

Joe Lombardo
Governor



Richard Whitley,
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Director



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MPH
Administrator

Ihsan Azzam,
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Chief Medical
Officer

NOTICE OF INTENT TO ACT UPON REGULATION

LCB FILE NO. R145-23

NEVADA ADMINISTRATIVE CODE CHAPTER 652, MEDICAL LABORATORIES

NOTICE IS HEREBY GIVEN that the State Board of Health will hold a public hearing to consider amendments to Chapter 652 of the Nevada Administrative Code (NAC). This public hearing is to be held in conjunction with the State Board of Health meeting on Sept. 6, 2024.

The State Board of Health will be conducted via videoconference beginning at 9 a.m., on Sept. 6, 2024, at the following locations:

- Click or type into a web browser the following link to join the meeting online:
https://teams.microsoft.com/l/meetup-join/19%3ameeting_ZjcxNGQzYjQtMzMlOS00MTNiLTg1ZWYtMmExODkwZTBkMTQ0%40thread.v2/0?context=%7b%22Tid%22%3a%22e4a340e6-b89e-4e68-8eaa-1544d2703980%22%2c%22Oid%22%3a%22768e443d-3be6-48f0-9bb0-7e72f1276b8d%22%7d
- Phone number: (775) 321-6111
 - Conference ID: 382 183 728#
- Division of Public and Behavioral Health
Hearing Room 303
4150 Technology Way
Carson City, NV 89706
- Southern Nevada Health District
Red Rock Trail Rooms A & B
208 S. Decatur Blvd.
Las Vegas, NV 89107

The proposed changes to LCB File No. R145-23, as authorized by [2023's Assembly Bill \(AB\) 432](#), proposed changes pursuant to Governor Lombardo's efforts to streamline burdensome regulations, and regulation changes to update and clarify, include the following:

- Bring the NAC into compliance with AB 432 of the 2023 Legislative Session; Chapter 230 Statutes of Nevada 2023 at page 1462; and changes to the Federal Register 42 CFR part 493 effective Dec. 28, 2024.
- Remove the requirement that an application for the issuance or renewal of a laboratory personnel certificate, and laboratory license, registration or permit be submitted on a form provided by the Division of Public and Behavioral Health (DPBH) and instead require such an application to be made in the form prescribed by DPBH.
- Replaces a requirement that DPBH provide that form to the holder of such certification not less than 90 days before the expiration of the certificate with a requirement that DPBH notify the

holder of the impending expiration of the certificate.

- Revise the qualifications for certification as a histotechnologist, a histologic technician and a technologist, respectively, in a manner that expands the persons eligible for such certification.
- Revises the length of such a period of temporary employment to not more than 6 months while the application is being processed, authorizes an additional period of temporary employment for not more than 30 days after an application has been reviewed and DPBH has requested additional information from the applicant, and revises the date by which substantiating documents for an application for certification as laboratory personnel must be submitted.
- Requires registered laboratory director of a laboratory to ensure that an office laboratory assistant performing certain testing is appropriately trained and educated and requires an office laboratory assistant performing certain testing to possess the qualifications required by certain federal regulations.
- Repeals NAC 652.600 which requires regulatory requirements for a program of training for certification as a technician in accordance with Governor Lombardo's effort to streamline burdensome regulations.
- Updates the names of certifying organizations.
- Clarifies when laboratories that are licensed by the state are to submit applications to update the changes to their laboratory.
- Adds a certifying organization that has been approved by the Centers for Medicare and Medicaid Services (CMS), to certify persons with an earned doctoral degree in a chemical, biologic or clinical laboratory science, to qualify for a Registered or Licensed laboratory director.
- In accordance with a change in the regulatory requirements of the Clinical Laboratory Improvement Amendments (CLIA) program that will occur on Dec. 28, 2024, the CLIA requirements for laboratory personnel, will remove the qualification of a person with a degree in a Physical Science. The regulation update to NAC Chapter 652 will also remove this qualification as of Jan. 1, 2025, but allow for persons that were qualified with this degree, continue to be qualified.
- Adds students that are in an accredited school for Licensed Practical Nursing (LPN) to be qualified for a Point-of-Care Analyst (POC) certification.

1. Anticipated effects on the business which LCB File No. R145-23 regulates:

- Adverse effects:* There are no anticipated adverse economic effects on businesses in the State of Nevada.
- Beneficial effects:* There are no anticipated beneficial or positive economic effects on businesses in the State of Nevada.
- Immediate:* As soon as the proposed regulations become effective, there are no anticipated immediate economic effects on businesses in the State of Nevada.
- Long-term:* There are no anticipated long-term economic benefits or adverse effects to businesses in the State of Nevada.

2. Anticipated effects on the public:

- Adverse:* There are no anticipated adverse effects for the public receiving medical laboratory services in health care facilities associated with the proposed regulation changes.
- Beneficial:* There are no anticipated beneficial effects to the public receiving medical laboratory services in health care facilities associated with the proposed regulation changes.
- Immediate:* There are no anticipated immediate effects to the public receiving medical laboratory services in health care facilities associated with the proposed regulation changes.
- Long-term:* There are no anticipated immediate effects to the public receiving medical laboratory services in health care facilities associated with the proposed regulation changes.

3. DPBH determined the impact on small businesses by distributing an email containing a link to the small-business impact questionnaire to 18,788 actively licensed medical laboratory facilities, and actively licensed and certified laboratory personnel, along with a copy of the proposed regulation changes to NAC Chapter 652. The results from the questionnaire were analyzed and tallied and then documented in a small business impact statement. DPBH also conducted a public workshop on July 12, 2024, and received additional information suggested to add an additional certifying agency for the qualification of laboratory personnel. This suggestion is incorporated into the proposed changes.

4. There should be no additional costs to the agency to enforce the proposed regulation changes.

5. The proposed regulations do not overlap or duplicate any other Nevada state or federal regulations.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8-1/2" x 11" pages must submit the material to the Board's Secretary, Cody Phinney, to be received no later than Aug. 30, 2024, at the following address:

Secretary, State Board of Health
Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89706
stateBOH@health.nv.gov

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

A copy of the notice and proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

- Nevada Division of Public and Behavioral Health
4150 Technology Way, Suite 300
Carson City, NV 89706
- Nevada Division of Public and Behavioral Health
4220 S. Maryland Parkway, Bldg. A, Ste. 100
Las Vegas, NV 89119
- Nevada State Library and Archives
100 Stewart Street
Carson City, NV, 89701

A copy of the regulations and small-business impact statement can be found online by going to the Health Facility Regulation Development Processes web page at https://dpbh.nv.gov/Reg/HealthFacilities/State_of_Nevada_Health_Facility_Regulation_Public_Workshops/

A copy of the public hearing notice can also be found at the Nevada Legislature web page here: <https://www.leg.state.nv.us/App/Notice/A/>

Copies may be obtained in person, by mail, or by calling the Division of Public and Behavioral Health at:

Division of Public and Behavioral Health
Bureau of Health Care Quality and Compliance
4220 S. Maryland Parkway, Building A, Suite 100
Las Vegas, NV 89119
(702) 486-6515
tcarney@health.nv.gov

Copies may also be obtained from the Nevada State Library at the address listed below:

Nevada State Library & Archives
100 N. Stewart Street
Carson City, NV 89701

Per NRS 233B.064(2), upon adoption of any regulation, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

Joe Lombardo
Governor



Richard Whitley,
MS
Director

**DEPARTMENT OF
HEALTH AND HUMAN SERVICES**

 **NEVADA DIVISION of PUBLIC
and BEHAVIORAL HEALTH**



Cody Phinney,
MPH
Administrator

Ihsan Azzam,
Ph.D., M.D.
Chief Medical
Officer

MEMORANDUM

DATE: August 16, 2024

TO: Jon Pennell, DVM, Chairperson, State Board of Health

FROM: Cody Phinney, MPH, Administrator, Division of Public and Behavioral Health (DPBH)

RE: Consideration and adoption of the proposed regulation amendment to Nevada Administrative Code (NAC) Chapter 652, Legislative Council Bureau (LCB) File No. R145-23RP1.

