ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R176-07

Effective January 30, 2008

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

AUTHORITY: §§1-3, NRS 439.200, 652.123, 652.130 and 652.235; §§4 and 5, NRS 439.200, 652.130 and 652.140; §§6-10, NRS 652.123, 652.125 and 652.130; §11, NRS 439.150, 652.100 and 652.125.

A REGULATION relating to medical laboratories; revising provisions governing medical laboratories; authorizing the Bureau of Licensure and Certification of the Health Division of the Department of Health and Human Services to investigate medical laboratories upon receipt of a complaint; revising requirements governing reports made by medical laboratories; revising the required qualifications of certain employees of medical laboratories; increasing certain fees relating to certain medical laboratories; and providing other matters properly relating thereto.

Section 1. NAC 652.155 is hereby amended to read as follows:

652.155 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 NAC 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 ***this*** 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]~~ ***from*** 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 in 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 ***this*** 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;

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

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

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

Sec. 2. NAC 652.175 is hereby amended to read as follows:

652.175 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 physician licensed as a doctor of medicine pursuant to chapter 630 of NRS;***

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

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

~~[(b)]~~ ***(d)*** A podiatric physician licensed pursuant to chapter 635 of NRS.

Sec. 3. 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]~~ ***shall*** 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. 4. 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 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 its 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.

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. 5. 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 full name of or a number which identifies the person from whom the specimen was taken.***

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

Sec. 8. 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) 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]~~ ***A person*** may upgrade ~~[their classification]~~ ***his 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. 9. NAC 652.480 is hereby amended to read as follows:

652.480 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]~~ ***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]~~ ***course of*** 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. 10. NAC 652.483 is hereby amended to read as follows:

652.483 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~~] ***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. 11. NAC 652.488 is hereby amended to read as follows:

652.488 The following nonrefundable fees will be charged:

1. Licensure of laboratory ***not described in subsection 2***

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 laboratory operated by health district, district board of health, county board of health or city or town board of health, or the State Hygienic 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

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

3. Licensure of director ***pursuant to paragraph (b) of subsection 3 of NAC 652.175, or NAC 652.380, 652.385 or 652.395***

Initial ..... ~~[$250]~~ ***$500***

Biennial renewal ..... ~~[150]~~ ***300***

Reinstatement ..... ~~[250]~~ ***500***

~~[3.]~~ ***4.*** 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.]~~ ***5.*** 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.]~~ ***6.*** 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.]~~ ***7.*** Placement of license or certificate in inactive status ..... ~~[$20]~~ ***$50***

~~[7.]~~ ***8.*** Issuance of original duplicate license or certificate ..... ~~[$20]~~ ***$50***

~~[8.]~~ ***9.*** Permit to operate laboratory at temporary location ..... ~~[$35]~~ ***$300***

~~[9.]~~ ***10.*** Change of location of laboratory ..... ~~[$250]~~ ***$300***

~~[10.]~~ ***11.*** Change of director of laboratory ..... ~~[$250]~~ ***$300***

~~[11.]~~ ***12.*** Change of name of laboratory ..... ~~[$250]~~ ***$300***

~~[12.]~~ ***13.*** Inspection for additional specialties and subspecialties in which tests will be performed at laboratory ..... ~~[$250]~~ ***$300***

Plus $50 for each additional specialty or subspecialty

~~[13.]~~ ***14.*** Inspection of an outpatient center of a laboratory (per site)

Initial inspection ..... ~~[$100]~~ ***$300***

Inspection at time of biennial renewal ..... ~~[50]~~ ***150***

~~[14.]~~ ***15.*** 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.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R176-07

The State Board of Health adopted regulations assigned LCB File No. R176-07 which pertain to chapter 652 of the Nevada Administrative Code.

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.

A Small Business Impact Questionnaire was mailed to Licensed Laboratories, Registered Laboratories, and Exempt Laboratories on September 3, 2007. 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 October 8, 2007, in Carson City and on October 9, 2007, in Las Vegas, was published in the Las Vegas Review Journal and Reno Gazette Journal on or before September 21, 2007. Notices of public workshops, and proposed regulations were mailed to all county libraries in Nevada, Licensed Laboratories, Registered Laboratories, Exempt Laboratories, Laboratory Directors, laboratory personnel, and interested parties on September 10, 2007. The Small Business Impact Summary was available at both workshops.

