ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R078-04

Effective August 5, 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, a person who holds a certificate or any 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, "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.

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 which is registered pursuant to section 3 of this regulation; and

(b) Do not apply to an exempt laboratory which is 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 categorized pursuant to 42 C.F.R. § 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 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; ~~[or]~~

(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 .]~~ ***fee prescribed in NAC 652.488.***

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6. A ~~[copy of this section will be provided upon request to persons who are certified on or after September 6, 1988.]~~ ***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

Technologist.....75

Technician.....75

Pathologist's assistant.....75

Point-of-care test analyst.....50

Laboratory, blood-gas or office laboratory assistant.....40

Biennial renewal:

General supervisor.....100

Technologist.....50

Technician.....50

Pathologist's assistant.....50

Point-of-care test analyst.....40

Laboratory, blood-gas or office laboratory assistant.....30

Reinstatement:

General supervisor.....150

Technologist.....75

Technician.....75

Pathologist's assistant.....75

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. ***Change of name of laboratory.....$250***

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 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.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R078-04

The Health Division of the Department of Human Resources adopted regulations assigned LCB File No. R078-04 which pertain to chapter 652 of the Nevada Administrative Code on June 25, 2004.

Notice date: 5/25/2004 **Date of adoption by agency:** 6/25/2004
Hearing date: 6/25/2004 **Filing date:** 8/5/2004

INFORMATIONAL STATEMENT

1. DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION OF HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

The Medical Laboratory Advisory Committee reviewed and recommended approval of the summary of changes at the January 30, 2004 meeting.

A Small Business Impact Questionnaire was mailed to the Medical Laboratories on February 27, 2004. Attachment A is the Small Business Impact Statement Questionnaire. Attachment B is a copy of the small business impact summary.

Notice of public workshops held on March 29, 2004, in Las Vegas and on April 1, 2004, in Reno was published in the Las Vegas Review Journal and Reno Gazette Journal on March 10, 2004. Notices of public workshops, and proposed regulations were mailed to all county libraries in Nevada, Medical Laboratories, and interested parties on February 27, 2004. The small business impact summary was available at both workshops.

Five individuals commented during the workshops, the comments were subject to General Supervisor qualifications, one comment was on language consistency regarding respiratory technicians.

Notice of public hearing regarding the Board's intent to adopt amendments was published in the Las Vegas Review Journal, and Reno Gazette Journal on May 25, 2004. Notices of public hearing, and proposed regulations were mailed to all county libraries in Nevada, Medical Laboratories, and interested parties on May 24, 2004. The notice of public hearing was mailed to the Clark County Health District, and the Washoe County District Health Department on May 24, 2004.

Copies of the workshop minutes and Board of Health hearing minutes may be obtained by calling the Bureau of Licensure and Certification at (775) 687-4475.

2. THE NUMBER OF PERSONS WHO:

(A) ATTENDED THE HEARING;

Approximately 69 people attended the June 25, 2004, Board of Health hearing.

(B) TESTIFIED AT EACH HEARING; AND

No one in attendance testified on Medical Laboratories regulations.

(C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

Written public comment was received from Fuller Royal, MD, HMD requesting the addition of homeopathic physician, advanced practitioner of homeopathy and homeopathic assistant to the chapter addressing director qualifications and personnel allowed to laboratory testing. A thorough review of the regulations and discussion with legal counsel revealed that homeopathic physicians are included because they are required to be a medical doctor or doctor of osteopathy prior to receiving a homeopathic license. The regulations addressing who can perform waived testing did not require modification because advanced practitioners of homeopathy and homeopathic assistants must work under the supervision of a physician and may currently be certified as office laboratory assistants.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY

Comment was solicited from affected or potentially affected businesses by mailing appropriate facilities and all interested parties the proposed regulations, a small business impact questionnaire, a copy of the small business impact summary, and the notices for the workshops and Board of Health hearings. Copies of the workshop minutes and Board of Health hearing minutes may be obtained by calling the Bureau of Licensure and Certification at (775) 687-4475.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

No testimony was received in opposition to the proposed regulation or which suggested changes to the proposed regulation.

Fees have been calculated to meet the legislatively approved budget.

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

(A) BOTH ADVERSE AND BENEFICIAL EFFECTS; AND

Anticipated effects on the business which NAC 652 regulates.

Adverse: There will be increased costs to laboratories making changes to existing licenses and certificates to reflect current costs of doing business to evaluate and process applications and print certificates and licenses and to be consistent with BLC facility licensure fees. A cost for name change will be established consistent with existing BLC facility licensure fee.

Beneficial: There will increased General Supervisor staff availability for licensed laboratories and directors with Board certification in Forensic Toxicology and Medical Genetics will not need to request a variance to comply with director qualifications. The sections for appeal will now be consistent with statutory requirements currently in place and include provisions for certification consistent with licensure requirements. The applicability section will be clarified and include a provision for nurse practitioners and physician assistants to perform microscopy tests on their own patients without further certification in a Registered Exempt laboratory.

Anticipated effects on the public.