PURPOSE OF THE AMENDMENT

The purpose of the proposed regulations revises current regulations regarding updating the language of Chapter 652 when the chapter refers to completing applications. The current verbiage refers to completing an actual form when completing an application for laboratory licensing or laboratory personnel licensing or certification. The language change would refer to completing a form as prescribed by the Division so that any changes in the future would not require regulatory updates.

The proposed regulation changes also address the following:

- The amendment will remove Physical Science as an acceptable education qualification for laboratory directors and medical technologists which will be consistent with the federal change by the CMS/CLIA program which will occur on 12/28/2024. There has been language added that states that anyone that has been approved with a Physical Science education prior to 1/01/2025, will continue to be found qualified for the associated license or certification in which there is a requirement.
- The amendment adds the American Society of Clinical Pathology as an approved certification agency for laboratory directors to be qualified.
- It adds an Optometrist licensed by their board in the State of Nevada, as being qualified to be a laboratory director of an EXEMPT laboratory as approved by the Nevada Legislature and Governor Lombardo via 2023's Assembly Bill (AB) 432.
- It broadens the opportunity to hold a Nevada laboratory certification as a histotechnologist or a histologic technician by expanding the accrediting organizations used for acceptable qualification.
- It requires laboratory directors who employ office laboratory assistants that perform moderate or high complexity laboratory tests, ensure that the testing employees have the appropriate level of education and training to meet federal requirements.
- It adds Licensed Practical Nurses (LPN's) who are enrolled in an approved school of nursing, to be qualified for a point-of-care analyst certification.

- It reduces the time in which the Division of Public and Behavioral Health (DPBH) allows for laboratory personnel application processing.
- It adds molecular biology as an acceptable certification for the qualification for a technologist.
- It repeals an unused training regulation for certification of medical laboratory technicians as part of Governor Lombardo's effort to streamline burdensome State regulations.

POSSIBLE OUTCOME IF PROPOSED AMENDMENTS ARE NOT APPROVED

If the proposed amendments are not approved by the Nevada Board of Health, the applicable current regulations would not align with statutory changes that resulted with the passage of AB 432 and Governor Lombardo's directive to repeal burdensome regulation. In addition, if the proposed provisions are not moved forward, the issues that would be resolved by these proposed regulation amendments, would not be realized.

APPLICABILITY OF PROPOSED AMENDMENTS

The proposed regulation amendments will apply statewide to laboratories licensed by DPBH, laboratories that are licensed by DPBH in other states and laboratory personnel who are licensed or certified by DPBH.

PUBLIC COMMENT RECEIVED

Pursuant to NRS 233B.0608(2)(a), the Division of Public and Behavioral Health has requested input from laboratories and laboratory personnel that are licensed or certified by DPBH pursuant to Chapter 652-Medical Laboratories.

On April 9, 2024, information was sent to all laboratories and laboratory personnel who are licensed or certified by DPBH regarding how small businesses would be affected by the regulation amendments. The information was sent to 18,788 email destinations in which the respondents could provide input on the proposed regulation amendments and how to access the small business impact questionnaire and the proposed regulation amendments through a link to the Division webpage. The timeframe for a response from the laboratory community was from April 9, 2024, through April 26, 2024.

The results of the small business impact study are summarized in the attached Small Business Impact Statement.

On June 25, 2024, a Notice of Public Workshop was sent and posted to request input regarding regulation amendments to Chapter 652 from the laboratory community and from other interested parties.

The Public Workshop was held on July 12, 2024, to receive recommendations and commentary regarding the regulatory amendments to Chapter 652. There were seven (7) DPBH participants, six (6) members of the public and one (1) unverified phone participant. There were two (2) members of the public that provided public commentary.

One of the comments from the public was from a person from the American Society of Clinical Pathology (ASCP). He stated that there is a new exam for certification through the American Society for Clinical Pathology for laboratory directors who have earned a Ph.D. in a biologic science. He suggested to add the American Society of Clinical Pathology certification to be added to the list of acceptable organizations in which laboratory directors may be licensed. It was confirmed that this certification has been accepted by the federal Clinical Laboratory Improvement Amendments (CLIA) program for the qualification of laboratory directors of laboratories that perform moderate and high complexity testing. This suggestion was added to the regulatory amendments of R145-23RP1 under section eight (8) and section nine (9).

The same individual suggested to update the terminology for laboratory personnel to be more in line with the terminology used by the ASCP. Specifically, he suggested that instead of referring to technologists as “Clinical Laboratory Technologist”, that we consider changing to the terminology that is currently used by the ASCP which is “Medical Laboratory Scientist”. This suggestion was not considered at this time due to the cost that would be associated with the change in not only the terminology for a Clinical Laboratory Technologist” in the certification by the Division, but for perhaps other laboratory personnel certifications that could also be affected.

The last public comment was from a member of the public which was to clarify the certification by the ASCP for laboratory directors was not in place of an earned Ph.D. but an exam for certification after a person had received their Ph.D.

There were no additional written or oral comments from the public regarding the regulatory amendments for LCB File R145-23RP1.

Staff recommendation

The staff recommends the Nevada State Board of Health adopt the proposed regulation amendments to Nevada Administrative Code (NAC) 652, “Medical Laboratories”, LCB File No. R145-23RP1.

Presenter

Bradley Waples, BS, MT (ASCP), Health Facility Inspection Manager-Medical Laboratory Services

Attachments:

LCB File No. R145-23RP1

Small Business Impact Statement

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

LCB File No. R145-23

August 5, 2024

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

AUTHORITY: §§ 1, 2 and 5, NRS 439.200, 652.090 and 652.130; §§ 3 and 4, NRS 439.200 and 652.130; § 6, NRS 439.200, 652.090, 652.125 and 652.130, §§ 7-9, 11-23, 26 and 27, NRS 439.200, 652.125 and 652.130; § 10, NRS 439.200, 652.125 and 652.130, as amended by section 29 of Assembly Bill No. 432, chapter 230, Statutes of Nevada 2023, at page 1462; §§ 24 and 25, NRS 439.200 and 652.125.

