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16.02.06 - Rules Governing Quality Assurance for Idaho Clinical Laboratories

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16.02.06 - RULES GOVERNING QUALITY ASSURANCE FOR IDAHO CLINICAL LABORATORIES

000. (RESERVED).

001. LEGAL AUTHORITY.
Title 39, Chapter 1, of the Idaho Code, (Section 39-101, et seq.) the "Environmental Protection and Health Act of 1972" provides for the protection of the environment and the promotion of personal health and thereby, protects and promotes the health, safety, and general welfare of the people of Idaho. (12-31-91)

01. Laboratory Defined. Section 56-1001(4), Idaho Code: "Laboratory" means not only facilities for biological, serological, biophysical, cytological and pathological tests but also facilities for the chemical or other examinations of material from water, air or other substances. (1-1-87)

02. Director -- Powers and Duties. Section 56-1003, Idaho Code: The powers and duties of the Director of the Idaho Department of Health and Welfare include: "The supervision and administration of laboratories and the supervision and administration of standards of tests for environmental pollution, chemical analyses and communicable diseases. The administrator may require that laboratories operated by any city, county, institution, person, firm or corporation for health, environmental or law enforcement purposes conform to standards set by the Board." (1-1-87)

002. PURPOSE.
The people of Idaho are entitled to receive the highest level of competency, reliability and accuracy that may be expected from clinical laboratories. Inaccurate and misleading laboratory results have been known to cause unnecessary anxiety, physical suffering, financial burdens, and even jeopardize life itself. It is the intent of these rules to protect the public and individual health by requiring that all Idaho clinical laboratories develop satisfactory quality assurance programs that shall meet minimal standards approved by the Board. (12-31-91)

003. DEFINITION.

01. 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 impairment of, or the assessment of the health of man. (1-1-77)

a. A "hospital laboratory" is a laboratory which is physically housed in a hospital and is routinely performing tests on hospital patient specimens regardless of financial and/or administrative relationship between the laboratory director and the hospital administrator. (1-1-77)

b. An "independent laboratory" is a laboratory not located in a hospital and not located in a physician's office or group practice clinic. Independent laboratories do not limit provision of laboratory services to any specific physician or group of physicians. (1-1-87)

c. A "private laboratory" is a laboratory operating in a private physician's office or a private physicians' group clinic. Private labs do not perform tests for physicians other than those involved in the office or clinic group practice. (1-1-77)

d. "Other laboratory" is a public or private facility which performs tests on material derived from the human body but which is not a part of a "hospital laboratory," "independent laboratory," or "private laboratory" as described above. (1-1-77)

02. Board. The Idaho State Board of Health and Welfare. (12-31-91)

03. Department. The Department of Health and Welfare. (1-1-77)

04. **Director**. The Director of the Department of Health and Welfare or his designee. (12-31-91)

05. **State**. The state of Idaho. (1-1-77)

06. **Person**. Any human being, any municipality or other governmental or political subdivision, or other public agency; any public or private corporation, any partnership, firm, association or other organization; any receiver, trustee, assignee, agent or other legal representative of the foregoing, or any legal entity. (1-1-77)

07. **Laboratory Supervisor**. The person under whose supervision the laboratory is operating. (1-1-77)

08. **Quality Control**. A day-to-day analysis of reference materials to insure reproducibility and accuracy of laboratory results, and also includes an acceptable system to assure proper functioning of instruments, equipment and reagents. (1-1-87)

09. **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. (1-1-77)

10. **Reviewer**. An employee or other designated representative of the Department of Health and Welfare, Bureau of Laboratories, who is knowledgeable and experienced in clinical laboratory methods and procedures. (1-1-77)

11. **Clinical Laboratory Technologist**. A technically trained individual meeting the personnel requirements specified in the Medicare Independent Laboratory Regulations for Clinical Technologists (Subpart M, Part 405.1315(b), Chapter 3 of Title 20 of the Code of Federal Regulations). (1-1-87)

12. **Clinical Laboratory Technician**. A technically trained individual meeting the personnel requirements specified in the Medicare Independent Laboratory Regulations for Clinical Technicians, Subpart M, Part 405.1315(e) of Title 42 of the Code of Federal Regulations. (1-1-87)

13. **Pathologist**. Board certified by the American Board of Anatomic and Clinical Pathology and licensed as a physician by the Idaho State Board of Medicine. (1-1-87)

004. -- 010. (RESERVED).

