LCB File No. R176-07

PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

MEDICAL LABORATORIES

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

The following sections have not been revised or modified: NAC 652.010 thru 652.148, 652.170 thru 652.290, 652.310, 652.342 thru 652.370, 652.425 thru 652.465, 652.474 thru 652.478, 652.484 thru 652.486, and 652.493 thru 652.510.

Section 1. Chapter 652 of NAC is hereby amended by adding thereto the provisions set forth as section 2 through 13 inclusive, of this regulation.

Sec. 2. NAC 652.155 is hereby amended to read as follows:

NAC 652.155 Applicability; exemptions from compliance. **(**NRS 439.200**,** 652.123**,** 652.125**,** 652.130, 652.235**)**

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 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 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, ***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 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, ***and pay the applicable fees as set forth by NAC 652.488.***

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 categorized pursuant to 42 C.F.R. § 493.19.

5. As used in this section, "licensed physician" includes:

(a) A physician licensed as a doctor of medicine pursuant to chapter 630 of NRS, or

(b)A physician licensed as a doctor of osteopathic medicine pursuant to chapter 633 of NRS, or

(b) A chiropractic physician licensed pursuant to chapter 634 of NRS, or

(c) A podiatric physician licensed pursuant to chapter 635 of NRS.

Sec 3. NAC 652.175 Laboratory operated by licensed physician: Registration as exempt or nonexempt laboratory. (NRS 439.200**,** 652.130**,** 652.235**)**

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 ***is licensed as a director and*** 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, "licensed physician" includes:

(a) A chiropractic physician licensed pursuant to chapter 634 of NRS; and

(b) A podiatric physician licensed pursuant to chapter 635 of NRS.

(c) a physician licensed as a doctor of medicine pursuant to chapter 630 of NRS, or

(d) a physician licensed as a doctor of osteopathic medicine pursuant to chapter 633 of NRS..

Sec. 4 NAC 652.300 is hereby amended to read as follows:

NAC 652.300 Request or authorization for test; report of findings; required contents of request. **(**NRS 439.200**,** 652.123**,** 652.130**)**

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]~~ ***or*** 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. 5 NAC 652.320 is hereby amended to read as follows:

NAC 652.320 Inspections: Duties of Bureau; submission of plan for correction of deficiencies**.** **(**NRS 652.123**,** 652.130**)**

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 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 Bureau if the reports of the inspections are available to the Bureau.

2. Upon receipt of a complaint against a laboratory or personnel, except for a complaint concerning the cost of services, the bureau 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.

~~[2.]~~ ***3***. 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. 6 NAC 652.340 is hereby amended to read as follows:

NAC 652.340 Reports by laboratory: Contents; terminology; retention of copies**. (**NRS 652.123**,** 652.130**,** 652.135**)**

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

(a) The full name of or a number which identifies the person for whom the specimen was taken.

(~~[a]~~ ***b***) The name and address of the reporting laboratory.

(~~[b]~~ ***c***) The date and time the specimen was received in the laboratory.

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

(~~[d]~~ ***e***) The type of test or specific test performed.

(~~[e]~~ ***f***) The result of the test.

(~~[f]~~ ***g***) The date of the test.

(~~[g]~~ ***h***) 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 maintained by the laboratory in accordance with 42 C.F.R. Part 493 and in a manner which allows ready identification and accessibility.

Sec. 7 NAC 652.410 is hereby amended to read as follows:

NAC 652.410 General supervisor of licensed laboratory: Qualifications. **(**NRS 652.123**,** 652.125**,** 652.130**)**

1. To qualify for a certificate as a general supervisor of a licensed laboratory, a person must, except as otherwise provided in this section, be:

(a) ~~**[**A licensed director;**]**~~

~~**[**(b)**]**~~ A qualified physician serving on behalf of the director; or

~~**[**(c)**]**~~ ***(b)*** A clinical laboratory technologist who has had at least 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 has had at least 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. 8 NAC 652.420 is hereby amended to read as follows:

NAC 652.420 Clinical laboratory technologist: Activities and qualifications. **(**NRS 652.123**,** 652.125**,** 652.130**)**

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

Sec. 9 NAC 652.470 is hereby amended to read as follows:

NAC 652.470 Certification of personnel**. (**NRS 652.123**,** 652.125**,** 652.130**)**

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) 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]~~ ***certificate*** after completing the appropriate additional experience, training or academic requirements, or any combination thereof, by applying to the ~~[Board]~~ ***Bureau*** 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 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 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. 10 NAC 652.480 is hereby amended to read as follows:

NAC 652.480 Technologists: Certification in specialty for which national examination is given; application for certification; designation on certificate. (NRS 652.123**,** 652.125**,** 652.130**)**

1. Except as otherwise provided in NAC 652.483, to be certified by the Bureau in a specialty, a technologist must pass a national examination for certification in the specialty and must have:

(a) 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

~~[(b) Successfully completed 3 years of academic study, with a minimum of 90 semester hours or the equivalent, at an accredited college or university in one of the chemical, physical or biological sciences, and have 4 years of full-time experience 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]~~.