A REGULATION relating to medical laboratories; requiring a laboratory to notify the Division of Public and Behavioral Health of the Department of Health and Human Services before certain changes are made to the laboratory; revising the procedure to apply for the issuance or renewal of certain licenses, registrations, permits and certifications; revising the required qualifications of certain laboratory personnel; revising provisions governing the temporary employment of certain laboratory personnel; revising provisions governing office laboratory assistants; repealing certain requirements governing programs of training for certification as a technician; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law: (1) requires the State Board of Health to adopt regulations carrying out provisions governing the requirements for an application for a license to operate a medical laboratory; and (2) authorizes the Board to adopt regulations for the certification and licensure of laboratory directors and certain laboratory personnel. (NRS 652.090, 652.130) Existing law also exempts certain laboratories operated by licensed physicians from requirements governing medical laboratories if those exempt laboratories register with the Division of Public and Behavioral Health of the Department of Health and Human Services and comply with certain other requirements. (NRS 652.072) Existing regulations require a licensed laboratory that wishes to collect specimens or perform tests, or both, at a location other than the location set forth in its license to obtain a permit from the Division. (NAC 652.195) **Section 1** of this regulation requires a licensed or registered laboratory to notify the Division before certain changes are made to the laboratory. **Sections 2-7, 17 and 23-25** of this regulation remove the requirement that an application for the issuance or renewal of such a certificate, license, registration or permit be submitted on a form provided by the Division and instead require such an application to be made

in the form prescribed by the Division. **Section 19** of this regulation similarly replaces references to a form for the renewal of certification as laboratory personnel with references to an application for the renewal of such certification. **Section 19** accordingly replaces a requirement that the Division provide that form to the holder of such certification not less than 90 days before the expiration of the certificate with a requirement that the Division notify the holder of the impending expiration of the certificate.

Sections 8, 9, 11, 12, 14, 21 and 22 of this regulation remove a degree in physical science as a qualifying degree for licensure as a director of a licensed or registered laboratory, a certificate as a general supervisor of a licensed laboratory, a clinical laboratory technologist, a histologic technician or certification as a technologist in a specialty. **Section 26** of this regulation provides that a person who: (1) holds such a degree remains qualified for licensure or certification, as applicable, if he or she applies for licensure or certification on or before December 31, 2024, or the effective date of this regulation, whichever is later; or (2) holds such a license or certificate on December 31, 2024, or the effective date of this regulation, whichever is later, is deemed to be qualified to continue holding the license or certificate.

Existing law requires that regulations adopted by the Board that require the directors of laboratories that perform only certain tests to be licensed physicians must include licensed optometrists among such physicians. (NRS 652.130, as amended by section 29 of Assembly Bill No. 432, chapter 230, Statutes of Nevada 2023, at page 1462) **Section 10** of this regulation provides that a licensed optometrist may serve as the director of a laboratory that performs only such tests or provider-performed microscopy procedures.

Sections 13, 14 and 20 of this regulation revise the qualifications for certification as a histotechnologist, a histologic technician and a technologist, respectively. **Section 15** of this regulation corrects a typographical error.

Existing regulations authorize certain persons, including a registered nurse, a licensed practical nurse or a student enrolled in an accredited school of professional nursing or certain graduates of such a school, to obtain a certificate as a point-of-care test analyst. (NAC 652.454) **Section 16** of this regulation additionally authorizes a student enrolled in an accredited school of practical nursing or certain graduates of such a school to obtain such a certificate.

Existing regulations generally require the technical personnel of a laboratory to be certified by the Division. However, existing regulations authorize a laboratory to temporarily employ uncertified personnel for not more than 12 months while an application for certification is being processed. (NAC 652.470) **Section 17**: (1) revises the length of such a period of temporary employment to not more than 6 months while the application is being processed; and (2) authorizes an additional period of temporary employment for not more than 30 days after an application has been reviewed and the Division has requested additional information from the applicant. **Section 17** also revises the date by which substantiating documents for an application for certification as laboratory personnel must be submitted.

Existing regulations generally require any technical personnel newly employed in a laboratory which only performs tests on patients of a particular physician and the partner and associates of his or her private practice to be certified as at least an office laboratory assistant. However, existing regulations authorize a person who does not hold such certification to serve as an office laboratory trainee for not more than 6 months. (NAC 652.472) **Section 18** of this regulation removes such authorization, thereby requiring any person newly employed in such a laboratory to be certified as at least an office laboratory assistant. **Section 18** also requires: (1) the director of such a laboratory to ensure that an office laboratory assistant performing certain

testing is appropriately trained and educated; and (2) an office laboratory assistant performing certain testing to possess the qualifications required by certain federal regulations.

Section 27 of this regulation repeals a requirement that a program of training intended to prepare a person for certification as a technician be approved by the Division. **Sections 8 and 9** make conforming changes to remove references to the repealed section. **Sections 8, 9, 13 and 14** update the names of certain organizations. **Sections 24 and 25** of this regulation correct certain references to sections of the Nevada Administrative Code.

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

1. Before any of the information provided to the Division on an application for the issuance or renewal of a license or registration for a laboratory changes, the applicant, licensee or registrant, as applicable, shall notify the Division in the form prescribed by the Division. Such changes may include, without limitation:

- (a) A change to the name of the laboratory;*
- (b) The addition of a test or analyte; or*
- (c) A change in the methodology for performing a test.*

2. Upon receipt of a completed application pursuant to subsection 1, the Division shall inspect the facility to determine whether the laboratory is in substantial compliance with this chapter for the procedures for testing that the laboratory desires to provide. Such an inspection may include, without limitation:

- (a) An examination of the policies and procedures used by the laboratory; and*
- (b) A validation or verification of the instruments and methodologies of the laboratory.*

Sec. 2. NAC 652.170 is hereby amended to read as follows:

652.170 1. An *initial* application for a license or registration for a laboratory must be made ~~on a~~ *in the* form ~~provided~~ *prescribed* by the Division. Upon receipt of a completed application, the Division shall conduct an inspection of the facility which may include an

examination of 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 Division shall notify the applicant of the disposition of the application within 30 days after receipt of the application.

3. The laboratory director shall include at least one of the following forms of proof of identity with the application:

(a) An electronic signature;

(b) A notarized statement;

(c) A copy of a form of government-issued identification, which may include, without limitation, a driver's license, passport, identification card issued by the Department of Motor Vehicles or other government-issued identification acceptable to the Division; or

(d) Other proof of identity acceptable to the Division.

4. As used in this section, "electronic signature" means a user name attached to or logically associated with a record and executed or adopted by an applicant with the intent to sign an electronic application or other document.

Sec. 3. NAC 652.175 is hereby amended to read as follows:

652.175 1. A laboratory operated by a licensed physician pursuant to NRS 652.072 must register with the Division as an exempt laboratory or a nonexempt laboratory.

2. A laboratory operated by a licensed physician pursuant to NRS 652.072 may register with the Division as an exempt laboratory if:

(a) The operating physician submits an application for registration as an exempt laboratory ~~on a~~ *in the* form ~~provided~~ *prescribed* by the Division;

(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 or her own patients and makes his or her 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 652.072 may register with the Division as a nonexempt laboratory if:

(a) The operating physician submits an application for registration as a nonexempt laboratory ~~on a~~ *in the* form ~~provided~~ *prescribed* by the Division;

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

Sec. 4. NAC 652.180 is hereby amended to read as follows:

652.180 1. Except as otherwise provided in subsection 2, the Division shall issue a certificate of registration to each laboratory which registers with the Division pursuant to NRS 652.072. A certificate of registration issued pursuant to this section is effective for 2 years after the date of issuance.

2. The Division may issue one certificate of registration for any number of laboratories which test specimens to protect the public health if each laboratory:

- (a) Is supervised by the Division or a health district; and
- (b) Performs at least 1 but not more than 15 tests which are classified pursuant to 42 C.F.R.