011. REGISTRATION.
Every person responsible for the operation of a laboratory performing tests on material derived from the human body shall register such facility with the Department within thirty (30) days after first accepting specimens for testing. Existing laboratories shall submit a completed laboratory registration form every two (2) years and indicate any changes in laboratory operations. Registration shall be made on a form prescribed by the Department. Forms (available from the Department) shall include, but not be limited to the following information: Name and location of the laboratory; name of the laboratory owner and name of the laboratory supervisor; the type of laboratory tests performed in the laboratory; the name, education, experience and training of the person(s) actually performing the laboratory examinations and services; annual volume of laboratory work performed; such other information as the Department deems necessary to evaluate the performance of the laboratory. (1-1-87)

012. EXCLUSIONS.

01. **Physicians on Own Patients**. Tests performed directly, personally, and physically by licensed doctors of medicine and doctors of osteopathy on their own patients shall be excluded from the provisions of these rules with the exception of the registration requirement, Section 011. The right to this exclusion shall not be delegated or assigned to another person. (12-31-91)

02. **Other Certifying Agencies**. Laboratories shall be excluded from compliance with these rules (except Sections 011 and 022) upon submission of annual evidence of certification from one (1) of the following agencies: (12-31-91)

a. Center for Disease Control for testing of specimens in interstate commerce; (1-1-77)

b. College of American Pathologists; (1-1-77)

c. Medicare Title XVIII standards, providing they are also in compliance with Sections 022 and 023; (12-31-91)

d. Laboratories located in hospitals approved by the Joint Commission on Accreditation of Hospitals; (1-1-87)

e. Such other certification programs as may be approved by the Director. (12-31-91)

03. Facilities and Laboratories. The following laboratories and facilities shall also be excluded from compliance with this chapter: (12-31-91)

a. Laboratories operated for teaching or research purposes only, provided tests results are not used for diagnosis or treatment; (1-1-77)

b. Prosthetic dental laboratories; (1-1-77)

c. Facilities performing skin testing solely for detection of allergies and sensitivities. (1-1-87)

013. INSPECTION.
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. (1-1-77)

014. GENERAL PROVISIONS.

01. Laboratory Facilities. Each laboratory shall have adequate space, equipment and supplies to perform the services offered, with accuracy, precision and safety. (1-1-77)

02. Records. (7-1-93)

a. Laboratory records shall identify the person responsible for performing the procedure. (1-1-77)

b. Each laboratory shall maintain a suitable record of each test result for a period of at least three (3) years. Reports of tests shall be filed in a manner which permits ready identification and accessibility. (1-1-87)

c. Laboratory records and reports shall identify specimens referred to other laboratories and shall identify the reference laboratory testing such referred specimens. (1-1-77)

015. TESTING CATEGORIES.
Laboratories may register for performance of tests procedures in one (1) of the following different levels: (1-1-87)

01. Level 1 Procedures: (7-1-93)

a. Urine specific gravity; (1-1-87)

b. Chemical examination of urine by dipstick; (1-1-87)

c. Chemical examination of blood by dipstick; (1-1-87)

d. Slide agglutination tests; (1-1-87)

e. Solid-phase qualitative immunoassays with visual color development; (1-1-87)

f. Spun hematocrit; (1-1-87)

g. Erythrocyte sedimentation rate; (1-1-87)

h. Test for occult blood; (1-1-87)

i. Primary culturing for transmittal to an approved laboratory, including preincubation if required; (1-1-87)

j. Other tests like the ones listed in this subsection that are mechanically simple to perform and require no interpretation of results. (1-1-87)

02. Level 2 Procedures. Any of the procedures listed under Level 1 plus: (1-1-87)

a. Manual white blood cell, red blood cell and platelet counts; (1-1-87)

b. Scotch tape test (microscopic) for pinworm; (1-1-87)

c. Wet mount (microscopic) for Trichomonas or yeast; (1-1-87)

d. Automated instrumentation for chemistry, hematology, or coagulation; (1-1-87)

e. White blood cell differential count with red blood cell morphology; (1-1-87)

f. Microscopic examination of urine sediments; (1-1-87)

g. Direct gram stain (microscopic); (1-1-87)

h. Manual spectrophotometric tests; (1-1-87)

i. Throat culture screen for beta-hemolytic Streptococci; (1-1-87)

j. Screens and colony counts for urine infections; (1-1-87)

k. Other tests like the ones listed in this subsection that are mechanically not as simple to perform as Level 1 procedures and which require a degree of interpretation of results. (1-1-87)

03. Level 3 Procedures. All other clinical laboratory tests not included in Levels 1 and 2 above. (1-1-87)

04. Level Placement. If a laboratory performs a test not expressly placed in Level 1 or Level 2 and if the laboratory does not believe the procedure is a Level 3 procedure, the laboratory shall report the test with its next annual registration, together with a recommendation from its laboratory consultant for level placement. The Department shall provisionally place the procedure within the appropriate level until final action can be taken following review of the procedure and the appropriate testing category by the advisory committee pursuant to Subsection 015.05. (12-31-91)

