

## Wyoming Administrative Rules

# Health, Department of

## Clinical Laboratories, Licensure of

### Chapter 2: Licensure

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**RULES AND REGULATIONS FOR  
LICENSURE OF CLINICAL LABORATORIES**

**CHAPTER II  
LICENSURE**

Section 1.      License Required.

All clinical laboratories in Wyoming Shall have a valid license issued by the state agency. In order to receive a license, a laboratory shall have a director certified by the state agency, and meet the appropriate inspection and proficiency testing requirements as specified in Chapters III, IV, and V following.

Section 2.      Qualifications for Laboratory Personnel.

(a)      Laboratory Director

(i)      A physician licensed by the Board of Medical Examiners; or is a Ph.D. with a major in chemical, physical, or biological science and is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysts, or another national accrediting board in a laboratory specialty acceptable to HHS, and has at least one (1) year of general laboratory training and experience.

(ii)     Document continuing education of a minimum ten (10) contact hours per year or twenty (20) contact hours per two (2) years appropriate to specific need.

(b)      Laboratory Supervisor

(i)      Holds a master's degree from an accredited institution with an undergraduate degree in a laboratory science and have at least two (2) years pertinent laboratory experience; or is a Clinical Laboratory Scientist and have two (2) years of pertinent laboratory experience; or has earned a bachelors's degree in one (1) of the chemical, physical, or biological sciences and has at least two (2) years of clinical laboratory experience; or has successfully completed three (3) years (ninety (90) semester hours or equivalents) in an accredited college or university with the following distribution of courses:

(A)      Sixteen (16) semester hours in chemistry

(B)      Sixteen (16) semester hours in biology

(C)      Three (3) semester hours in mathematics

and has two (2) years of clinical laboratory experience.

(ii)     Document continuing education of a minimum ten (10) contact hours per year or twenty (20) contact hours per two (2)years appropriate to specific need.

(c)      Clinical Laboratory Scientist

(i) Holds a bachelor's degree in medical technology from an accredited college or university; or has earned a bachelor's degree in the chemical, physical, or biological sciences and has two (2) years of clinical laboratory experience and/or training; or has successfully completed three (3) years (ninety (90) semester hours or equivalent) from an accredited college or university with the following distribution:

(A) Sixteen (16) semester hours in chemistry

(B) Sixteen (16) semester hours in biology

(C) Three (3) semester hours in mathematics

and has two (2) years of clinical laboratory experience; or has passed the (HEW) examination.

(ii) Document continuing education of a minimum ten (10) contact hours per year or twenty (20) contact hours per two (2) years appropriate to specific need.

(d) Clinical Laboratory Technician

(i) Has successfully completed sixty (60) semester hours including chemistry, biology, and medical laboratory techniques at an accredited institution; or has successfully attained a science related associated degree and has one (1) year pertinent laboratory experience and/or training; or is a high school graduate or equivalent and has successfully completed an official military medical laboratory procedure course of at least fifty (50) weeks duration and has held the military occupation speciality of Medical Laboratory Specialist.

(ii) Document continuing education of a minimum five (5) contact hours per year or ten (10) contact hours per two (2) years appropriate to specific need.

(e) Clinical Laboratory Aid

(i) High school graduate or equivalent and has completed one (1) year in a medical technician program or other medical assistant program; or is a high school graduate or equivalent and has two (2) years of pertinent laboratory experience as a trainee with documentation of training.

(ii) Document continuing of a minimum five (5) contact hours per year or ten (10) contact hours per two (2) years in a clinical laboratory discipline.

(f) Clinical Phlebotomist

(i) High school graduate or equivalent and has documentation of training pertinent for specimen collection in the current laboratory position.

### Section 3. Issuance of Certificate of Qualification.

(a) The state agency shall send a qualification form for a certificate, in care of the laboratory director, to all clinical laboratories known to be operating in the state as of January 1, 1985. After January 1, 1985, an individual shall request, in writing, a qualification form for a certificate from the state agency.

(b) The state agency shall issue a certificate to individuals meeting the qualifications of Laboratory Director as specified in Chapter II, Section 2.