Part 493, Subpart A, as moderate complexity tests or waived tests.

3. An application for renewal of a certificate must be ~~on a~~ *in the* form ~~provided~~ *prescribed* by the Division.

4. The failure to apply for renewal within 30 days after a certificate expires will result in termination of the laboratory's authority to operate in this State.

5. Upon acceptance of an application for renewal, the Division shall provide the laboratory with a new certificate of registration.

Sec. 5. NAC 652.195 is hereby amended to read as follows:

652.195 1. A licensed laboratory that wishes to collect specimens or perform tests, or both, at a location other than the location set forth in its license must obtain a permit to operate a laboratory at a temporary location.

2. An application for a permit to operate a laboratory at a temporary location must be:

- (a) Made ~~on a~~ *in the* form ~~provided~~ *prescribed* by the Division;
- (b) Submitted to the Division in the manner set forth in NAC 652.170; and
- (c) Accompanied by the fee set forth in NAC 652.488.

3. The Division shall notify an applicant of the disposition of an application within 30 days after receipt of a completed application.

4. A permit to operate a laboratory at a temporary location issued pursuant to this section expires 90 days after the effective date of the permit.

Sec. 6. NAC 652.200 is hereby amended to read as follows:

652.200 An application for a license as a director must be ~~on a~~ *in the* form ~~provided~~ *prescribed* by the Division, giving complete information as indicated, including educational background, experience and the identity of the laboratory to be directed.

Sec. 7. NAC 652.230 is hereby amended to read as follows:

652.230 1. An application for renewal of a license as a director must be:

- (a) Made ~~on a~~ *in the* form ~~provided~~ *prescribed* by the Division; and
- (b) Accompanied by the appropriate fee for renewal.

2. The failure to apply for renewal within 30 days after a license expires will result in termination of the licensee's authority to act as a director in this State.

Sec. 8. NAC 652.380 is hereby amended to read as follows:

652.380 Except as otherwise provided in NAC 652.383, 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 application for a license, have successfully completed a 4-year program accredited by the National Accrediting Agency for Clinical Laboratory 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,~~ biological or clinical laboratory science as the major, have at least 1 year of experience directing or supervising laboratory testing or performing laboratory testing at the level of a technologist in a laboratory which meets the requirements of NAC 652.170 to ~~652.600,~~ 652.590, inclusive, *and section 1 of this regulation*, and sections 3, 4 and 5 of LCB File No. 126-21, 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;
- (4) The American Board of Medical Laboratory Immunology;
- (5) The American Board of Forensic Toxicology;
- (6) The American Board of Medical Genetics and Genomics;
- (7) The National Registry of Certified Chemists;
- (8) The American ~~Board of~~ *Society for* Histocompatibility and Immunogenetics; ~~or~~
- (9) *The American Society for Clinical Pathology; or*
- (10) Any other institution approved by the United States Department of Health and Human Services in accordance with 42 C.F.R. § 493.1443(b)(3); or

(b) Possess qualifications which are equivalent to those required for certification by any of the institutions listed in paragraph (a).

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 ~~652.600,~~ *652.590*, inclusive, *and section 1 of this regulation*, and sections 3, 4 and 5 of LCB File No. R126-21;
 - (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 or performing laboratory testing at the level of a technologist in a laboratory which meets the requirements of NAC 652.170 to ~~652.600,~~ **652.590**, inclusive, *and section 1 of this regulation*, and sections 3, 4 and 5 of LCB File No. R126-21;

(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;

(4) The American Board of Clinical Chemistry;

(5) The American Board of Forensic Toxicology;

(6) The American Board of Medical Genetics and Genomics;

(7) The National Registry of Certified Chemists;

(8) The American ~~Board of~~ *Society for* Histocompatibility and Immunogenetics; ~~or~~

(9) *The American Society for Clinical Pathology; or*

(10) Any other institution approved by the United States Department of Health and Human Services in accordance with 42 C.F.R. § 493.1443(b)(3); or

(c) Possess qualifications which are equivalent to those required for certification by any of the institutions listed in paragraph (b).

Sec. 10. NAC 652.397 is hereby amended to read as follows:

652.397 1. Except as otherwise provided in subsection 2 and NAC 652.395, to qualify to serve as a director of an exempt laboratory or a licensed laboratory only for the collection of specimens, a person must be:

- (a) A licensed physician;
- (b) Qualified for a license as a director of a licensed laboratory pursuant to NAC 652.380;
- (c) Qualified for a license as a director of a registered laboratory pursuant to NAC 652.395;
- (d) An advanced practice registered nurse licensed pursuant to chapter 632 of NRS;
- (e) A physician assistant licensed pursuant to chapter 630 or 633 of NRS;
- (f) A general supervisor of a licensed laboratory certified in accordance with NAC 652.410;
- (g) A clinical laboratory technologist certified in accordance with NAC 652.420; ~~or~~
- (h) A dentist licensed pursuant to chapter 631 of NRS ~~H~~; *or*
- (i) An optometrist licensed pursuant to chapter 636 of NRS.*

2. To qualify to serve as a director of an exempt laboratory in which the only tests performed are glucose tests that are classified as waived tests pursuant to 42 C.F.R. Part 493, Subpart A, a person must be:

- (a) A person identified in subsection 1;
- (b) A nurse licensed pursuant to chapter 632 of NRS;
- (c) A pharmacist registered pursuant to chapter 639 of NRS; or
- (d) A person licensed or certified pursuant to chapter 652 of NRS, other than a certified blood-gas assistant, certified laboratory assistant or certified office laboratory assistant.

3. 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. 11. 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 qualified physician serving on behalf of the director; or
- (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 at the level of a technologist:

- (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 at the level of a technologist:

- (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 or her specialty.

3. A person who possesses a doctoral degree from an accredited institution with a major in chemical ~~[-physical]~~ or biological science, clinical laboratory science or medical technology and who has had at least 1 year of clinical experience at the level of a technologist 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, clinical laboratory science or medical technology and who has had at least 2 years of clinical experience at the level of a technologist 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. 12. 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 the technologist has had adequate education, training and experience and in which he or she 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 a course of study for a bachelor's degree in one of the chemical ~~[-, physical]~~ or biological sciences, clinical laboratory science or medical technology at an accredited college or university, have at least 1 year of additional full-time clinical experience or training at the level of a technologist in a licensed laboratory, or laboratory of a hospital, health

department or university in the specialty or subspecialty in which the person performs tests, and pass a national examination for certification approved by the Board; or

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

Sec. 13. NAC 652.433 is hereby amended to read as follows:

652.433 1. To qualify for a certificate as a histotechnologist, a person must have:

(a) A baccalaureate degree from an accredited college or university with at least 32 semester hours in science, of which 12 hours are in chemistry and 16 hours are in the areas of general biology, histology, zoology, anatomy and physiology, and 1 year of experience in a histopathology laboratory under the supervision of a pathologist certified by the American Board of Pathology ~~and Anatomic Pathology~~ or a pathologist eligible to be certified in anatomic pathology;

(b) A baccalaureate degree from an accredited college or university, including the semester hours required in paragraph (a), and successfully completed ~~an~~ *an accredited* program ~~in~~ in histotechnology ; ~~certified by the Committee on Allied Health Education and Accreditation;~~ or

(c) National certification as a histotechnologist and 8 years of full-time experience before August 1980, in an approved histopathology laboratory.

