DIVISION OF PUBLIC & BEHAVIORAL HEALTH
BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE
LCB File No. R145-23

Informational Statement per NAC Chapter 652

1. The purpose of the proposed regulations revise 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.

2. A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary.

Below is a summary of how public comment was solicited and a summary of the public's response. For full details on revisions made or not made to the proposed regulations based on input received below, please refer to number 5.

Public Workshop:
Below is a summary of how public comment was solicited and a summary of the public's response. For full details on revisions made or not made to the proposed regulations based on input received below, please refer to number 5.

July 12, 2024 – Public Workshop
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.

September 6, 2024 – Board of Health Hearing

No written or oral testimony was provided at the public hearing.

How other interested persons may obtain a copy of the summary:
Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Bradley Waples, BS, MT (ASCP)-Health Facility Inspection Manager-Medical Laboratory Services at 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, Suite 100, Building A
Las Vegas, NV 89119
Bradley Waples
Phone: 775-430-0034
Email: bwaples@health.nv.gov

3. A statement indicating the number of persons who attended each hearing, testified at each hearing, and submitted written statements regarding the proposed regulation. This statement should include for each person identified pursuant to this section that testified and/or provided written statements at each hearing regarding the proposed regulation, the following information, if provided to the agency conducting the hearing:

(a) Name
(b) Telephone Number
(c) Business Address
(d) Business telephone number
(e) Electronic mail address; and
(f) Name of entity or organization represented

July 12, 2024 – Public Workshop
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.

The following names and information were provided by those providing testimony:

- Matthew Schulze (via Microsoft TEAMS meeting)
- Alexander Stojanoff (comments via phone-in call)

September 6, 2024 – Board of Health Public Hearing
Although 67 participants participated virtually, and 11 individuals participated at the Southern Nevada Health District location and 14 individuals participated at the Division of Public and Behavioral Health location at 4150 Technology Way in Carson City, these individuals may have been attending to hear other agenda items and may have not been attending to hear LCB File No. R145-23. The number of individuals attending to hear LCB File No. R145-23, if any, is unknown.

No written or oral testimony was provided at the public hearing.

4. A description of how comment was solicited (i.e., notices) from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

Small Business Impact:

Pursuant to NRS 233B.0608 (2)(a), DPBH had 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. Responses to the small-business questionnaire was accepted through April 26, 2024, at 5:00 pm PST. 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 Response

Summary of Comments Received **(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.

5. If, after consideration of public comment, the regulations were adopted without changing any part of the proposed regulations, a summary of the reasons for adopting the regulations without change. The statement should also explain the reasons for making any changes to the regulation as proposed.

   After consideration of public comment, the regulations were adopted with one public comment added for a suggested change. This change was to add the American Society of Clinical Pathologists as a certifying organization for persons that hold an earned doctoral degree in seeking laboratory personnel licensure as a Licensed Laboratory Director and a Registered Laboratory Director. The reason for adopting the regulation updates along with this one change that came about through Public Comment, is because industry did not testify that the suggested change made through Public Comment and existing fees would result in a financial hardship to industry.

6. The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must include:
   Both adverse and beneficial effects; and
   Both immediate and long-term effects.

   Anticipated effects on the business which NAC 228 regulates:

   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.

   Anticipated effects on the public:
   A. *Adverse*: There are no anticipated adverse effects on the public.
   B. *Beneficial:* The benefit to the public is to provide updated language to better understand the application process for laboratory personnel licensure and certification for personnel. It would also allow for persons seeking to be licensed with a Ph.D. in a Chemical or Biologic science to have an additional national exam that is acceptable for State laboratory director licensure.
   C. *Immediate*: There are no anticipated immediate adverse or beneficial effects on the public.
   D. *Long-term:* There are no anticipated long-term adverse or beneficial effects on the public.

7. The estimated cost to the agency for enforcement of the proposed regulation.
   There is no estimated cost to the agency for enforcement of the regulation updates and changes.

8. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is

necessary. If the regulation overlaps or duplicates a federal regulation, name the regulating federal agency.

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

9. If the regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

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

10. If the regulation establishes no new fees or fee increases on existing fees, a statement indicating the total annual amount the agency expects to collect and the manner in which the money will be used.

There are no new fees that have been established with the regulation changes and updates.