Adverse: None

Beneficial: Access to better care, by increasing the laboratory staffing options for General Supervisors, and allow reinstatement for personnel whose certification has lapsed for up to five years.

(B) BOTH IMMEDIATE AND LONG TERM EFFECTS.

Anticipated effects on the business which NAC 652 regulates.

Immediate**:** Increased General Supervisor staffing for Licensed Laboratory coverage. Laboratory directors for specialty laboratories in toxicology and genetics will qualify with the addition of the American Board of Forensic Toxicology and the American Board of Medical Genetics certification. The slight fee increases will provide more rapid response for laboratories in need of changes.

Long-term: Laboratories will be able to staff round the clock with more selection of General Supervisor to help with staffing shortages predicted. Nurse practitioners and Physicians assistants will not be required to have Office Laboratory Assistant certificates to perform microscopy testing on their own patients in a Registered Exempt laboratory.

The updates incorporated into this revision are designed to clarify requirements for the general population and include current terminology.

Anticipated effects on the public.

Immediate: None

Long-term: Overall long-term benefits include better access to laboratories facing staffing shortages without decreasing the fundamental knowledge and skills for testing personnel, and thus providing accurate, reliable results.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

Estimated cost to the Health Division for enforcement of the proposed regulations: It is anticipated that no additional staff time will be required for enforcement of the proposed regulations. Directors certified by the National Board of Forensic Toxicology and the American Board of Medical Genetics will not be required to obtain a variance to direct a laboratory in their specialty areas of Toxicology and Clinical Cytogenetics.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, NAME THE REGULATING FEDERAL AGENCY.

There is no duplication or overlap of other state or local government agency's regulations.

8. IF THE REGULATION INCLUDES PROVISION WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISION.

The proposed regulations do not overlap or duplicate federal regulations. The regulations do not have a counterpart in the code of federal regulations.

9. IF THE 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.

None.

SMALL BUSINESS IMPACT STATEMENT

Proposed Amendment of Nevada Administrative Code Chapter 652

Medical Laboratories

PROPOSED REVISIONS TO REGULATIONS for Medical Laboratories have been generated by the Bureau of Licensure and Certification (BLC).

Background

The purpose of the proposed revised regulations is to clarify the different types of laboratories and provide a section for nurse practitioners and physicians assistants to perform microscopy tests on their own patients without further certification in Registered Exempt laboratories. The regulations addressing director qualifications for licensed and registered labs have been updated to include certification by the American Board of Forensic Toxicology and The American Board of Medical Genetics. Individuals directing these specialty laboratories will no longer require a variance to the Nevada State Board of Health as a result of these regulation revisions. The requirements for General Supervisor have been revised from 6 years laboratory technical experience to 3 years of experience, and include allowance for additional education and less experience. The section for certification of personnel has been revised to allow reinstatement for lapsed certification for 5 years. The appeals sections have been revised to reflect current practices in NRS 439 and provide a new section for certificates. The regulation which defines part-time status has been deleted and is not referenced throughout the regulations. The regulation which defines rural area has been updated so that Henderson and North Las Vegas are not considered rural areas. The names of the certification agencies for Blood Gas Technologist have been updated to reflect their current names. The federal name change from Health Care Financing Administration has been updated to Centers for Medicare and Medicaid Services in the section for inspections. Fees have been slightly adjusted to reflect the current fees for changes consistent with other BLC facility fees for changes in location, director, name and the addition of tests to existing licenses and certificates.

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

Pursuant to NRS 233B.0608(2)(a), BLC has requested input from laboratory directors of laboratories licensed in accordance with NRS 652.080, and NRS 652.235, and NAC 652.155.

The BLC received 101 responses from laboratories (listed below) that met the definition of a small business; the responses and comments are summarized and attached to the summary. Two suggestions were received which were not part of the small business impact questionnaire and are summarized at the end regarding requests to include homeopathic physicians, physician assistants, and assistants.

Laboratory Type	Number of Responses
Registered Exempt	68
Registered Non-Exempt	19
Licensed	11

Three (3) responses did not check yes or no on any of the questions.

Interested parties can obtain a copy of the information packet, including the Small Business Impact Questionnaire sent to all licensed facilities, from Shirley Rains, Administrative Assistant III, Bureau of Licensure and Certification, 1550 East College Parkway, Suite 158, Carson City, Nevada 89706

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 and both direct and indirect effects.

Anticipated Adverse effects: There will be increased costs to Registered Non-Exempt and Licensed Laboratories that make changes to existing licenses and certificates. A fee for name change has been added where previously there was none. These fees are consistent with BLC facility licensure fees. The fee for inspection pursuant to NAC 652.320 has been deleted.

Anticipated Beneficial effects: There will be increased General Supervisor staff availability for licensed laboratories and directors with Board certifications in Forensic Toxicology and Medical Genetics will not need to request a variance to comply with director qualifications. The sections for appeal will now be consistent with licensure requirements. The applicability section will be clarified and include a provision for nurse practitioners and physicians assistants to perform microscopy tests on their own patients without further certification in a Registered Exempt laboratory.