2. A histotechnologist may perform only those procedures, under the minimal review of the director or general supervisor, for which he or she has adequate education, training and experience and in which he or she has demonstrated a proficiency. The histotechnologist may supervise the work of histologic technicians and assistants.

Sec. 14. NAC 652.437 is hereby amended to read as follows:

652.437 1. To qualify for a certificate as a histologic technician, a person must:

(a) Successfully complete ~~{a}~~ *an accredited* program in histotechnology ; ~~{certified by the Commission on Accreditation of Allied Health Education Programs;}~~

(b) Have an associate degree in chemistry ~~{}~~ *or* biology ~~{or a physical science}~~ or successfully complete at least 60 semester hours or the equivalent of academic credit from an accredited college or university with at least 12 semester hours in science, of which 6 hours are in chemistry and 6 hours are in biology, and have 1 year of full-time experience in histotechnology in a histology laboratory under the supervision of a pathologist certified in anatomic pathology by the American Board of Pathology ~~{incorporated}~~ or a pathologist eligible for certification in anatomic pathology; ~~{or}~~

(c) Be a high school graduate or the equivalent and have 2 years of full-time experience in histotechnology, within the preceding 5 years, in a histology laboratory under the supervision of a pathologist certified in anatomic pathology by the American Board of Pathology ~~{incorporated}~~ or a pathologist eligible for certification in anatomic pathology ~~{}~~ ; *or*

(d) Have a national certification as a histologic technician.

2. A histologic technician may only perform histologic procedures under the supervision of a histotechnologist or the director and may only perform cytologic procedures under the direction of a cytotechnologist, a histotechnologist or the director.

Sec. 15. NAC 652.440 is hereby amended to read as follows:

652.440 1. A medical technician may perform a test only if the test is classified pursuant to 42 C.F.R. Part 493, Subpart A, as:

- (a) A waived test;
- (b) A moderate complexity test; or
- (c) A high complexity test, and:

- (1) The results of the test are read directly from an instrument; and
- (2) The test requires no interpretation and no intervention by the operator of the test during its analytic phase.

2. To be certified as a medical technician, a person must pass a national examination for certification and must:

(a) Have an associate degree from an accredited institution as a medical technician or have successfully completed a program based on a course of study that includes chemistry, biology and a ~~structural~~ *structured* curriculum in techniques used in a laboratory;

(b) Have successfully completed 60 semester hours of academic credit, including chemistry, biology and a structured curriculum in techniques used in a laboratory, at an accredited institution;

(c) Be a high school graduate or the equivalent, have completed at least 1 year in a program for training technicians approved by the Board and have 3 years of experience in a laboratory within the preceding 5 years; or

(d) Be a high school graduate or the equivalent, have successfully completed an official 50-week course in procedures for a military laboratory and have been a medical laboratory specialist or laboratory technician in the military.

Sec. 16. NAC 652.454 is hereby amended to read as follows:

652.454 1. To qualify for a certificate as a point-of-care test analyst, a person must:

(a) Be a:

- (1) Registered nurse as defined in NRS 632.019;
- (2) Advanced practice registered nurse as defined in NRS 632.012;
- (3) Licensed practical nurse as defined in NRS 632.016;

- (4) Practitioner of respiratory care as defined in NRS 630.023;
- (5) Physician assistant as defined in NRS 630.015;
- (6) Registered pharmacist as defined in NRS 639.015 who has participated in the development of written guidelines and protocols as described in NRS 639.0124;
- (7) Certified laboratory assistant who has successfully completed training approved by a director in performing point-of-care tests;
- (8) Nursing assistant, as defined in NRS 632.0166; or
- (9) Student enrolled in an accredited school of professional nursing *or practical nursing* or *a* graduate of such a school pending the results of the first licensing examination scheduled by the State Board of Nursing following graduation; and

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

2. A nursing assistant who is certified as a point-of-care test analyst may only perform glucose testing classified as a waived test pursuant to 42 C.F.R. Part 493, Subpart A.

Sec. 17. NAC 652.470 is hereby amended to read as follows:

652.470 1. Before working in a laboratory at any technical level ~~†~~
~~—(a) An†~~, *an* application for certification must be made ~~†on a†~~ *in the* form ~~†provided†~~
prescribed by the Division 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†~~ *90 days* after the date of the application. ~~†~~

~~—(e)~~ The ~~{form}~~ *application* 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 may be granted:

(a) For a period not exceeding ~~{2}~~ :

(1) Six months while the application is being processed;

(2) An additional 30 days after the Division has reviewed an application and requested additional information from the applicant; or

(b) If the applicant has been issued a provisional certificate, until the expiration of the provisional certificate.

3. The Division shall issue the appropriate certificate on behalf of the Board when it is determined that all requirements for certification are satisfied.

4. A person may upgrade his or her certificate after completing the appropriate additional experience, training or academic requirements, or any combination thereof, by applying to the Division 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 Division 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 Division accompanied by the fee prescribed in NAC 652.488.

7. A certificate will be placed in an inactive status upon the approval of the Division and payment of the fee prescribed in NAC 652.488.

Sec. 18. NAC 652.472 is hereby amended to read as follows:

652.472 *1.* Technical personnel newly employed in a private registered laboratory must be certified as at least an office laboratory assistant. ~~If the person requires training to reach that level, the prospective assistant must apply as an office laboratory trainee and perform those duties for not more than 6 months. Upon the recommendation of the office operator, the trainee shall formally apply for certification as an office laboratory assistant.~~

2. An office laboratory assistant who performs:

(a) Moderate complexity testing must meet the requirements of 42 C.F.R. § 493.1423.

(b) High complexity testing must meet the requirements of 42 C.F.R. § 493.1489.

3. The director of a laboratory where an office laboratory assistant performs moderate complexity testing or high complexity testing shall ensure that the office laboratory assistant meets the requirements of subsection 2.

Sec. 19. NAC 652.476 is hereby amended to read as follows:

652.476 *1.* A person certified pursuant to NAC 652.470 who wishes to renew the certification must submit to the Division a completed ~~form~~ *application* for renewal. The Division shall, not less than 90 days before the expiration of the certificate, provide to the holder of the certificate ~~the proper form for renewal.~~ *notice of:*

(a) The date on which the certificate expires; and

(b) The need to renew the certificate.

2. The ~~form~~ *application* for renewal must include a request for information regarding the current residence of the person holding the certificate.

3. The ~~form~~ *application* for renewal must be accompanied by the fee for renewal.

4. A certificate issued pursuant to this section is effective for 2 years after the date of issuance. Failure to apply for renewal within 30 days after the certificate expires will result in the termination of the holder's authority to work in a laboratory at a technical level.

Sec. 20. NAC 652.478 is hereby amended to read as follows:

652.478 A technologist may:

1. Be certified:

(a) In chemistry;

(b) In microbiology;

(c) In hematology;

(d) In immunology;

(e) In immunohematology;

(f) In nuclear medicine;

(g) In histocompatibility;

(h) In histology;

(i) In cytology;

(j) As a biotechnologist; ~~or~~

(k) *In molecular biology; or*

(l) In more than one of the specialties set forth in this subsection.

