PROPOSED REGULATION OF THE

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LCB FILE NO. R145-23I

The following document is the initial draft regulation proposed by the agency submitted on 12/21/2023

PROPOSED REGULATION OF THE DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

Medical Laboratories

Blue Italics: New Proposed Language

Red: Removed Language

Authority: AB 432 of the 2023 legislative session; NRS 652.125; NRS 652.180

NAC 652.170 Laboratory: Application for license or registration; action by Division on application; proof of identity of laboratory director to be provided with application. (NRS 439.200, 652.090, 652.130)

- 1. An application for a license or registration for a laboratory must be made on a *format prescribed* form provided 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.

[Bd. of Health, Medical Laboratories Reg. §§ 2.1-2.1.5, eff. 8-5-74] — (NAC A 10-17-86; 1-4-88; 10-22-93; R078-04, 8-5-2004; R104-13, 3-28-2014; R149-15, 6-21-2017)

NAC 652.230 Director's license: Renewal. (NRS 439.200, 652.125)

- 1. An application for renewal of a license as a director must be:
- (a) Made on a form format prescribed provided 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.

[Bd. of Health, Medical Laboratories Reg. §§ 5.1.1.2.4.1 & 5.1.1.2.4.2, eff. 8-5-74] — (NAC A 10-17-86; 3-28-96; R104-13, 3-28-2014)

NAC 652.397 Director of exempt laboratory: Qualifications. (NRS 439.200, 652.123, 652.125, 652.130)

- 1. Except as otherwise provided in subsection 2 and <u>NAC 652.395</u>, to qualify to serve as a director of an exempt laboratory, 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; or
 - (g) A clinical laboratory technologist certified in accordance with NAC 652.420.
 - (h) A licensed optometrist 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 <u>chapter 652</u> of NRS, other than a certified bloodgas 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 <u>chapter 635</u> of NRS.
 - (Added to NAC by Bd. of Health by R149-15, eff. 6-21-2017)

- 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 a an accredited program on 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.

(Added to NAC by Bd. of Health, eff. 10-17-86; A 10-22-93)

NAC 652.437 Histologic technician: Qualifications and activities. (NRS 439.200, 652.123, 652.125, 652.130)

- 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, 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;
- (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 histotechnician.
- 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.

(Added to NAC by Bd. of Health, eff. 10-17-86; A 10-22-93; R149-15, 6-21-2017)

NAC 652.470 Certification of personnel. (NRS 439.200, 652.123, 652.125, 652.130)

- 1. Before working in a laboratory at any technical level:
- (a) An application for certification must be made on a *format prescribed* form provided 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;
 - (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 may be granted:
 - (a) For a period not exceeding 12 months 6 months while the application is being processed;
- (b) When an application has been reviewed and additional information from the applicant has been requested, the applicant will have 30 days in which to provide the requested information; or
- (b) (c) 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.

[Bd. of Health, Medical Laboratories Reg. §§ 5.3-5.3.4.4.4, eff. 8-5-74] — (NAC A 9-6-88; 9-6-88; R042-98, 5-18-98; R078-04, 8-5-2004; R176-07, 1-30-2008; R104-13, 3-28-2014; R149-15, 6-21-2017)

NAC 652.472 Minimal requirements for new employees. (NRS 439.200, 652.123, 652.125, 652.130)

- 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. The laboratory director is responsible for ensuring that any office laboratory assistant performing moderate or high complexity testing must have the appropriate education and training for the level of testing performed.

- (a) Office laboratory assistants performing moderate complexity testing must comply with 42 CFR § 493.1423.
- (b) Office laboratory assistants performing high complexity testing must comply with 42 CFR § 493.1489.

(Added to NAC by Bd. of Health, eff. 9-6-88)

NAC 652.476 Renewal of certification. (NRS 439.200, 652.123, 652.125)

- 1. A person certified pursuant to NAC 652.470 who wishes to renew the certification must submit to the Division a completed *application* form for renewal. The Division shall, not less than 90 days before the expiration of the certificate, provide to the holder of the certificate, notice of expiration and the necessity for renewal pursuant to NAC 652.157(1).
- 2. The *application* for renewal must include a request for information regarding the current residence of the person holding the certificate.
 - 3. The *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.

(Added to NAC by Bd. of Health, eff. 9-6-88; A 3-28-96; R042-98, 5-18-98; R104-13, 3-28-2014)

NAC 652.478 Technologists: Specialties; activities. (NRS 439.200, 652.123, 652.125, 652.130) 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;
- (k) In molecular biology; or
- (1) 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. (Added to NAC by Bd. of Health, eff. 10-22-93)

NAC 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.
- (Added to NAC by Bd. of Health, eff. 10-17-86; A 10-22-93; R104-13, 3-28-2014; R149-15, 6-21-2017) (Substituted in revision for NAC 652.510)