2. Each applicant for certification in a specialty must designate on the application the specialty in which he desires to be certified. The applicant must submit with his application:

(a) Verification of his successful completion of the academic study required by subsection 1; and

(b) A letter from the director of the laboratory in which he obtained his experience which verifies that the applicant has the experience required by subsection 1.

3. In addition to the requirements of subsection 1, an applicant for certification as a biotechnologist must obtain the written recommendation of his certification from the Committee before he is eligible for that certification.

4. Each certificate will designate the holder by:

(a) The title of "Technologist" in a specialty; or

(b) An equivalent title and will show his area of specialty by a subtitle.

Sec. 11 NAC 652.483 is hereby amended to read as follows:

NAC 652.483 Technologists: Certification in specialty for which national examination is not given. **(**NRS 652.123**,** 652.125**,** 652.130**)** The Bureau shall certify a technologist in a specialty for which a national examination is not given if he:

1. Has education and experience in the specialty which is acceptable to the Board;

2. Obtains a written recommendation of the proposed certification from:

(a) A director licensed in this State who holds a doctoral degree; and

(b) The Committee; and

3. Has successfully completed:

(a) 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 has 1 year of experience 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

~~[(b) Three years of academic study, with a minimum of 90 semester hours or the equivalent, at an accredited college or university in one of the chemical, physical or biological sciences, and has 4 years of full-time experience 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.~~ ~~]~~

Sec. 12 NAC 652.488 is hereby amended to read as follows:

NAC 652.488 Fees; assessed expenses. **(**NRS 439.150**,** 439.200**,** 652.100**,** 652.125**)** The following nonrefundable fees will be charged:

1. Licensure of laboratory

Initial:

Annual test volume less than 25,000	~~[$ 550]~~ ***$ 1,100***
Annual test volume at least 25,000 but less than 100,000	~~[800]~~ ***3,000***
Annual test volume 100,000 or more	~~[1,150]~~ ***4,000***

Biennial renewal:		
Annual test volume less than 25,000.	~~[400]~~	***800***
Annual test volume at least 25,000 but less than 100,000	~~[600]~~	***2,500***
Annual test volume 100,000 or more	~~[800]~~	***3,500***
Reinstatement:		
Annual test volume less than 25,000.	~~[550]~~	***1,100***
Annual test volume at least 25,000 but less than 100,000	~~[800]~~	***3,000***
Annual test volume 100,000 or more	~~[1,150]~~	***4,000***
2. Licensure of director ***pursuant to NAC 652.175(3)(b), 652.380, 652.385 and 652.395***		
Initial	~~[250]~~	***500***
Biennial renewal	~~[150]~~	***300***
Reinstatement.	~~[250]~~	***500***
3. Registration of laboratory operated pursuant to NRS 652.235 which is nonexempt pursuant to NAC 652.155		
Initial	~~[300]~~	***1,500***
Biennial renewal	~~[200]~~	***900***
Reinstatement	~~[300]~~	***1,500***
4. Registration of laboratory operated pursuant to NRS 652.235 which is exempt pursuant to NAC 652.155		
Initial	~~[100]~~	***500***
Biennial renewal	~~[50]~~	***300***
5. Certification of personnel		
Initial:		
General supervisor.	~~[150]~~	***225***
Technologist.	~~[75]~~	***113***
Technician	~~[75]~~	***113***
Pathologist's assistant.	~~[75]~~	***113***
Point-of-care test analyst	~~[50]~~	***75***
Laboratory, blood-gas or office laboratory assistant	~~[40]~~	***60***
Biennial renewal:		
General supervisor.	~~[100]~~	***150***
Technologist.	~~[50]~~	***75***
Technician	~~[50]~~	***75***
Pathologist's assistant.	~~[50]~~	***75***
Point-of-care test analyst	~~[40]~~	***60***
Laboratory, blood-gas or office laboratory assistant	~~[30]~~	***45***
Reinstatement:		
General supervisor.	~~[150]~~	***225***
Technologist.	~~[75]~~	***113***
Technician	~~[75]~~	***113***
Pathologist's assistant.	~~[75]~~	***113***

Point-of-care test analyst	~~[50]~~	***75***
Laboratory, blood-gas or office laboratory assistant	~~[40]~~	***60***
6. Placement of license or certificate in inactive status	~~[20]~~	***50***
7. Issuance of original duplicate license or certificate.	~~[20]~~	***50***
8. Permit to operate laboratory at temporary location.	~~[35]~~	***300***
9. Change of location of laboratory	~~[250]~~	***300***
10. Change of director of laboratory	~~[250]~~	***300***
11. Change of name of laboratory	~~[250]~~	***300***
12. Inspection for additional specialties and subspecialties in which tests will be performed at a laboratory.	~~[250]~~ Plus $50 for each additional specialty or subspecialty	***300***
13. Inspection of an outpatient center of a laboratory (per site)		
Initial inspection	~~[100]~~	***300***
Inspection at time of biennial renewal.	~~[50]~~	***150***

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.

