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IDAPA 16
TITLE 02
CHAPTER 06

16.02.06 - QUALITY ASSURANCE FOR IDAHO CLINICAL LABORATORIES

000. LEGAL AUTHORITY.
Under Section 56-1003, Idaho Code, the Idaho Legislature has delegated to the Board of Health and Welfare the authority to set standards for laboratories in the state of Idaho. (4-7-11)

001. TITLE AND SCOPE.

01. Title. The title of these rules is IDAPA 16.02.06, "Quality Assurance for Idaho Clinical Laboratories." (4-7-11)

02. Scope. These rules protect the public and individual health by requiring that all Idaho clinical laboratories develop satisfactory quality assurance programs that meet minimal standards approved by the Board. (4-7-11)

002. WRITTEN INTERPRETATIONS.
There are no written interpretations of these rules. (4-7-11)

003. ADMINISTRATIVE APPEALS.
Administrative appeals are governed by provisions of IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (4-7-11)

004. INCORPORATION BY REFERENCE.
No documents have been incorporated by reference into this chapter of rules. (4-7-11)

005. OFFICE HOURS -- MAILING ADDRESS -- STREET ADDRESS -- TELEPHONE -- WEBSITE.

01. Office Hours. Office hours are 8 a.m. to 5 p.m., Mountain Time, Monday through Friday, except holidays designated by the State of Idaho. (4-7-11)

02. Mailing Address. The mailing address for the business office is Idaho Department of Health and Welfare, P.O. Box 83720, Boise, Idaho 83720-0036. (4-7-11)

03. Street Address. (4-7-11)

a. The business office of the Idaho Department of Health and Welfare is located at 450 West State Street, Boise, Idaho 83702. (4-7-11)

b. The Idaho Bureau of Laboratories is located at 2220 Old Penitentiary Road, Boise, Idaho, 83712-8299. (4-7-11)

04. Telephone. (4-7-11)

a. The telephone number for the Idaho Department of Health and Welfare is (208) 334-5500. (4-7-11)

b. The telephone number for the Idaho Bureau of Laboratories is (208) 334-2235. (4-7-11)

05. Internet Website. (4-7-11)

a. The Department's internet website at http://www.healthandwelfare.idaho.gov. (4-7-11)

b. The webpage for the Department's Idaho Bureau of Laboratories (IBL) Website at http://www.statelab.idaho.gov. (4-7-11)

006. CONFIDENTIALITY OF RECORDS AND PUBLIC RECORDS REQUESTS.

01. Confidential Records. Any information about an individual covered by these rules and contained in the Department's records must comply with IDAPA 16.05.01, "Use and Disclosure of Department Records." (4-7-11)

02. Public Records. The Department will comply with Title 74, Chapter 1, Idaho Code, when requests for the examination and copying of public records are made. Unless otherwise exempted, all public records in the custody of the Department are subject to disclosure. (4-7-11)

007. -- 009. (RESERVED)

010. DEFINITIONS.
For the purposes of these rules, the following terms apply: (4-7-11)

01. Board. The Idaho Board of Health and Welfare. (4-7-11)

02. Department. The Idaho Department of Health and Welfare. (4-7-11)

03. Director. The Director of the Idaho Department of Health and Welfare, or his designee. (4-7-11)

04. Laboratory or Clinical Laboratory. A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examinations of material derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, or the impairment or assessment of human health. (4-7-11)

05. Laboratory Director. The person under whose supervision the laboratory is operating. (4-7-11)

06. Pathologist. A physician who is: (4-7-11)

a. Licensed by the Idaho State Board of Medicine in accordance with IDAPA 22.01.01, "Rules of the Board of Medicine for the Licensure to Practice Medicine and Surgery and Osteopathic Medicine and Surgery in Idaho"; and (4-7-11)

b. Board certified by the American Board of Anatomic and Clinical Pathology. (4-7-11)

07. Proficiency Testing. Evaluation of a laboratory's ability to perform laboratory procedures within acceptable limits of accuracy through analysis of unknown specimens distributed at periodic intervals. (4-7-11)

08. Quality Control. A day-to-day analysis of reference materials to ensure reproducibility and accuracy of laboratory results, and also includes an acceptable system to assure proper functioning of instruments, equipment and reagents. (4-7-11)

09. Reviewer. An employee or other designated representative of the Department's Idaho Bureau of Laboratories, who is knowledgeable and experienced in clinical laboratory methods and procedures. (4-7-11)

011. -- 099. (RESERVED)

