Health, Department of

Clinical Laboratories, Licensure of

Chapter 6: Enforcement

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RULES AND REGULATIONS FOR
LICENSURE OF CLINICAL LABORATORIES

CHAPTER VI
ENFORCEMENT

Section 1. General Provisions.

(a) Proceedings to revoke, annul, suspend, or limit a license shall be initiated by the state agency when:

(i) The facilities or equipment are deemed to be inadequate to provide the laboratory services for which the laboratory is licensed;

(ii) The laboratory personnel do not meet qualifications as specified in Chapter II, Section 2;

(iii) The laboratory has not been able to demonstrate that it can satisfactorily perform or meet applicable quality assurance standards for the laboratory tests for which it is licensed;

(iv) In the process of applying for a Certificate of Qualification or a laboratory license, or renewal of either, there is evidence of misrepresentation or that false information has been given to the state agency;

(v) There is evidence that laboratory personnel have falsified reports, violated confidentiality in reporting, or are negligent in receiving, processing, and reporting results on specimens submitted for testing.

(b) When the state agency has sufficient evidence to indicate that the laboratory should not continue to operate under the conditions of its license, the state agency shall issue notice that a hearing shall be made before it. All hearings shall be conducted as a contested case under the Wyoming Administrative Procedures Act, W.S. 16-3-101 to 16-3-115.

(c) Hearings shall be held twenty-one (21) days after the notice of hearing is made, in writing, to the laboratory director and/or owner.

(d) The state agency shall render its decision within ten (10) days after the hearing. At that time, the state agency shall enter its order pursuant to the Wyoming Administrative Procedures Act. The state agency may:

(i) Dismiss the proceedings;

(ii) Revoke or annul the license;

(iii) Suspend the license for some specific period of time or until some condition is met;

(iv) Limit the license;

(v) Recommend that legal action be taken pursuant to W.S. 33-34-109.

Section 2. Specific Proceedings.

(a) Deficiencies noted on inspection reports.

(i) Reference laboratories inspected for CLIA licensure, Medicare certification, JCAHO or CAP accreditation shall formulate a plan of corrective action and complete such plan in accordance with the requirements of that agency or organization.

(ii) When the state agency inspects a laboratory;

(A) All deficiencies shall be brought to the attention of the laboratory director or the supervisor at the end of the inspection;

(B) Within ten (10) days after the inspection, the state agency shall forward a copy of the inspection report to the laboratory director;

(C) Within ten (10) days of receipt of the inspection report, the laboratory shall return a plan of corrective action to the state agency and such plan; shall be completed within sixty (60) days of the date when the corrective action plan was sent to the state agency;

(D) At the end of the sixty (60) day corrective action period, the state agency may re-inspect the laboratory.

(iii) At any time during the corrective action process, the laboratory may request, in writing, consultation or assistance from the state agency in completing its corrective action plan;

(iv) When the laboratory demonstrates that it is unwilling or unable to take the necessary corrective action, the state agency shall initiate proceedings as noted in Section 1 of this Chapter.

(b) Unsatisfactory Performance on Proficiency Testing.

(i) When the laboratory performs unsatisfactorily in one (1) or more test areas on one shipment, no action will be taken.

(ii) When the laboratory performs unsatisfactorily in one (1) or more test areas for two (2) consecutive shipments, the state agency shall notify the laboratory director of the errors and offer its consultative services to assist in taking corrective action. For hospital laboratories only, such notice shall be made to the hospital administrator.

(iii) When the laboratory performs unsatisfactorily in one (1) or more test areas for three (3) consecutive shipments, the state agency shall notify the laboratory director by certified mail of the errors and indicate that proceedings noted in Section 1 of this Chapter shall be initiated unless the laboratory director responds to the notice within five (5) days of the mailing date of the notice. For hospital laboratories only, such notice shall be made to the hospital administrator who shall be responsible for reporting.

(iv) When the laboratory director or the hospital administrator respond to the notice in (3) above, the state agency may request that the laboratory suspend the provision of the test(s) in question for no more than thirty (30) days, so that a disposition concerning the laboratory's capability to perform the test(s) can be made.

(v) When the laboratory demonstrates that it is unwilling or unable to take the necessary corrective action, the state agency shall initiate proceedings as noted in Section 1 of this Chapter.