IDAPA 16 – IDAHO DEPARTMENT OF HEALTH AND WELFARE

Division of Public Health – Bureau of Laboratories

16.02.06 – Quality Assurance for Clinical Laboratories

Who does this rule apply to?
All laboratories that perform tests on material derived from the human body, hospitals, Public Health Districts, medical professionals and practices, and health care stakeholders.

What is the purpose of this rule?
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.

What is the legal authority for the agency to promulgate this rule?
This rule implements the following statute passed by the Idaho Legislature:

Public Assistance and Welfare -
- Section 56-1003, Idaho Code – Department of Health and Welfare: Powers and Duties of the Director

Where can I find information on Administrative Appeals?
Administrative appeals and contested cases are governed by the provisions of IDAPA 16.05.03, "Contested Case Proceedings and Declaratory Rulings."

How do I request public records?
Unless exempted, all public records are subject to disclosure by the Department that will comply with Title 74, Chapter 1, Idaho Code, upon requests. Confidential information may be restricted by state or federal law, federal regulation, and IDAPA 16.05.01, "Use and Disclosure of Department Records."

Who do I contact for more information on this rule?

Idaho Department of Health and Welfare
Bureau of Laboratories
2220 Old Penitentiary Road
Boise, ID 83712-8299

P.O. Box 83720
Boise, ID 83720-0036
Phone: (208) 334-2235
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16.02.06 – Quality Assurance for Clinical Laboratories

000. LEGAL AUTHORITY.
Section 56-1003, Idaho Code, authorizes the Board of Health and Welfare to set standards for Idaho laboratories. (7-1-24)

001. -- 009. (RESERVED)

010. DEFINITIONS.

01. Board. The Idaho Board of Health and Welfare. (7-1-24)

02. Department. The Idaho Department of Health and Welfare, or its designee. (7-1-24)

03. 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. (7-1-24)

04. Laboratory Director. The person under whose supervision the laboratory is operating. (7-1-24)

05. Nonwaived Test. A moderate or high complexity test system, assay, or examination that does not meet the criteria for a waiver as specified under Title 42 USC, Section 263a (3). (7-1-24)

06. 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. (7-1-24)

07. Quality Control. Analysis of reference materials to ensure reproducibility and accuracy of laboratory results and an acceptable system to assure proper functioning of instruments, equipment, and reagents. (7-1-24)

08. Reviewer. The Department's representative who is knowledgeable and experienced in clinical laboratory methods and procedures. (7-1-24)

09. Waived Test. A low complexity test system, assay, or examination that meets the criteria for waiver specified under Title 42 USC, Section 263a (3). (7-1-24)

011. -- 099. (RESERVED)

100. REGISTRATION REQUIREMENTS.

01. Registration Timeframes. (7-1-24)

a. A clinical laboratory must register with the Department prior to accepting specimens for testing. (7-1-24)

b. Registered clinical laboratories must submit a completed registration form every two (2) years and indicate any changes in laboratory operations. (7-1-24)

02. Registration Form. Each clinical laboratory must use the Department-approved form. Forms are available upon request from the Department. Each form must include the following: (7-1-24)

a. Name and location of the clinical laboratory; (7-1-24)

b. Name of the laboratory director; (7-1-24)

c. Tests performed in the laboratory; and (7-1-24)

d. Any other information requested by the Department to evaluate clinical laboratory performance. (7-1-24)

101. -- 109. (RESERVED)

110. EXCLUSIONS.

01. Other Certifying Agencies. Clinical Laboratories will be excluded from compliance with these rules (except Sections 100, 130, and 200) upon submission of evidence of certification from one (1) of the following: (7-1-24)

a. Centers for Medicare and Medicaid Services (CMS), Clinical Laboratory Improvement Amendment (CLIA) certification program; (7-1-24)

b. Agencies approved by CMS as accreditation organizations. To review the current list of CMS-approved accreditation organizations go to, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf; (7-1-24)

c. Other certification programs approved by the Department. (7-1-24)

02. Facilities and Laboratories. The following laboratories and facilities are also excluded from compliance with these rules: (7-1-24)

a. Teaching, research, forensic, and pre-employment drug screening laboratories if test results are not used for diagnosis or treatment; (7-1-24)

b. Prosthetic dental laboratories; and (7-1-24)

c. Facilities performing skin testing solely for detection of allergies and sensitivities. (7-1-24)

111. -- 119. (RESERVED)

120. DEPARTMENT INSPECTIONS.
A Department representative is authorized to inspect any registered clinical laboratory to determine the adequacy of the supervision, staffing, and quality control program. (7-1-24)

121. -- 129. (RESERVED)

130. GENERAL REQUIREMENTS.

01. Clinical Laboratory Facilities. Each clinical laboratory must have adequate space, equipment, and supplies to perform the services offered, with accuracy, precision, and safety. (7-1-24)

