

PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

LCB File No. R177-97

December 3, 1997

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

AUTHORITY: §§1, 2, 5 and 9, NRS 652.130; §3, NRS 652.123 (§4, chapter 310, Statutes of Nevada 1997, at page 1123) and 652.130; §§4, 6 and 7, NRS 652.130 and 652.135 (§3, chapter 310, Statutes of Nevada 1997, at page 1123); §8, NRS 652.100 and 652.130.

Section 1. Chapter 652 of NAC is hereby amended by adding thereto a new section to read as follows:

“Test” means a microbiological, serological, immunohematological (blood banking), cytological, histological, chemical, hematological, biophysical, toxicological or other method of examining the tissues, secretions or excretions of the human body.

Sec. 2. 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 section 1 of this regulation*, have the meanings ascribed to them in those sections.

Sec. 3. 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 [:

1. The] the operating physician performs the tests on his own patients and makes his own readings of the results of the tests . [; or

2. The following tests are performed by the operating physician or a laboratory assistant under the physician's direct supervision:

- (a) Screening of urine for proteinuria, glucosuria, or hematuria.
- (b) Testing of urine to determine pregnancy.
- (c) Collection of samples for submission to a licensed laboratory.
- (d) Determination of levels of hemoglobin.]

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. 4. NAC 652.282 is hereby amended to read as follows:

652.282 A director shall ensure that:

1. The testing systems developed and used for each of the tests performed in the laboratory result in services of high quality for the analytic phase of each test and any activities conducted before and after that phase.
2. Acceptable levels of analytical performance are established and maintained for each testing system.
3. The methodology selected for each test yields results of a sufficient quality to provide for the care of patients.
4. The procedures used for the verification of testing methods are adequate to determine the accuracy, precision, and other pertinent characteristics of performance for those methods.
5. Testing is performed in such a manner as required by federal and state statute and regulation, and any policies and protocols adopted by the laboratory.
6. The reports of testing results include the pertinent information required to interpret those results.
7. Programs of quality control and quality assurance are established and maintained to ensure the quality of the laboratory's services and to identify any failure of quality when it occurs [.] , *and that records of such programs are maintained by the laboratory for at least 2 years.*
8. Whenever there is a significant deviation from the laboratory's established specifications for performance:
 - (a) Any necessary remedial action is taken and documented; and
 - (b) The results of patients' tests are not reported until the deviation is corrected.

Sec. 5. NAC 652.300 is hereby amended to read as follows:

652.300 1. Except as otherwise provided in subsection 3, if a specimen is received by the laboratory, it must be accompanied by an authorized written request or a computerized authorization.

2. If the laboratory receives specimens referred from another laboratory, it must report the results to the laboratory submitting the specimens.

3. Verbal requests from authorized persons may be accepted by the laboratory with proper verification. *The laboratory shall obtain an authorized written request or a computerized authorization to supplement a verbal request within 30 days after the laboratory accepted the verbal request.*

4. *Each request must contain the following information:*

(a) *The full name of and a number which identifies the person from whom the specimen was taken.*

(b) *The name of the licensed physician, other authorized person or clinical laboratory that submitted the specimen.*

(c) *The date and time the specimen was collected for testing.*

(d) *The type of test or specific test required.*

Sec. 6. NAC 652.310 is hereby amended to read as follows:

652.310 1. A laboratory must maintain a daily record of accessions of specimens, each of which must be numbered or otherwise appropriately identified.

2. **[Each request must contain the following information:**

(a) **The full name and number of identification of the person from whom the specimen was taken.**

(b) The name of the licensed physician, other authorized person or clinical laboratory that submitted the specimen.

(c) The date and time the specimen was collected for testing.

(d) The type of test or specific test required.

(e) The type of specimen submitted.] *Daily records of accessions of specimens must:*

(a) *Be maintained in accordance with 42 C.F.R. Part 493; and*

(b) *Include the following information:*

(1) *A number that uniquely identifies each specimen, including, without limitation, an accession number or a number which identifies the person from whom the specimen was taken.*

(2) *The date and time each specimen was received by the laboratory.*

(3) *The condition and disposition of each specimen that does not meet the laboratory's criteria for the acceptability of specimens.*

(4) *The date on which each specimen is tested.*

(5) *The identity of the person who performs each test.*

Sec. 7. NAC 652.340 is hereby amended to read as follows:

652.340 1. A report by the laboratory to the source requesting the report must include , *without limitation*, the following:

(a) The *name and* address of the reporting laboratory.

(b) The date and time the specimen was received in the laboratory.

(c) The condition of a specimen if considered unsatisfactory on receipt, for example, broken, leaked, hemolyzed, or turbid.

(d) The type of test or specific test performed.

(e) The result of the test . [*including normal ranges where applicable.*]

(f) The date of the [report and the verification of the report by the technologist or supervisor.]

test.

(g) If the specimen is sent to a reference laboratory for testing, the identity of the reference laboratory.

2. A report on tissue must be written using acceptable and standardized terminology.

3. Duplicate copies or a suitable record of all reports by a laboratory must be [filed in] *maintained by* the laboratory *in accordance with 42 C.F.R. Part 493 and* in a manner which [permits] *allows* ready identification and accessibility. [There must be a written policy regarding their retention approved by the bureau.]

Sec. 8. 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 [350] 550

Annual test volume at least 25,000 but less than 100,000 [500] 800

Annual test volume 100,000 or more [750

Annual]

1,150

Biennial renewal:

Annual test volume less than 25,000 [200] 400

Annual test volume at least 25,000 but less than 100,000 [300] 600

Annual test volume 100,000 or more [400] 800

Inspection conducted pursuant to NAC 652.320 [150] 300

Reinstatement:

Annual test volume less than 25,000	[350] 550
Annual test volume at least 25,000 but less than 100,000	[500] 800
Annual test volume 100,000 or more	[750] 1,150

2. Licensure of director

Initial	\$175
Annual renewal	75
Reinstatement	175

3. Registration of laboratory

Initial	\$150
Annual renewal	75
Reinstatement	150
Inspection pursuant to NAC 652.320	50
Registration pursuant to NRS 652.235	20

4. Certification of personnel

Initial:

General supervisor	\$100
Technologist	50
Technician	50
Laboratory, blood-gas, or office laboratory assistant	25

Annual renewal:

General supervisor	50
Technologist	25

Technician	25
Laboratory, blood-gas, or office laboratory assistant	15
Reinstatement:	
General supervisor	100
Technologist	50
Technician	50
Laboratory, blood-gas, or office laboratory assistant	25
5. Reissuance of lost license or certificate	\$20
6. Issuance of original duplicate license or certificate	\$20
7. Permit to operate laboratory at temporary location	\$35
Sec. 9. NAC 652.345 is hereby repealed.	

TEXT OF REPEALED SECTION

652.345 Maintenance of log; inclusion of results of testing for quality control.

1. A log or an equivalent record approved by the bureau must be maintained in each area of the laboratory. The log must contain:

- (a) The patient's name or the number of accession; and

(b) The identification of the person doing the testing, if he is different from the person authenticating the final report.

2. Each log may contain the results of testing for quality control unless a separate log for quality control is used.