(c) The certificate shall indicate that the individual may direct a reference or physician office laboratory.

(d) The certificate will be valid for one (1) year from the date on which it was issued.

(e) The state agency will automatically renew the Certificate of Qualification on a yearly basis.

Section 4. Limits for Laboratory Directors.

(a) A laboratory director certified to direct a reference laboratory may direct no more than two (2) laboratories and concurrently provide provisional directorship for no more than six (6) laboratories.

(b) A laboratory director certified to direct a physician office laboratory may direct one (1) such laboratory.

Section 5. Application for License.

(a) The state agency shall send an application for license to all laboratories operating in the state as of January 1, 1985.

(b) The owner of the laboratory or his legally authorized representative shall complete the application for license.

(c) After January 1, 1985, the owner(s) or director-owner shall request, in writing, an application for license from the state agency.

(d) The license application shall be accompanied by the appropriate license fee.

(i) The fee shall be one hundred dollars (\$100.00) for each category of tests.

(ii) Test categories are: microbiology, serology, chemistry, hematology, biophysics, cytology, and pathology.

(iii) The license fee for any laboratory shall not exceed five hundred dollars (\$500.00)

(e) For reference laboratories, a certified reference laboratory director that provides provisional directorship may be named as director for licensure purposes. A laboratory requiring this arrangement shall document the visits by the director and such documentation shall accompany the license application. The state agency shall note the provisional status of the director in these instances.

Section 6. Issuance of License.

(a) The license application shall require:

(i) The name, address, and phone number of the laboratory;

- (ii) The name and address of the owner;
  - (iii) The name and Certificate of Qualification; number of the director;
  - (iv) A list of the laboratory tests performed;
  - (v) A list of personnel that perform the laboratory tests;
  - (vi) Documentation of participation in the appropriate proficiency testing program.
  - (vii) For reference laboratories, CLIA license number, Medicare provider number, documentation of accreditation from JCAHO or CAP, and a copy of the most recent inspection report.
- (b) The license shall be issued:
- (i) To the owner if he is the director of the laboratory or;
  - (ii) Jointly to the owner and director of the laboratory or;
  - (iii) Jointly to co-owners and directors of the laboratory.
- (c) The license shall specify the owner, the laboratory director, laboratory classification, location of the laboratory, and the laboratory procedures or categories of procedures authorized.
- (d) The license shall be valid for the calendar year in which it was issued.
- (e) A license shall automatically be voided if there is a change in the laboratory director.
- (f) A license shall automatically be voided thirty (30) days following a change in ownership or location.
- (g) Application for a new license may be made prior to any change in the laboratory director, ownership, or location of the laboratory or within the thirty (30) day expiration period noted in (f) above.
- (h) A laboratory shall notify the state agency, in writing, if the laboratory intends to offer a new test or tests for which it has not been licensed, during the license year. The state agency shall have thirty (30) days beginning with receipt of the notice to amend the existing license, reissue a license, or make no change in the existing license. During the thirty (30) day period, the state agency may, depending on the nature of the test(s) being considered, determine by inspection, check testing or both, that the laboratory can satisfactorily perform the new test(s).
- (i) The state agency shall renew a license on a yearly basis provided:
- (i) The appropriate fee is submitted with a completed renewal form;
  - (ii) The laboratory director has a valid Certificate of Qualification;

(iii) The laboratory has met the appropriate inspection and proficiency testing requirements.

Section 7. Acceptance, Collection, Reporting, and Examination of Specimens.

(a) All licensed laboratories shall accept only those specimens collected by a physician, laboratory director, dentist, trained personnel under the direction of a physician, laboratory director, dentist, or local, state, or federal health authorities.

(b) Examinations of specimens shall be made only at the request of a physician, dentist, or local, state, or federal health authorities authorized to use laboratory findings.

(c) Results of a test or tests shall only be reported to the submitter of the specimen or as directed by the submitter. The report shall be written, signed, and dated and shall include the name and address of the laboratory in which the test(s) were actually performed.

(d) All specimens shall be tested on the premises of the laboratory that accepted the specimen unless the specimen was forwarded to an approved reference laboratory.