2. Perform a test in a specialty only if certified in that specialty.

Sec. 21. 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 Division in a specialty, a technologist must pass a national examination for certification in the specialty and must have 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 at least 1 year of additional full-time clinical experience or training at the level of a technologist 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 or she desires to be certified. The applicant must submit with the application:

- (a) Verification of successful completion of the course of study required by subsection 1; and
- (b) A signed and dated letter from the director of the laboratory in which the applicant obtained his or her experience, which verifies that the applicant has the experience required by subsection 1.

3. Each certificate will designate the holder by:

- (a) The title of “Technologist” in a specialty; or
- (b) An equivalent title and will show his or her area of specialty by a subtitle.

Sec. 22. NAC 652.483 is hereby amended to read as follows:

652.483 The Division shall certify a technologist in a specialty for which a national examination is not given if he or she:

- 1. Has education and experience in the specialty which is acceptable to the Division;
- 2. Obtains a written recommendation of the proposed certification from a director licensed in this State who holds a doctoral degree; and
- 3. Has 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 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.

Sec. 23. NAC 652.486 is hereby amended to read as follows:

652.486 1. The Division shall issue a provisional certificate to a technologist or technician who is otherwise qualified for a certificate if he or she has not yet:

(a) Passed a required national examination for certification, but has been accepted as a candidate for testing; or

(b) Accumulated the amount of experience or training required for certification.

2. A technologist or technician must apply for a provisional certificate ~~on a~~ *in the* form ~~provided~~ *prescribed* by the Division and pay the fee for initial certification of personnel set forth in NAC 652.488.

3. A provisional certificate issued pursuant to this section expires 18 months after the date of issue and is not renewable.

Sec. 24. Section 2 of LCB File No. R090-18 is hereby amended to read as follows:

1. To apply for an initial license as a director by endorsement, an applicant who holds a valid, unrestricted license as a director in the District of Columbia or any state or territory of the United States which required the applicant to pass a background check and included the submission of fingerprints to the Federal Bureau of Investigation as a condition for obtaining that license must submit to the Division an application ~~on a~~ *in the* form prescribed by the Division.

The application must be accompanied by:

(a) Proof that the applicant has achieved a passing score on a nationally recognized examination for licensure as a director.

(b) An attestation, under penalty of perjury, that he or she meets the requirements prescribed in paragraphs (a) to (e), inclusive, of subsection 2 of NRS 622.530.

(c) Payment of the fee prescribed for initial licensure of a director who is not licensed by endorsement prescribed by paragraph ~~(d)~~ (e) of subsection 1 of NAC 652.488.

(d) Proof of the valid, unrestricted license as a director in the District of Columbia or any state or territory of the United States including, without limitation, the name of the regulatory authority that issued the license and the number of the license.

(e) The statement required by NRS 425.520.

2. The Division may request such additional documentation from an applicant as it deems necessary to ensure the provisions of this section and NRS 622.530 are met.

Sec. 25. Section 3 of LCB File No. R090-18 is hereby amended to read as follows:

1. To apply for an initial certificate as laboratory personnel by endorsement, an applicant who holds a valid, unrestricted certificate as laboratory personnel for a comparable type of laboratory personnel in the District of Columbia or any state or territory of the United States which required the applicant to pass a background check and included the submission of fingerprints to the Federal Bureau of Investigation as a condition for obtaining that certificate must submit to the Division an application ~~on a~~ *in the* form prescribed by the Division. The application must be accompanied by:

(a) Proof that the applicant has achieved a passing score on a nationally recognized examination for certification as laboratory personnel for the applicable type of laboratory personnel.

(b) An attestation, under penalty of perjury, that he or she meets the requirements prescribed in paragraphs (a) to (e), inclusive, of subsection 2 of NRS 622.530.

(c) Payment of the applicable fee prescribed for initial certification of personnel who are not certified by endorsement prescribed by paragraph ~~(g)~~ (h) of subsection 1 of NAC 652.488.

(d) Proof of the valid, unrestricted certificate as laboratory personnel in the District of Columbia or any state or territory of the United States including, without limitation, the name of the regulatory authority that issued the certificate and the number of the certificate.

(e) The statement required by NRS 425.520.

2. The Division may request such additional documentation from an applicant as it deems necessary to ensure the provisions of this section and NRS 622.530 are met.

Sec. 26. This regulation is hereby amended by adding thereto the following transitory language which has the force and effect of law but which will not be codified in the Nevada Administrative Code:

Notwithstanding the amendatory provisions of sections 8, 9, 11, 12, 14, 21 and 22 of this regulation, any person who:

1. Applies for a license pursuant to NAC 652.380 or 652.395 or a certificate pursuant to NAC 652.410, 652.420, 652.437, 652.480 or 652.483 on or before December 31, 2024, or the effective date of this regulation, whichever is later, and holds a degree in physical science at the level required by the applicable section, as it existed before the effective date of this regulation, remains eligible for such a license or certificate, as applicable, if he or she meets all other requirements for such licensure or certification.

2. Holds a license issued pursuant to NAC 652.380 or 652.395 or a certificate issued pursuant to NAC 652.410, 652.420, 652.437, 652.480 or 652.483 on December 31, 2024, or the effective date of this regulation, whichever is later, shall be deemed qualified to continue holding the license or certificate, as applicable.

Sec. 27. NAC 652.600 is hereby repealed.

TEXT OF REPEALED SECTION

652.600 Program of training for certification as technician. (NRS 439.200, 652.123, 652.125, 652.130)

1. Any program of training intended to prepare a person for certification as a technician must be approved by the Division. Application for approval must be submitted to the Division in the manner prescribed by the Division. The application must include:

- (a) A description of the goals of the program;
- (b) A description of the methods of instruction;
- (c) A description of the contents of the courses;
- (d) A description of the qualifications of the instructors;
- (e) A description of the methods of evaluating the performance of the trainee; and
- (f) The name of the director who is responsible for the program.

2. The director shall certify in writing to the Division each trainee who has successfully completed the program.

Joe Lombardo
Governor



Richard Whitley,
MS
Director



Cody Phinney,
MPH
Administrator

Ihsan Azzam,
Ph.D., M.D.
Chief Medical Officer

SMALL BUSINESS IMPACT STATEMENT

PROPOSED AMENDMENTS TO NEVADA ADMINISTRATIVE CODE CHAPTER 652

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendments should not have a negative impact upon a small business or restrict the formation, operation or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes (NRS) Chapter 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees."

This small business impact statement is made pursuant to NRS 233B.0608 (3) and complies with the requirements of NRS 233B.0609. As required by NRS 233B.0608(3), this statement identifies the methods used by the agency in determining the impact of the proposed regulation on a small business in sections 1, 2, 3, and 4 below and provides the reasons for the conclusions of the agency in section 8 below followed by the certification by the person responsible for the agency.

Background

The following are the regulation changes that were solicited and a brief description of each:

Existing law: (1) requires the State Board of Health to adopt regulations carrying out provisions governing the requirements for an application for a license to operate a medical laboratory; and (2) authorizes the Board to adopt regulations for the certification and licensure of laboratory directors and certain laboratory personnel. (NRS 652.090. 652.130)

Existing law also exempts certain laboratories operated by licensed physicians from requirements governing medical laboratories if those exempt laboratories register with the Division of Public and Behavioral Health of the Department of Health and Human Services and comply with certain other requirements. (NRS 652.072)

Existing regulations require a licensed laboratory that wishes to collect specimens or perform tests, or both, at a location other than the location set forth in its license to obtain a permit from DPBH. (Nevada Administrative Code Ch. 652.195)

Sections 1-6, 13 and 17-19 of this regulation remove the requirement that an application for the issuance or renewal of such a certificate, license, registration, or permit be submitted on a form provided by DPBH and instead require such an application to be made in the form prescribed by DPBH.