016. PERSONNEL REQUIREMENTS.

01. Personnel. The laboratory supervisor must insure that the staff of the laboratory: (1-1-87)

a. Has appropriate education, experience and training to perform and report laboratory tests promptly and proficiently; (1-1-87)

b. Is sufficient in number for the scope and complexity of the services provided; (1-1-87)

c. Receives in-service training appropriate to the type and complexity of the laboratory services

offered. (1-1-87)

d. Does not perform procedures and tests which are outside the scope of training of the laboratory personnel. (1-1-87)

02. Personnel - Level 3. Personnel in a Level 3 laboratory performing tests not included in Level 1 or 2 must meet the personnel requirements specified in the Medicare Independent Laboratory Regulations for Clinical Laboratory Technologists (Subpart M, Part 405.1315(b), Title 42 of the Code of Federal Regulations), or must meet the personnel requirements specified in the Medicare Independent Laboratory Regulations for Clinical Laboratory Technicians, Part 405.1315(e), and work under the direct supervision of a clinical laboratory technologist. (1-1-87)

03. Personnel. Individuals performing laboratory tests in all types of clinical laboratories on the date these rules are approved by the Board shall be deemed to meet the requirements specified in Subsections 016.01 and 016.02. (12-31-91)

017. CONSULTANT SERVICES.
Level 1 and Level 2 laboratories not supervised by a clinical laboratory technologist shall make arrangements to have a pathologist licensed by the Idaho State Board of Medicine or a clinical laboratory technologist with a minimum of five (5) years' experience in clinical laboratory operation provide laboratory consultation services. These services must include a minimum of: (1-1-87)

01. Visits. Four (4) on-site visits per year. (1-1-87)

02. Availability. Availability by telephone during all operational hours. (1-1-87)

03. Checklist. Completion of a checklist provided by the Department, to be submitted to the Director. (12-31-91)

04. Laboratory Consultant Responsibilities. Responsibilities of the laboratory consultant shall also include development of an internal quality control program, preparation of a testing procedures manual, assuring participation in a proficiency testing service meeting the Department's standards, teaching proper laboratory techniques and the importance of quality control and proficiency testing, answering questions, providing on-going educational services, review of the results of the laboratory's proficiency testing program and determination and work to correct the sources of error. (1-1-87)

05. Reduced On-Site Visits. Level 1 laboratories may seek a reduction in the number of on-site visits from four (4) to two (2) each year after at least one (1) full year of consultation visits at the rate of four (4) each year upon certification by the laboratory consultant that an internal quality control program is in place and functioning well, and that a good procedures manual is in place and being utilized. The Department reserves the right to reinstate the four (4) on-site visits per year upon failure of the laboratory to obtain satisfactory results in the Department's proficiency testing programs as defined in Subsection 026.01 or for other good cause. (12-31-91)

06. Consultant Services Waiver. Level 1 laboratories performing less than three (3) types of clinical laboratory tests may request a waiver of the consultant services requirement. (1-1-87)

018. -- 021. (RESERVED).

022. PROFICIENCY TESTING.

01. Scope. All laboratories shall subscribe to and satisfactorily participate in a proficiency testing program which has been approved by the Director. (1-1-77)

02. Results to Director. The laboratory supervisor shall furnish the Director 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. (12-31-91)

023. QUALITY CONTROL.

01. Establishment of Quality Control Program. To insure reliability of day-to-day results, each laboratory shall establish a quality control program compatible with regional and statewide practices. (1-1-77)

02. Program Scope. An acceptable quality control program shall include at least the following: (1-1-87)

a. An effective preventive maintenance program which insures proper functioning of all instruments and equipment; (1-1-77)

b. Routine testing of quality control materials along with patient specimens; (1-1-77)

c. Quality control checks on reagents and media utilized in the performance of tests; (1-1-77)

d. Maintenance of quality control records which will enable determination of reliability of all procedures performed. (1-1-77)

024. APPROVAL.
The Department shall approve clinical laboratories for performance of tests on material from the human body if the laboratory meets the minimum standards specified in these regulations. Laboratories may be approved for performance of tests in one (1) or more of the following categories: urinalysis; hematology; clinical chemistry; serology; immunohematology; histology and cytology; microbiology. (12-31-91)

025. DENIAL OF APPROVAL.
Approval may be revoked in total or in part for the following reasons: (12-31-91)

01. Failure to Participate in Proficiency Testing. The approved laboratory fails to participate in a proficiency testing program as outlined in Section 022. (12-31-91)

02. Failure to Participate in Quality Control. The approved laboratory fails to implement a quality control program as outlined in Section 023. (12-31-91)

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. (1-1-87)