100. REGISTRATION REQUIREMENTS FOR CLINICAL LABORATORIES.

01. Registration Timeframes. (4-7-11)

a. Every person responsible for the operation of a laboratory that performs tests on material derived from the human body must register such facility with the Department within thirty (30) days after first accepting specimens for testing. (4-7-11)

b. Existing laboratories must submit a completed laboratory registration form every two (2) years and

indicate any changes in laboratory operations. (4-7-11)

02. Registration Form. Each laboratory must submit its registration information on the Department-approved form. These forms are available upon request from the Department. Each completed registration form must include the following information: (4-7-11)

a. Name and location of the laboratory; (4-7-11)

b. Name of the laboratory director; (4-7-11)

c. Types of laboratory tests performed in the laboratory; and (4-7-11)

d. Other information requested by the Department that it deems necessary to evaluate the performance of the laboratory. (4-7-11)

101. -- 109. (RESERVED)

110. EXCLUSIONS.

01. Other Certifying Agencies. Laboratories will be excluded from compliance with these rules (except Sections 100 and 200) upon submission of evidence of certification from one (1) of the following agencies: (4-7-11)

a. Centers for Medicare and Medicaid Services (CMS), Clinical Laboratory Improvement Amendment (CLIA) certification program (http://www.cms.gov/CLIA/01_Overview.asp); (4-7-11)

b. College of American Pathologists; (4-7-11)

c. Agencies approved by CMS as accreditation organizations. To review the current list of CMS-approved accreditation organizations go to, http://www.cms.gov/CLIA/downloads/AO.List.pdf; (4-7-11)

d. Laboratories located in hospitals approved by the Joint Commission (http://www.jointcommission.org/); and (4-7-11)

e. Other certification programs approved by the Department. (4-7-11)

03. Facilities and Laboratories. The following laboratories and facilities are also excluded from compliance with this chapter: (4-7-11)

a. Laboratories operated for teaching or research purposes only, provided tests results are not used for diagnosis or treatment; (4-7-11)

b. Prosthetic dental laboratories; and (4-7-11)

c. Facilities performing skin testing solely for detection of allergies and sensitivities. (4-7-11)

111. -- 119. (RESERVED)

120. DEPARTMENT INSPECTIONS OF CLINICAL LABORATORIES.
A qualified representative of the Department is authorized to inspect the premises and operations of all approved laboratories for the purpose of determining the adequacy of the quality control program and supervision of each laboratory. (4-7-11)

121. -- 129. (RESERVED)

130. GENERAL REQUIREMENTS FOR CLINICAL LABORATORIES.

01. Laboratory Facilities. Each laboratory must have adequate space, equipment, and supplies to perform the services offered, with accuracy, precision, and safety. (4-7-11)

02. Records. (4-7-11)

a. Laboratory records must identify the person responsible for performing the procedure. (4-7-11)

b. Each laboratory must maintain a suitable record of each test result for a period of at least two (2) years. Reports of tests must be filed in a manner that permits ready identification and accessibility. (4-7-11)

c. Laboratory records and reports must identify specimens referred to other laboratories and must identify the reference laboratory testing such referred specimens. (4-7-11)

131. -- 149. (RESERVED)

150. PERSONNEL REQUIREMENTS FOR CLINICAL LABORATORIES.
The laboratory director must ensure that the staff of the laboratory: (4-7-11)

01. Appropriate Education, Experience, and Training. Have appropriate education, experience, and training to perform and report laboratory tests promptly and proficiently; (4-7-11)

02. Sufficient in Number for the Scope and Complexity. Are sufficient in number for the scope and complexity of the services provided; (4-7-11)

03. In-service Training. Receive in-service training appropriate to the type and complexity of the laboratory services offered; and (4-7-11)

04. Procedures and Tests that are Outside the Scope of Training. Do not perform procedures and tests that are outside the scope of training of the laboratory personnel. (4-7-11)

151. -- 199. (RESERVED)

200. PROFICIENCY TESTING OF CLINICAL LABORATORIES.

01. Scope. All laboratories must subscribe to, and satisfactorily participate in, a proficiency testing program that has been approved by the Department. (4-7-11)

02. Results to the Bureau of Laboratories. The laboratory director must furnish the Laboratory Improvement Section with copies of all proficiency testing results within thirty (30) days of receipt or make provisions for a duplicate of the results to be sent by the testing service directly to the Department. (4-7-11)

201. -- 209. (RESERVED)

210. QUALITY CONTROL PROGRAM REQUIREMENTS FOR CLINICAL LABORATORIES.

01. Establishment of Quality Control Program. To ensure reliability of day-to-day results, each laboratory must establish a quality control program compatible with regional and statewide practices. (4-7-11)