The slight fee increase for the changes to existing Registered Non-Exempt and Licensed laboratories will have both direct and indirect beneficial economic effect to provide more rapid response to begin testing.

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

The BLC considered several methodologies for revising the regulations and with discussions with the Medical Laboratory Advisory Committee and staff, several suggestions were proposed.

These proposed changes will be beneficial to many laboratories. Fees remain unchanged for all laboratories, laboratory personnel and laboratory directors for initial, reinstatement, and renewal.

1) A fee for substantiated complaints was discussed but not utilized.
2) A fee for name change, and changes to existing Registered Non-Exempt and Licensed laboratories which is consistent with these fees for health facilities has been proposed to

cover expenses in providing more timely responses. Fees for inspection pursuant to NAC 652.320 were discussed and deleted.

3) Fee increases for laboratories, directors, and personnel were discussed but not utilized.

The methodology adopted was a combination of actual workload and streamlining activities using the website to increase productivity without substantial fee increases.

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

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

5. Total amount BLC expects to collect from any fees and the manner in which the money will be used.

The total amount BLC expects to collect from any fees is unknown since it is based on changes which cannot be predicted. Any fees collected will be used to cover the cost of staff review and the cost of printing certificates and licenses.

6. An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.

No duplication or more stringent provision are either created or already in existence.

Summary of comments from laboratories:

Question #2 Will a specific regulation have an adverse economic effect upon your business?

YES	9
NO	83

5 were unsure or did not know, and 4 were blank

Comments:

Yes Responses:

Registered Exempt Laboratories

1) "I have exempt lab in the office that runs very few waived tests. Any significant regulatory changes that increase licensing fees would inevitably impose a greater economic burden in a small office like mine."
Neither yes or no was marked, but this comment was written.

2) "I think for a small doctor's office with very limited lab testing the fees are very high."

3) "We already pay for federal fees plus inspection fees for this will place an economic burden."

4) "Increased Fees-increase costs & bureaucracy."

5) "Yes, but probably minimal secondary to increased license fees."

6) "Fees seem high for an office that only does 2000 labs per year."

7) "Increased cost"

8) "Physician should not have to perform blood draw on patients. Additional classification for physician to run"? (Unable to read the handwriting)

Registered Non-Exempt

1) "Any fee increase"

2) "Requires more admin efforts with related costs & personnel."

Question #3 Will the regulation have any beneficial effect upon your business?

YES	12
NO	79

5 were unsure or did not know and 5 were blank

Comments:

Yes Reponses:

Registered Exempt Laboratories

1) "Will allow nurse practitioners to more efficiently care for patients."

2) "Take too much of physician time away from patient continuing education for physician too excessive."

3) "The tests will be more accurate."

Registered Non-Exempt

1) "Easier to obtain general supervisor license."

2) "Because by following the regulations we will have more accurate/successful results for each test performed."

Licensed Laboratories

1) “Personnel qualifications reduced from 6 to 3 years opens up more personnel for supervisory positions.” Comment only, did not mark yes or no.

2) “Increases the number of generally supervisors in the area, larger market.”

3) “Availability to more general supervisors.”

4) “May improve opportunities to hire Technologists to staff laboratory.”

5) “Increased general supervisor staff availability for laboratories facing staffing shortages without decreasing the fundamental knowledge and skills for testing personnel.”

6) “HOPEFULLY! We can find a 3 year tech easier than a 6 year tech; that is willing to move to rural Nevada.”

7) “It will increase availability of general supervisors, especially on nights and weekends.”

Question #4 Do you anticipate any indirect adverse effects upon your business?

YES	6
NO	86

4 were unsure or did not know and 5 were blank

Comments:

Yes Responses:

Registered Exempt Laboratories

1) “Increased cost.”

2) “Increased expense.”

3) “Increased expenses with decreased reimbursement!”

4) “Time away from patient care too costly. Surveys for existing facilities should only be done every 3 years.”

Registered Non-Exempt Laboratories

1) “Cost to patients will probably go up.”

2) “Possible time demands, fines for non-compliance, etc.”

Question #5 Do you anticipate any indirect beneficial effects upon your business?

YES	2
NO	89

5 were unsure of did not know and 5 were blank
Comments:

Yes Responses:

Registered Exempt Laboratories

1) “Can only be better with accuracy.”

Licensed Laboratories

1) “Increases number of available Technologists and staffing options.”

No Responses:

Registered Non-Exempt Laboratories

1) “Not sure”

There was one response with “Don’t Know” on every question and an editorial comment along the side, “In general, business is jungle warfare and you must watch every step of the way. If you find trouble, work with your professional organization. On a personal basis, protect your assets with limited liability partnerships and minimize your overhead expenses.”

Two suggestions were received which were not sent the Small Business Impact Questionnaire as follows:

David A. Edwards, MD, HMD requested the addition of Advanced Practitioners of Homeopathy as defined in NRS 630A.015, Homeopathic Assistants as defined in NRS 630A.035 be added to NAC 652.1555 section 5, and licensed homeopathic physician pursuant to NRS 630A.050 be added to section 6.

The State of Nevada Board of Homeopathic Medical Examiners has requested the same.