

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

LCB File No. R057-99

July 12, 1999

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

AUTHORITY: §§2-6, NRS 652.123; §§7-9, NRS 652.123, 652.125 and 652.130; §10, NRS 652.130 and 652.235; §11, NRS 652.125; §12, NRS 439.150.

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

Sec. 2. *“Point-of-care test” means a test that is:*

- 1. Performed by means of a point-of-care testing device; and*
- 2. Classified as a waived test or a moderate complexity test pursuant to 42 C.F.R. Part 493, Subpart A.*

Sec. 3. *“Point-of-care testing device” means a portable laboratory testing system, analytical instrument, kit or procedure that may be transported to the site of a patient in order to perform point-of-care tests.*

Sec. 4. *The provisions of sections 5, 6 and 7 of this regulation do not apply to a licensed nurse or licensed or certified personnel of a laboratory performing a point-of-care test under the circumstances set forth in NRS 652.217.*

Sec. 5. *A point-of-care testing device may be used only:*

1. If the device:

- (a) Performs tests on biological specimens that require no preparation after collection; and*

(b) Provides testing results directly from the device without calculation or discretionary intervention by the testing personnel during the preanalytic and postanalytic phases of the test.

2. Within a medical facility that is licensed pursuant to chapter 449 of NRS and has a laboratory that is licensed pursuant to chapter 652 of NRS.

Sec. 6. *A point-of-care testing device must be used:*

1. In accordance with the testing management system and programs of quality control and quality assurance established by the laboratory performing the point-of-care test;

2. In accordance with the instructions of the manufacturer of the device; and

3. By qualified personnel under the supervision of a director.

Sec. 7. *To be qualified to use a point-of-care testing device, a person must be licensed or certified as a:*

1. Director;

2. General supervisor;

3. Clinical laboratory technologist;

4. Medical technician;

5. Blood-gas technologist;

6. Blood-gas technician;

7. Technologist;

8. Technician; or

9. Point-of-care test analyst.

Sec. 8. *To qualify for a certificate as a point-of-care test analyst, a person must:*

1. Be a:

(a) Registered nurse as defined in NRS 632.019;

(b) *Advanced practitioner of nursing as defined in NRS 632.012;*
(c) *Licensed practical nurse as defined in NRS 632.016;*
(d) *Practitioner of respiratory care as defined in NRS 640B.040;*
(e) *Physician's assistant as defined in NRS 630.015;*
(f) *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) *Certified laboratory assistant who has successfully completed training approved by the board in performing point-of-care tests; and*

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

Sec. 9. 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 652.148, inclusive, *and sections 2 and 3 of this regulation*, have the meanings ascribed to them in those sections.

Sec. 10. NAC 652.155 is hereby amended to read as follows:

652.155 ~~[1.]~~ 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.

~~[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 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.]~~

Sec. 11. NAC 652.455 is hereby amended to read as follows:

652.455 1. Each director, general supervisor, technologist, technician, ~~[and]~~ pathologist's assistant *and point-of-care test analyst* licensed or certified pursuant to this chapter shall complete 2 units of continuing education within the 2 years immediately preceding the application for renewal of his license or certificate. At least half of the total units of continuing education required must be from approved courses.

2. Each laboratory assistant or blood-gas assistant shall complete 1 unit of continuing education within the 2 years immediately preceding the application for renewal of his certificate.

Sec. 12. 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
Technologist	75
Technician.....	75
<i>Point-of-care test analyst</i>	<i>50</i>
Laboratory, blood-gas or office laboratory assistant	40
Biennial renewal:	
General supervisor	100
Technologist	50
Technician.....	50
<i>Point-of-care test analyst</i>	<i>40</i>
Laboratory, blood-gas or office laboratory assistant	30
Reinstatement:	
General supervisor	150
Technologist	75
Technician.....	75

<i>Point-of-care test analyst</i>	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
10. Change of director of laboratory	\$160
11. Inspection for additional specialties and subspecialties in which tests will be performed at laboratory	\$160

plus \$50 for each additional
specialty or subspecialty