02. Program Scope. An acceptable quality control program must include the following: (4-7-11)

a. An effective preventive maintenance program that ensures proper functioning of all instruments and equipment; (4-7-11)

b. Routine testing of quality control materials along with patient specimens; (4-7-11)

c. Quality control checks on reagents and media utilized in the performance of tests; (4-7-11)

d. Maintenance of quality control records that will enable determination of reliability of all procedures performed. (4-7-11)

211. -- 219. (RESERVED)

220. DEPARTMENT APPROVAL OF CLINICAL LABORATORIES.
The Department will approve clinical laboratories for performance of tests on material from the human body if the laboratory meets the minimum standards specified in these regulations. (4-7-11)

221. -- 229. (RESERVED)

230. DEPARTMENT REVOCATION OF APPROVAL.
The Department may revoke approval, either in total or in part, for the following reasons: (4-7-11)

01. Failure to Participate in Proficiency Testing. The approved laboratory fails to participate in a proficiency testing program as outlined in Section 200. (4-7-11)

02. Failure to Participate in Quality Control. The approved laboratory fails to implement a quality control program as outlined in Section 210. (4-7-11)

03. Failure to Obtain Satisfactory Results. The Department, through the quality review process, determines that the approved laboratory has failed to obtain satisfactory results on two (2) consecutive or on two (2) out of three (3) consecutive sets of proficiency test program specimens in one (1) or more testing categories. (4-7-11)

04. Failure to Submit Documentation. Failure to submit documentation of corrective action as indicated in Subsection 240.02. (4-7-11)

231. -- 239. (RESERVED)

240. REVOCATION PROCEDURE.

01. Unacceptable Results. Laboratories that fail to obtain passing results on two (2) consecutive proficiency testing events, or two (2) out of three (3) events, will be required to submit documentation of corrective action within fifteen (15) working days after receipt of the notification of the failures. Evaluation of proficiency testing results may overlap from one year to the next. (4-7-11)

02. Corrective Action. Upon receipt of documentation of corrective action, a reviewer will determine the adequacy of the action taken. If, in the opinion of the reviewer, the corrective action is not adequate, the laboratory will be required to submit to an on-site inspection that may include on-site testing of unknown samples. (4-7-11)

03. On-Site Inspection. If the results of the on-site inspection indicate that the laboratory's performance is unacceptable in one or more testing categories, the approval to perform the test(s) in question will be revoked. (4-7-11)

04. Satisfactory Performance. The laboratory will continue to be approved for performance of all test procedures for which it has demonstrated satisfactory performance. (4-7-11)

05. Other Deficiencies. Failure to comply with other provisions of these rules may invoke revocation procedures. (4-7-11)

241. -- 249. (RESERVED)

250. RENEWAL OF APPROVAL OF TEST OR TESTS WHICH HAVE BEEN DISAPPROVED.

01. Renewal Granted. (4-7-11)

a. A laboratory that has lost approval to perform certain tests for reasons outlined in Section 240 may gain reapproval by documenting corrective action taken, and by requesting the Department review the unacceptable performance and the corrective action taken. (4-7-11)

b. Within ten (10) days after completion of this review, the reviewer will submit his report to the Chief of the Bureau of Laboratories. (4-7-11)

c. Upon determination that corrections leading to satisfactory and acceptable performance have been made, the Chief of the Bureau of Laboratories may reinstate approval. (4-7-11)

02. Renewal Denied. If the Chief of the Bureau of Laboratories does not grant reapproval of the laboratory, he will provide the laboratory supervisor with written notice of actions to be taken to correct deficiencies. The laboratory supervisor may request a new review at any time after thirty (30) days from the date of last review. The laboratory supervisor may also file a written appeal in accordance with IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings," Section 400. (4-7-11)

251. -- 269. (RESERVED)

270. LIST OF APPROVED LABORATORIES.
The Department will maintain a list of laboratories approved in accordance with this chapter. This list must include the name and address of each approved laboratory, and the name of the person directing the laboratory. (4-7-11)

271. -- 299. (RESERVED)

300. PENALTY FOR FAILURE TO REGISTER OR OPERATION OF A NONAPPROVED CLINICAL LABORATORY.
Failure to register a clinical laboratory, operation of a nonapproved clinical laboratory, or performance of unapproved testing constitutes a violation of these rules. Any violation of these rules constitutes a misdemeanor under Section 56-1008, Idaho Code. (4-7-11)

301. -- 999. (RESERVED)

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