

Digest for Adopted Regulation R_104-13

Existing law allows the State Board of Health to prescribe regulations relating to the location and construction of medical laboratories, sanitary conditions within medical laboratories and their surroundings, laboratory equipment and the determination of the accuracy of test results produced by a laboratory. (NRS 652.130) **Section 3** of this regulation requires any medical laboratory that applies for a license to: (1) adopt nationally recognized laboratory safety guidelines, which must include infection control guidelines; (2) follow manufacturers' guidelines concerning the use of laboratory equipment; and (3) train and evaluate certain employees concerning these guidelines. **Section 45** of this regulation repeals an existing regulation concerning the sanitary disposal of sharp objects and biohazards.

Existing law requires the Board to adopt regulations prescribing qualifications for an assistant in a medical laboratory. (NRS 652.127) **Section 4** of this regulation requires a person to be a high school graduate or have a general equivalency diploma and meet certain requirements concerning education, training or experience to qualify for certification as a laboratory assistant. **Section 31** of this regulation provides that a laboratory assistant may only perform certain tests.

Existing law allows the Division of Public and Behavioral Health of the Department of Health and Human Services to conduct inspections of laboratories and impose administrative penalties on a laboratory that is in violation of chapter 652 of NRS or the regulations adopted pursuant thereto after providing notice and the opportunity for a hearing. (NRS 652.140, 652.220, 652.225, 652.260) **Sections 5-12 and 42** of this regulation establish a system in which the Division, based on the severity and frequency of violations, imposes such penalties and provides notice and the opportunity to appeal such penalties.

Existing law requires the Board to adopt regulations governing applications for certain licenses and certifications. (NRS 652.090, 652.125) **Section 13** of this regulation: (1) requires any application submitted pursuant to these regulations to contain a method of communication other than telephone and mail by which the Division may communicate with the applicant, unless the applicant attests that this is not feasible; and (2) provides a penalty for the failure of an applicant to notify the Division of certain changes. **Section 14** of this regulation provides that certain persons qualify for a license as a director of a laboratory that performs tests only in the subspecialty of oral pathology. **Section 15** of this regulation provides that certain notice is deemed sufficient if the notice is sent to the last address or electronic mail address provided to the Division by the licensee, certificate holder or license holder to whom notice is due. **Section 17** of this regulation amends the definition of “outpatient center of a laboratory” to include any facility at a permanent location that is operated by a licensed laboratory and is used to collect specimens or perform certain tests. **Sections 18-26, 32, 34-40, 44 and 45** of this regulation transfer certain responsibilities of the Bureau of Licensure and Certification of the Division to the Division. **Sections 22, 25, 29, 36-38, 40 and 41** of this regulation amend certain requirements related to the licensure and certification of laboratories and laboratory personnel. **Sections 27, 28, 30, 33, 37, 38 and 43** of this regulation transfer certain responsibilities of the Board to the Division. **Section 28** also requires the director of a laboratory to be on the premises of that laboratory at least once each month or provide a licensed substitute, unless the laboratory is in a rural area and the Division determines that a substitute is not necessary.