Section 15 of this regulation similarly replaces references to a form for the renewal of certification as laboratory personnel with references to an application for the renewal of such certification. Section 15 accordingly replaces a requirement that DPBH provide that form to the holder of such certification not less than 90 days before the expiration of the certificate with a requirement that DPBH notify the holder of the impending expiration of the certificate. Existing law requires that regulations adopted by the Board that require the directors of laboratories that perform only certain tests to be licensed physicians must

include licensed optometrists among such physicians. (NRS 652.130, as amended by section 29 of Assembly Bill 432, chapter 230, Statutes of Nevada 2023, at page 1462)

Section 9 of this regulation provides that a licensed optometrist may serve as the director of a laboratory that performs only such tests or provider-performed microscopy procedures.

Sections 10, 11 and 16 of this regulation revise the qualifications for certification as a histotechnologist, a histologic technician, and a technologist, respectively, in a manner that expands the persons eligible for such certification. Section 12 of this regulation corrects a typographical error. Existing regulations generally require the technical personnel of a laboratory to be certified by DPBH. However, existing regulations authorize a laboratory to temporarily employ uncertified personnel for not more than 12 months while an application for certification is being processed. (NAC 652.470)

Section 13: (1) revises the length of such a period of temporary employment to not more than 6 months while the application is being processed; and (2) authorizes an additional period of temporary employment for not more than 30 days after an application has been reviewed and DPBH has requested additional information from the applicant. Section 13 also revises the date by which substantiating documents for an application for certification as laboratory personnel must be submitted.

Existing regulations generally require any technical personnel newly employed in a laboratory which only performs tests on patients of a particular physician and the partner and associates of his or her private practice to be certified as at least an office laboratory assistant. However, existing regulations authorize a person who does not hold such certification to serve as an office laboratory trainee for not more than 6 months. (NAC 652.472) Section 14 of this regulation removes such authorization, thereby requiring any person newly employed in such a laboratory to be certified as at least an office laboratory assistant. Section 14 also: (1) requires the laboratory director of such a laboratory to ensure that an office laboratory assistant performing certain testing is appropriately trained and educated; and (2) requires an office laboratory assistant performing certain testing to possess the qualifications required by certain federal regulations. Section 20 of this regulation repeals a requirement that a program of training intended to prepare a person for certification be approved by DPBH. Sections 7 and 8 of this regulation make conforming changes to remove references to the repealed section. Sections 7, 8, 10 and 11 update the names of certain organizations. Sections 18 and 19 of this regulation correct certain references to sections of the Nevada Administrative Code.

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), DPBH has requested input from medical laboratories that meet the definition of a small business. A Small-Business Impact Questionnaire was sent to 18,788 medical laboratory facility and personnel emails, along with a copy of the proposed regulation changes, on April 9, 2024. The questions on the questionnaire were:

- 1) How many employees are currently employed by your business?
- 2) Will a specific regulation have an adverse economic effect upon your business?
- 3) Will the regulation(s) have any beneficial effect upon your business?
- 4) Do you anticipate any indirect adverse effects upon your business?
- 5) Do you anticipate any indirect beneficial effects upon your business?

Summary of Responses

Two (2) responses were received out of 18,788 small business impact questionnaires distributed.

Will a specific regulation have an adverse economic effect upon your business?	Will the regulation (s) have any beneficial effect upon your business?	Do you anticipate any indirect adverse effects upon your business?	Do you anticipate any indirect beneficial effects upon your business?
2 – no	2 - yes	2 – no	1 – no 1 – yes
Comments – none	Comments: 1. Yes. It may reduce the costs associated with the additional training of my laboratory personnel. 2. Yes. Decreased labor costs.	Comments – none	Comments: 1. Yes. With expansion of qualified individuals able to work in the lab, it will bring awareness of this job industry.

1. Describe the manner in which the analysis was conducted.

An analysis of industry input collected was conducted by the acting Medical Laboratory Services manager. The analysis involved analyzing feedback obtained from the small-business impact questionnaire and review of statutes to determine how DPBH could implement the various proposed changes to NAC Ch. 652 while at the same time not being overly burdensome. See number 4 for the methods the agency considered to reduce the impact of the proposed regulations on small businesses. This information was used to complete this small-business impact statement, including the conclusion on the impact of the proposed regulation on a small business found in number 8.

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.

Direct Economic Beneficial Effects: No known direct economic beneficial effects.

Indirect Economic Beneficial Effects: No known indirect economic beneficial effects.

Direct Economic Adverse effects: No known direct adverse economic effects.

Indirect Economic Adverse Effects: No known indirect adverse economic effects.

3. Provide a description of the methods that 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.

DPBH has held several opportunities for medical laboratories to provide input and comments regarding the proposed regulations, including the economic impact that the proposed regulations may have on them. Modifications to the proposed regulations have been made as a result of this input. A workshop will be held on July 12, 2024, allowing for further input by the medical laboratory community and other interested individuals regarding the proposed regulations and how they will affect medical laboratories. These comments will be taken into consideration for possible further revisions to the regulations to reduce the economic impact on facilities.

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

There will be no additional costs to the agency for enforcement of the proposed regulation changes.

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

The total annual amount DPBH expects to collect is unknown because it is based on the number and type of applications received. For example, if no applications were received, DPBH would collect no additional fees. If one initial application was received for a new laboratory which would have an optometrist as the laboratory director, it would add \$500 for the initial application and \$300 for the biennial renewal of each of the state laboratory applications received.

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

There are no other state or federal regulations addressing the same activity.

7. Provide a summary of the reasons for the conclusions of the agency regarding the impact of a regulation on small businesses.

The reasons for DPBH's conclusion on the impact of the proposed regulations and regulation changes on small businesses is based on feedback received from the industry and its analysis as outlined in number two. The proposed regulations do establish fees to be collected, therefore there will be a financial impact on small business who apply for and operate medical laboratories.

Any persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to:

Division of Public and Behavioral Health
Attn: Bradley Waples
4220S. Maryland Pkwy, Suite 100, Bldg. A
Las Vegas, NV 89119
Phone: 775-430-0034
Email: bwaples@health.nv.gov

Certification by Person Responsible for the Agency

I, Cody Phinney, Administrator of the Division of Public and Behavioral Health certify to the best of my knowledge or belief, a concerted effort was made to determine the impact of the proposed regulation on small businesses and the information contained in this statement was prepared properly and is accurate.

Signature:



Date: May 28, 2024

Joe Lombardo
Governor



Richard Whitley,
MS
Director



Cody Phinney,
MPH
Administrator

Ihsan Azzam,
Ph.D., M.D.
Chief Medical
Officer

NOTICE OF PUBLIC WORKSHOP

BACKGROUND

NOTICE IS HEREBY GIVEN that the Division of Public and Behavioral Health (DPBH) will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) Chapter 652.