The minutes of that meeting, attached hereto, contain a summary of the discussion held regarding the proposed amendments.

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

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 or before November 7, 2007. Notices of public hearing, and proposed regulations were mailed to all county libraries in Nevada, Licensed Laboratories, Registered Laboratories, Exempt Laboratories, Laboratory Directors, laboratory personnel, and interested parties on November 5, 2007. The notice of public hearing was mailed to Southern Nevada Health District and Washoe County District Health Department on November 5, 2007.

Copies of the Board of Health hearing minutes may be obtained by calling the Nevada State Health Division at (775) 684-4200.

2. THE NUMBER OF PERSONS WHO:

(A) ATTENDED THE HEARING;

Approximately 50 people attended the December 7, 2007 Board of Health hearing.

(B) TESTIFIED AT EACH HEARING; AND
December 7, 2007: 2
(C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.
December 7, 2007: 3

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.

Numerous comments were received concerning proposed fee increases, expressing concern with the costs for certain licensed laboratory personnel and for small volume laboratories. Additionally there was comment about sections of the regulations relating to the qualifications of laboratory personnel, including: technologists in the military being able to qualify as technologists in Nevada, ability of people without bachelor's degrees to qualify for certain laboratory personnel positions, people without qualifications being able to perform waived tests.

Copies of the workshop minutes may be obtained by calling the Bureau of Licensure and Certification at (775) 687-4475. Copies of the Board of Health hearing minutes may be obtained by calling the Nevada State Health Division at (775) 684-4200.

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.

The State Board of Health adopted the proposed amendments to NAC 652, "Medical Laboratories" LCB File No. R176-07 with an errata.

Although testimony received in opposition to the proposed regulation was considered by the State Board of Health, the Board determined it necessary to adopt fee increases to support the legislatively approved budget and well as clarify particular language regarding the qualifications of laboratory personnel. The proposed regulation was adopted with an errata prepared by the Bureau of Licensure and Certification relating to fees for public health laboratories, attached hereto.

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: The potential adverse effect may be an increase in licensing fees associated with the time and effort expended in evaluating new applicants and conducting initial surveys.

Beneficial: The beneficial impact for laboratories and the patients is reducing the long waiting period to begin testing. The beneficial impact for laboratories and technical personnel working in a laboratory is having regulations that reflect current standards of practice in a clear and concise manner.

Anticipated effects on the public:

Adverse: Healthcare consumers may experience an increase in fees for laboratory services as a result of pass through of licensure fee increases for laboratories.

Beneficial: The beneficial impact for the general public is increasing access to newly licensed laboratories.

(B) BOTH IMMEDIATE AND LONG TERM EFFECTS.

Anticipated effects on the business which NAC 652 regulates.

Immediate: The immediate impact may be an increase in licensing fees for new applicants and renewals.

Long-term: Revising and updating the medical laboratory licensing fees will allow the Bureau of Licensure and Certification to have adequate revenue to support the legislatively approved budget for the medical laboratory licensing program.

Anticipated effects on the public:

Immediate: Same

Long-term: The long-term effect will be increased availability of licensed laboratories and physicians performing in office testing, resulting from the agency's increased capacity to conduct initial surveys.

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

There is no anticipated additional cost to the agency for enforcement of the proposed regulation changes.

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.

These 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.

These amendments do not establish new fees. The fee increases have been established to generate revenue equal to the legislatively approved program budget. Funds will be used to hire two additional medical laboratory program staff to increase the number and timeliness of initial licensure inspections and complaint investigations.

10. IS THE PROPOSED REGULATION LIKELY TO IMPOSE A DIRECT AND SIGNIFICANT ECONOMIC BURDEN UPON A SMALL BUSINESS OR DIRECTLY RESTRICT THE FORMATION, OPERATION OR EXPANSION OF A SMALL BUSINESS? WHAT METHODS DID THE AGENCY USE IN DETERMINING THE IMPACT OF THE REGULATION ON A SMALL BUSINESS?

The agency received 108 responses to the 9,100 Small Business Impact Questionnaires that were distributed. Concerns were expressed about the amount of fee increase for certain laboratory personnel and for small volume laboratories. The agency revised the percent increases and created a graduated structure of fee increases for lab personnel and small volume laboratories to reduce the cost impact to individuals and small volume laboratories.