, inclusive, is not required to be inspected by the Bureau if the reports of the inspections are available to the Bureau.

2. The Bureau shall report deficiencies noted at the time of each inspection by forwarding to the director a statement of deficiencies and a form for the director to submit a plan of correction. The director shall return the form to the Bureau, containing thereon the plan of correction for

each of the deficiencies, within 10 working days after he receives the form. The plan must indicate the date by which each deficiency will be corrected.

Sec. 8. NAC 652.380 is hereby amended to read as follows:

652.380 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 his application for a license, have successfully completed a 4-year program accredited by the National Accrediting Agency for Clinical Laboratory ~~Science;~~ *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 ~~;~~ or biological science as his 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; ~~or~~
- (4) The American Board of Medical Laboratory Immunology;
- (5) The American Board of Forensic Toxicology; or*
- (6) The American Board of Medical Genetics; or*

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

3. In a geographical area which does not have a person who meets the qualifications set forth in subsection 1 or 2, be a physician, licensed to practice in the State of Nevada, whose experience is acceptable to the Board.

Sec. 9. NAC 652.395 is hereby amended to read as follows:

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

1. Be a physician licensed to practice in this State and have:
 - (a) At least 1 year of experience directing or supervising laboratory testing in a laboratory which meets the requirements of NAC 652.170 to 652.510, 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~~ 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 652.510, 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; ~~for~~
 - (4) The American Board of Clinical Chemistry;
 - (5) The American Board of Forensic Toxicology; or*
 - (6) 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).

Sec. 10. 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 ~~subsection 2,~~ *this section*, be:

- (a) A licensed director;
- (b) A qualified physician serving on behalf of the director; or
- (c) A clinical laboratory technologist who ~~[, after qualifying for certification,]~~ has had at least ~~[6]~~ *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:
 - (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 ~~[, after qualifying for certification in the specialty,]~~ has had at least ~~[6]~~ 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:

(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 specialty.

3. A person who possesses a doctoral degree from an accredited institution with a major in chemical, physical or biological science and who has had at least 1 year of experience 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 and who has had at least 2 years of experience 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. 11. 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 he has had adequate education, training [§] and experience and in which he 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 3 years of academic study, with a minimum of 90 semester hours or the equivalent, at an accredited college or university in a curriculum involving biological or physical science [§] and at least 12 months of training at a school of medical technology approved by a national accrediting agency, and pass a national examination for certification approved by the Board;

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

~~(d) [Successfully complete 3 years of academic study, with a minimum of 90 semester hours or the equivalent, at an accredited college or university in a curriculum involving biological or physical science, have 4 years full-time experience in a laboratory, and pass a national examination for certification approved by the Board; or~~

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

Sec. 12. NAC 652.443 is hereby amended to read as follows:

652.443 1. To qualify for a certificate as a blood-gas technologist, a person must:

(a) Have credentials from the National Board for Respiratory Care as a certified respiratory

~~[therapy technician;]~~ *therapist; or*

(b) Be certified by the National Board for Respiratory Care as a registered respiratory

therapist . ~~;~~

~~(c) Have credentials from the National Board of Cardiopulmonary Credentialing as a certified cardiopulmonary technologist; or~~

~~(d) Be certified by the National Board of Cardiopulmonary Credentialing as a registered cardiopulmonary technologist.]~~

2. A blood-gas technologist may only perform, under the minimal review of the director or general supervisor, those diagnostic and therapeutic procedures for which he has adequate education, training ~~;~~ and experience and in which he has demonstrated a proficiency. He may supervise the work of blood-gas technicians and assistants.

Sec. 13. NAC 652.470 is hereby amended to read as follows:

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

(a) An application for certification must be made on a form provided by the Bureau 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) ~~[A fee, which is not refundable,]~~ *The fee prescribed in NAC 652.488* must accompany the application.

2. Temporary employment, for a period not exceeding 6 months, may be granted while the application is being processed, or when the applicant has been issued a provisional certificate.