The workshop will be conducted via videoconference beginning at 9:00 a.m. on July 12, 2024, at the following locations:

- [Click here to join the workshop via Microsoft Teams.](#)
- Join by phone: (775) 321-6111 | Phone conference ID: 956 470 639#
- Division of Public and Behavioral Health, 4220 South Maryland Parkway, Ste. 100 Building A, Las Vegas, NV 89119

This workshop will be conducted in accordance with NRS 241.020, Nevada's Open Meeting Law.

AGENDA

1. Introduction of workshop process
2. Public comment on proposed amendments to NAC Chapter 652.
3. General Public Comment

The proposed changes will revise Chapter 652 of the Nevada Administrative Code and are being proposed in accordance with §§ 1 and 4, NRS 439.200, 652.090 and 652.130; §§ 2 and 3, NRS 439.200 and 652.130; §§ 5-8, 10-17 and 20, NRS 439.200, 652.125 and 652.130; § 9, NRS 439.200, 652.125 and 652.130, as amended by section 29 of Assembly Bill No. 432; chapter 230 of Statutes of Nevada 2023, at page 1462; §§ 18 and 19 of NRS 439.200 and 652.125.

The proposed regulations provide provisions for the following:

1. Bring the NAC into compliance with Assembly Bill (AB) 432 of the 2023 Legislative Session; Chapter 230 Statutes of Nevada 2023 at page 1462; and changes to the Federal Register 42 CFR part 493 effective Dec. 28, 2024.
2. The proposed amendments would enact the legislation as follows:

Sections 1-6, 13 and 17-19 of this proposed regulation change remove the requirement that an application for the issuance or renewal of a laboratory personnel certificate, and laboratory license, registration or permit be submitted on a form provided by DPBH and instead require such an application to be made in the form prescribed by DPBH. Section 15 of this proposed regulation change similarly replaces references to a form for the renewal of certification as laboratory personnel with references to an application for the renewal of such certification. Section 15 accordingly replaces a requirement that DPBH provide that form to the holder of such certification

not less than 90 days before the expiration of the certificate with a requirement that DPBH notify the holder of the impending expiration of the certificate.

Existing law requires that regulations adopted by the Board of Health (BOH) that require the directors of laboratories that perform only certain tests to be licensed physicians must include licensed optometrists among such physicians (NRS 652.130 as amended by Section 29 of Assembly Bill No. 432; and Chapter 230 Statutes of Nevada 2023 at page 1462). Section 9 of this regulation provides that a licensed optometrist may serve as the director of a laboratory that performs only such tests or provider-performed microscopy procedures.

Sections 10, 11 and 16 of this proposed regulation change revise the qualifications for certification as a histotechnologist, a histologic technician and a technologist, respectively, in a manner that expands the persons eligible for such certification. Section 12 of this proposed regulation change corrects a typographical error.

Existing regulations generally require the technical personnel of a laboratory to be certified by DPBH. However, existing regulations authorize a laboratory to temporarily employ uncertified personnel for not more than 12 months while an application for certification is being processed (NAC 652.470). Section 13 of this proposed regulation change (1) revises the length of such a period of temporary employment to not more than 6 months while the application is being processed; and (2) authorizes an additional period of temporary employment for not more than 30 days after an application has been reviewed and DPBH has requested additional information from the applicant. Section 13 of this proposed regulation change also revises the date by which substantiating documents for an application for certification as laboratory personnel must be submitted.

Existing regulations generally require any technical personnel newly employed in a laboratory which only performs tests on patients of a particular physician and the partner and associates of his or her private practice to be certified as at least an office laboratory assistant. However, existing regulations authorize a person who does not hold such certification to serve as an office laboratory trainee for not more than 6 months (NAC 652.472). Section 14 of this proposed regulation change removes such authorization, thereby requiring any person newly employed in such a laboratory to be certified as at least an office laboratory assistant. Section 14 also: (1) requires the laboratory director of such a laboratory to ensure that an office laboratory assistant performing certain testing is appropriately trained and educated; and (2) requires an office laboratory assistant performing certain testing to possess the qualifications required by certain federal regulations.

Section 20 of this proposed regulation change repeals a requirement that a program of training intended to prepare a person for certification be approved by DPBH. Sections 7 and 8 of this regulation make conforming changes to remove references to the repealed section. Sections 7, 8, 10 and 11 update the names of certain organizations. Sections 18 and 19 of this regulation correct certain references to sections of the NAC.

Sections 7, 8, 11, 12, 13, 14, and 15 of this proposed regulation change make conforming changes to update laboratory personnel qualifications according to 42 CFR Part 493 changes that will be effective Dec. 28, 2024.

Section 10 of this proposed regulation change allows for students enrolled in an accredited school for Licensed Practical Nursing (LPN) to be eligible for a Point of Care (POC) Analyst personnel certification.

3. All laboratory personnel applying for licensure or certification, facilities applying for State of Nevada laboratory licensure, and optometrists pursuant to Chapter 636 of NRS will be impacted by this proposed amendment.
4. No fees will be impacted by this proposed amendment.
5. There are no agreements or compliance issues with this proposed amendment.
6. There are no additional or updated definitions or boundaries of this proposed amendment.
7. This amendment clarifies that LPN students are eligible for POC Analyst certification; clarifies the personnel licensure process; clarifies updated laboratory personnel requirements; and repeals NAC 652.600
8. This proposed amendment expands the personnel certification of POC analysts by clarifying that LPN students are eligible for POC analyst certification.
9. This proposed amendment details that the forms used for application are prescribed by DPBH. It also details the personnel requirement changes prescribed by 42 CFR 493 updates effective Dec. 28, 2024.
10. This proposed amendment updates the regulatory language regarding facility and personnel applications with DPBH. It also expands the eligibility criteria for the POC Analyst personnel certification and updates the state personnel requirements to be in compliance with the changes to 42 CFR 493, effective Dec. 28, 2024.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to the manager of the affected Regulatory Unit: Bradley Waples, Health Facility Inspection Manager, Medical Laboratory Services at the following address:

Division of Public and Behavioral Health
 4220 South Maryland Parkway, Suite 100, Building A
 Las Vegas, NV 89119
 Phone: 775-430-0034
 Fax: 702-486-6520
bwaples@health.nv.gov

Members of the public who require special accommodations or assistance at the workshops are required to notify Bradley Waples in writing to the Division of Public and Behavioral Health, 4220 South Maryland Parkway, Ste. 100, Bldg. A, Las Vegas, NV 89119, or by calling 775-430-0034 at least five (5) working days prior to the date of the public workshop.

Contact Bradley Waples by calling 775-430-0034 for further information on the proposed regulations or how to obtain copies of the supporting documents.

A copy of the notice and/or the proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Division of Public and Behavioral Health
 4150 Technology Way, First Floor Lobby
 Carson City, NV 89706

Division of Public and Behavioral Health
 4220 S. Maryland Parkway, Suite 100, Bldg. A
 Las Vegas, NV 89119

Division of Public and Behavioral Health
 727 Fairview Drive, Suite E
 Carson City, NV 89701

Nevada State Library and Archives
 100 Stewart Street
 Carson City, NV 89701

A copy of the regulations and small business impact statement can be found on the [Division of Public and Behavioral Health's web page linked here](#).

A copy of the public workshop notice can also be found at the [Nevada Legislature web page linked here.](#)

Copies may be obtained in person, by mail, or by calling the Division of Public and Behavioral Health at (702) 486-6515.

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.