02. Records. (7-1-24)

a. Clinical laboratory records must identify the person responsible for performing the procedure. (7-1-24)

b. Clinical Laboratories must maintain testing records for at least two (2) years. Test reports must be readily accessible upon request. (7-1-24)

c. Clinical laboratory records and reports must identify specimens referred to other certified laboratories and must identify the reference laboratory by name and address. (7-1-24)

03. Test Orders and Results. (7-1-24)

a. Practitioners legally authorized to diagnose, treat, and prescribe are authorized to order both waived and nonwaived tests and receive results. (7-1-24)

b. Laboratory directors are authorized to order the waived tests listed on their approved registration form and receive test results. (7-1-24)

131. -- 149. (RESERVED)

150. PERSONNEL REQUIREMENTS.
The laboratory director must ensure that clinical laboratory staff have appropriate education, experience, and training to maintain records, perform tests, and report results. The clinical laboratory must employ enough staff to provide timely and accurate test results. Staff must receive in-service training appropriate to the type and complexity of testing. Staff must not perform testing outside of their scope of training. (7-1-24)

151. -- 199. (RESERVED)

200. PROFICIENCY TESTING.

01. Scope. Clinical laboratories must satisfactorily participate in proficiency testing programs approved by the Department. (7-1-24)

02. Results to the Department. The clinical laboratory must ensure that all proficiency testing results are available to the Department. (7-1-24)

201. -- 209. (RESERVED)

210. QUALITY CONTROL PROGRAM REQUIREMENTS.

01. Establishment of Quality Control Program. Clinical laboratories must establish a quality control program. (7-1-24)

02. Program Scope. An acceptable quality control program must include written documentation of: (7-1-24)

a. A preventive maintenance program that ensures proper functioning of all instruments and equipment; (7-1-24)

b. Proper testing of quality control materials along with patient specimens; (7-1-24)

c. Quality control checks on reagents and media utilized in the performance of tests; (7-1-24)

d. Quality control records that demonstrate the reliability of all procedures performed. (7-1-24)

211. -- 219. (RESERVED)

220. DEPARTMENT APPROVAL.
The Department will approve clinical laboratories for performance of tests on material from the human body if the laboratory meets the standards specified in these rules. (7-1-24)

221. -- 229. (RESERVED)

230. DEPARTMENT REVOCATION OF APPROVAL.
The Department may revoke approval, either in total or in part, for any one (1) of the following reasons: (7-1-24)

01. Failure to Participate in Proficiency Testing. The clinical laboratory fails to participate in a proficiency testing program. (7-1-24)

02. Failure to Participate in Quality Control. The clinical laboratory fails to implement a quality control program. (7-1-24)

03. Failure to Obtain Satisfactory Results. The Department, through the quality review process, determines that the clinical 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. (7-1-24)

04. Failure to Submit Documentation. Failure to submit documentation of corrective action required by the Department. (7-1-24)

231. -- 239. (RESERVED)

240. REVOCATION PROCEDURE.

01. Unacceptable Results. Clinical 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. (7-1-24)

02. Corrective Action. Upon receipt of documentation of corrective action, a reviewer will determine the adequacy of the action taken. If the reviewer determines the corrective action is not adequate, the clinical laboratory must submit to an on-site inspection that may include on-site testing of unknown samples. (7-1-24)

03. On-Site Inspection. If the results of the on-site inspection indicate that the clinical laboratory performance is unacceptable in one (1) or more testing categories, the approval to perform the test(s) in question will be revoked. (7-1-24)

04. Satisfactory Performance. The clinical laboratory will continue to be approved for performance of all test procedures for which it has demonstrated satisfactory performance. (7-1-24)

05. Other Deficiencies. Failure to comply with other provisions of these rules may invoke revocation procedures. (7-1-24)

241. -- 249. (RESERVED)

250. RENEWAL OF APPROVAL OF DISAPPROVED TEST(S).

01. Renewal Granted. (7-1-24)

a. A clinical laboratory that has lost approval to perform certain tests may gain reapproval by requesting the Department review the unacceptable performance and the corrective action taken. (7-1-24)

b. Within ten (10) days after completion of this review, the reviewer will submit their report to the Department. (7-1-24)

c. Upon determination that corrections leading to satisfactory and acceptable performance have been made, the Department may reinstate approval. (7-1-24)

02. Renewal Denied. If the Department does not grant reapproval of the clinical laboratory, they will provide written notice of actions to be taken to correct deficiencies. The clinical laboratory may request a new review at any time after thirty (30) days from the date of last review. The clinical laboratory may also file a written appeal under IDAPA 16.05.03, "Contested Case Proceedings and Declaratory Rulings." (7-1-24)

251. -- 269. (RESERVED)

270. REGISTERED LABORATORIES.
The Department will maintain a list of registered clinical laboratories. (7-1-24)

271. -- 299. (RESERVED)

300. FAILURE TO REGISTER OR OPERATION OF AN UNREGISTERED CLINICAL LABORATORY.

Failure to register a clinical laboratory, operation of an unregistered 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. (7-1-24)

301. -- 999. (RESERVED)