SMALL BUSINESS IMPACT STATEMENT
(Nevada Revised Statutes 233B.0608)

Proposed Amendment of Nevada Administrative Code (NAC) 652

Medical Laboratory Services

The regulations may impose a burden upon small businesses and may directly restrict the formation, operation, or expansion of a small business in Nevada. A small business is defined in Nevada Revised Statutes (NRS) 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees." This small business impact statement complies with the requirements of NRS 233B.0609.

Background

In 1974, the Nevada Legislature required the Board to adopt regulations concerning Medical Laboratories, to develop, establish and enforce minimum qualifications for directors and the certification of laboratory personnel, performance standards for laboratories and requirements for the retention of the health care and other regularly maintained records of laboratories. These latest proposed revisions clarify wording which has been difficult to enforce, and increase fees to conduct the required duties to determine accurate and reliable results for the performance of tests. The BLC has worked with representatives from the Medical Laboratory Advisory Committee (MLAC), and individuals within the laboratory communities, and although the proposed increase has generated a level of concern that certain categories of personnel, such as Laboratory Assistant, may not be able to afford to pay the increased fee, the necessity based on the increased number of laboratories and personnel, with additional complaints is evident as the program has not been self supporting for the past three years. Ten years ago, a biennial cycle was established to effectively conduct the duties without increasing the fees, which brings us to this step.

1. A description of the manner in which comment was solicited from affected small businesses, a summary and an explanation of the manner in which other interested parties may obtain a copy of the summary.

The 1999 legislature amended Nevada Revised Statutes (NRS) Chapter 233B to require that state agencies assess the impact of regulation changes or development on small businesses. In keeping with this requirement, all identified facilities and personnel were sent a small business impact questionnaire (See Attachment A) and a copy of the draft regulations to allow them to express their concerns over the economic impact of these proposed regulations on their businesses. A total of 9,100 questionnaires were sent on September 10, 2007 and one hundred eight (108) were returned. Thirteen responses did not meet the Small Business Impact statutory definition, exceeding the 150 employees limit. The comments received are summarized as follows:

Twenty seven (27) were returned indicating there would be no direct adverse effect. Fifty one (51) indicated that there would be an adverse effect.

Sixty six (66) were returned indicating there would be no beneficial effect on the businesses. Three (3) questionnaires were returned indicating there would be a beneficial effect.

Twenty-nine (29) questionnaires were returned indicating there would be an indirect adverse effect on the businesses. Thirty eight (38) indicated that there would be no indirect adverse effect. One (1) indicated that they were not sure as to whether or not there would be an indirect effect.

Sixty four (64) questionnaires were returned indicating there would be no indirect beneficial effect on the businesses. Three (3) questionnaires were returned indicating there would be a beneficial effect. Two (2) questionnaires indicated that they were not sure as to whether or not there would be no indirect beneficial effect.

The comments in Attachment B are the responses to the questions on the small business impact questionnaires.

Copies of the questionnaire summaries containing all comments are available from the office of the Bureau of Licensure and Certification, 1550 E. College Parkway, Suite 158, Carson City, Nevada 89706, (775) 687-4475 or 4220 South Maryland Parkway, Building D, Suite 810, Las Vegas, Nevada 89119. (702) 486-6515

2. The estimated economic effect of the proposed regulation on the small business which it is to regulate including without limitation both adverse and beneficial effects.

These regulations will have an adverse economic effect on small businesses. The anticipated beneficial effect is to survey laboratories timely and improve the patient care, and clarify wording to improve compliance.

3. A description of the methods the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods.

The agency reviewed the suggestions for changes that would lessen the economic impact. Wherever possible, in keeping with existing state laws, these changes will be made.

4. The estimated cost to the agency for enforcement of proposed regulations.

There is no cost to the agency for enforcement of the proposed regulations.

5. If the proposed regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

There are no new fees associated with the enforcement of the proposed regulations; the increased fees will enable initial surveys to be timely so that businesses can begin operating sooner. The increase in fees will provide adequate funding to support the program.

6. If the proposed regulation includes provisions which duplicate or are more stringent than federal, state or local standards regulating the same activity, an explanation of why such duplicative or more stringent provisions are necessary.

These proposed regulations do not duplicate existing state or federal regulations.