04. Failure to Submit Documentation. Failure to submit documentation of corrective action as indicated in Subsection 026.02. (12-31-91)

05. Failure to Utilize Appropriate Personnel. The approved laboratory fails to utilize personnel with qualifications for the tests being performed. (1-1-87)

026. REVOCATION PROCEDURE.

01. Unacceptable Results. Laboratories which fail to obtain satisfactory results on two (2) consecutive sets of unknown proficiency testing samples and laboratories which obtain unacceptable results on two (2) out of three (3) consecutive sets of proficiency testing samples will be required to submit documentation of corrective action within fifteen (15) working days after receipt of notification of the second consecutive unacceptable report or second unacceptable report on the last three (3) sets of samples. Evaluation of test results may overlap from one (1) year to the next. (1-1-87)

02. Corrective Action. On 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. (1-1-87)

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. (1-1-87)

04. Satisfactory Performance. The laboratory will continue to be approved for performance of all test procedures for which it has demonstrated satisfactory performance. (1-1-87)

05. Other Deficiencies. Failure to comply with other provisions of these rules may invoke revocation procedures. (1-1-87)

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

01. Renewal Granted. A laboratory which has lost approval to perform certain tests for reasons outlined in Section 026 may gain reapproval by documenting corrective action taken and by requesting review of the unacceptable performance and the corrective action taken. Within ten (10) days after completion of this review, the reviewer shall submit his report to the Director. Upon determination that corrections leading to satisfactory and acceptable performance have been made, the Director may reinstate approval, conditioned upon subsequent compliance with these rules. (12-31-91)

02. Renewal Denied. If the Director 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 request a hearing as outlined in Idaho Department of Health and Welfare Rules, IDAPA 16, Title 05, Chapter 03, Sections 300, et seq., and Section 402, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (12-31-91)

028. QUALITY REVIEW.

01. Advisory Committee. The Director shall appoint a committee consisting of a representative from the Idaho Medical Association, Idaho Hospital Association, Idaho Society of Pathologists, Idaho Society for Medical Technology, Idaho State Society of American Medical Technologists, the owner or director of an independent laboratory, a representative from a hospital laboratory, a representative from a physician's office laboratory, and a consumer, which shall serve as an advisory committee to the Department's Laboratories, in the application of these rules and regulations to private, hospital, independent and other clinical laboratories. This advisory committee shall have the following duties and responsibilities: (12-31-91)

a. Assist in the establishment of criteria to be used to determine satisfactory laboratory performance. (1-1-77)

b. Review and make recommendations concerning clinical laboratory standards and regulations adopted by the Board. (12-31-91)

c. Review and make recommendations concerning revision of this chapter. (12-31-91)

02. Ex Officio Membership of Bureau Chief. The Chief of the Bureau of Laboratories of the Department or his designee will serve as ex officio member of the advisory committee and will represent the Director at committee meetings. (12-31-91)

029. LIST OF APPROVED LABORATORIES.

The Department shall publish annually a list of laboratories approved in accordance with this chapter. This list shall include the name and address of the laboratory, the name of the owner of the laboratory, and the name of the person supervising the laboratory. The annual list of approved laboratories shall be sent to all approved laboratories, the State Board of Medicine, and all state and federal agencies responsible for administration of medical assistance programs. The Department shall keep owners and supervisors of all approved laboratories informed regarding any discrepancies which might lead to revocation of approval. (12-31-91)

030. -- 040. (RESERVED).

041. PENALTY FOR FAILURE TO REGISTER OR OPERATION OF A NONAPPROVED LABORATORY.
Failure to register a clinical laboratory, operation of a nonapproved clinical laboratory or performance of unapproved testing shall constitute a violation of these rules. Violations of these rules will constitute a misdemeanor pursuant to Section 56-1008, Idaho Code. (1-1-87)

042. -- 995. (RESERVED).

996. ADMINISTRATIVE PROVISIONS.
Contested case appeals shall be governed by Idaho Department of Health and Welfare Rules, IDAPA 16, Title 05 Chapter 03, Sections 300, et seq., and Section 402, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (12-31-91)

997. CONFIDENTIALITY OF RECORDS.
Any disclosure of information obtained by the Department is subject to the restrictions contained in Idaho Department of Health and Welfare Rules, IDAPA 16.05.01, "Use and Disclosure of Department Records." (12-31-91)

998. INCLUSIVE GENDER AND NUMBER.
For the purposes of these rules, words used in the masculine gender include the feminine, or vice versa, where appropriate. (12-31-91)

999. SEVERABILITY.
If any clause, sentence, paragraph, section or part of these rules shall be deemed to be invalid, the judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined to its application to the clause, sentence, paragraph, section or part thereof directly involved in the controversy in which the judgment shall have been rendered. (12-31-91)

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