3. The Bureau 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. Certified personnel may upgrade their classification after completing the appropriate additional experience, training ~~;~~ *or* academic requirements, or any combination thereof, by applying to the Board 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 Bureau accompanied by the ~~[required fee.~~

~~—6.— A copy of this section will be provided upon request to persons who are certified on or after September 6, 1988.]~~ *fee prescribed in NAC 652.488.*

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

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

Sec. 14. NAC 652.488 is hereby amended to read as follows:

652.488 The following nonrefundable fees will be charged:

1. Licensure of 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

~~Inspection conducted pursuant to NAC 652.320..... 300~~

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

2. Licensure of director

Initial.....	\$250
Biennial renewal.....	150
Reinstatement	250

3. Registration of laboratory operated pursuant to NRS 652.235 which is

nonexempt pursuant to NAC 652.155

Initial.....	\$300
Biennial renewal.....	200
Reinstatement	300

~~Inspection pursuant to NAC 652.320~~ ~~100~~

4. Registration of laboratory operated pursuant to NRS 652.235 which is exempt pursuant to NAC 652.155

Initial.....\$100

Biennial renewal.....50

~~Inspection pursuant to NAC 652.320.....100~~

5. Certification of personnel

Initial:

General supervisor.....\$150

Technologist75

Technician.....75

Pathologist's assistant.....75

Point-of-care test analyst50

Laboratory, blood-gas or office laboratory assistant40

Biennial renewal:

General supervisor.....100

Technologist50

Technician.....50

Pathologist's assistant.....50

Point-of-care test analyst40

Laboratory, blood-gas or office laboratory assistant30

Reinstatement:

General supervisor.....150

Technologist	75
Technician.....	75
<i>Pathologist's assistant</i>	<i>75</i>
Point-of-care test analyst	50
Laboratory, blood-gas or office laboratory assistant	40
6. Placement of license or certificate in inactive status	\$20
7. Issuance of original duplicate license or certificate	\$20
8. Permit to operate laboratory at temporary location.....	\$35
9. Change of location of laboratory.....	[\$160] \$250
10. Change of director of laboratory	[\$160] \$250
11. <i>Change of name of laboratory</i>	<i>\$250</i>
12. Inspection for additional specialties and subspecialties in which tests will be performed at laboratory	[\$160] \$250
	plus \$50 for each additional specialty or subspecialty
12.] 13. Inspection of an outpatient center of a laboratory (per site)	
Initial inspection	\$100
Inspection at time of biennial renewal.....	50
13.] 14. If the Bureau conducts an inspection of a laboratory that is located outside of this State, the Bureau shall assess the expenses that the Bureau incurs as a result of the inspection to the laboratory. The laboratory shall reimburse the Bureau for the expenses assessed pursuant to this subsection.	

Sec. 15. NAC 652.493 is hereby amended to read as follows:

652.493 If a person is aggrieved by a decision of the Health Division relating to the denial, suspension or revocation of a license or certificate based upon any of the grounds set forth in subsections 1 to 6, inclusive, of NRS 652.220 , ~~or~~ NAC 652.461 ~~or~~ *or section 2 of this regulation*, the aggrieved person may appeal the decision pursuant to the procedures set forth in NAC 439.300 to 439.395, inclusive.

Sec. 16. NAC 652.100 and 652.490 are hereby repealed.

TEXT OF REPEALED SECTIONS

NAC 652.100 “Part-time status” defined. “Part-time status” means work in a clinical laboratory for less than 15 hours per week.

NAC 652.490 Appeal to Board of decision of Bureau to deny license or certificate.
(NRS 439.200, 652.125, 652.130)

1. If a person is aggrieved by a decision of the Bureau to deny a license or certificate based upon the failure of the aggrieved person to meet the minimum standards prescribed by the Board, the aggrieved person may appeal that decision to the Board.

2. The aggrieved person must set forth in writing all pertinent information and describe to what extent the decision is unfavorable. The appeal must be mailed or delivered to the ex officio secretary of the Committee at the following address:

Medical Laboratory Advisory Committee

Bureau of Licensure and Certification

1550 E. College Parkway, Suite 158

Carson City, Nevada 89710

The appeal must be received by the Bureau within 15 working days after receipt of the decision by the appellant.

3. The appeal will be placed on the agenda of the next regularly scheduled meeting of the Board. The appellant may request a delay.

4. At the hearing, the staff of the Health Division shall present a report, any relevant information and the Committee's recommendations concerning the appeal. These documents must be mailed to the appellant at least 5 days before the hearing. At the hearing, the appellant has the burden of proof.

5. The Board will, within 14 days after the hearing, prepare its written formal findings of fact and its written decision and notify the appellant in writing of its decision. Within 30 days after the appellant receives the written notice of the final decision, he may seek judicial review.