Dear Senators LODGE, Broadsword & LeFavour, and
Representatives BLOCK, Nielsen & Rusche:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Dept. Of Health & Welfare:

IDAPA 16.02.06 - Quality Assurance for Idaho Clinical Laboratories

(Docket #16-0206-1001) Proposed Chapter Repeal;

16.02.06 - Quality Assurance for Idaho Clinical Laboratories

(Docket #16-0206-1002) Proposed Chapter Rewrite.

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 8-12-10. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 9-9-10.

The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-4845, or send a written request to the address or FAX number indicated on the memorandum attached.

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

Jeff Youtz
Director

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Research & Legislation Staff - Paige Alan Parker PAP

DATE: July 26, 2010

SUBJECT: Department of Health and Welfare - IDAPA 16.02.06 - Quality Assurance for Idaho Clinical Laboratories, Docket No. 16-0206-1001 (Proposed Chapter Repeal) and Docket No. 16-0206-1002 (Proposed Chapter Rewrite)

By these Proposed Rule dockets, the Department of Health and Welfare proposes to rewrite IDAPA chapter 16.02.06 (Rules Governing Quality Assurance for Idaho Clinical Laboratories), by repealing the existing chapter (Docket No. 16-0206-1001) and rewriting the chapter (Docket No. 16-0206-1002). The Department explains that the reason for this chapter rewrite is that there have been significant technological changes since 1987 and that significant technological changes have rendered much of the chapter obsolete and outdated. Further, the Department states that the present rules doe not reflect more recent changes in federal regulations, the organizational structure of the Bureau of Laboratories and the Bureau's current practices.

According to the Department, the new chapter is authorized pursuant to section 56-1003, Idaho Code. No federal regulations are cited as authority for the chapter rewrite.

Section 56-1003 provides powers and duties to the Department's director in the area of public health. Section 56-1003(3)(a) grants the Department's director the power and duty to supervise and administer laboratories and standards of test for environmental pollution, chemical analyses and communicable diseases. The director also has the power to require that laboratories operated by any city, county, institution, person firm or corporation for health or environmental purposes to conform to the standards set by the Board of Health and Welfare and the Board of Environmental Quality.

According to the Department, negotiated rulemaking was conducted but no details regarding with whom have been provided. No fee is imposed by the chapter rewrite and there is

no impact to the General Fund since the Department informs that the functions administered under the chapter rewrite are 100 percent federally funded under the Clinical Laboratory Improvement Amendments of 1988 grant. Public hearings will be scheduled if requested by 25 persons, a political subdivision or an agency not later than August 18, 2010. The Department will accept written comments through August 25, 2010.

ANALYSIS

The chapter rewrite shortened the chapter from eight to six pages. Much of what is in the existing chapter has been retained, with grammatical improvement. A major change is the dropping of testing categories by the new chapter. Under the existing chapter, laboratories could register for performance of tests in one of three different levels. Existing chapter, section 016. The chapter rewrite does not register laboratories by level. Dropping these levels has resulted in the removal of personnel requirements for Level 3 (existing chapter, section 016.03) and the consulting service requirements for Level 1 and 2 laboratories when not supervised by a clinical laboratory technologist (existing chapter, section 017). Another major change is the dropping of the section on Quality Review (existing chapter, section 028) by the chapter rewrite. This Quality Review section provided for an advisory committee appointed by the Department's Director, representing specified organizations, to assist in the establishment of criteria to be used to determine satisfactory laboratory performance and to review and make recommendations concerning clinical laboratory standards and regulations and chapter revisions.

A. Standard Rule Sections

Legal Authority, section 000, appropriately identifies section 56-1003, Idaho Code, as the authority for the chapter rewrite rulemaking authority. The Purpose (existing chapter, section 002) is removed and replaced with a new Scope (chapter rewrite, section 001.02) that succinctly states that the "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."

The chapter rewrite has adopted the standard rule chapter language for Written Interpretations [none], Incorporation By Reference [none], Office Hours - Mailing Address - Street Address - Telephone - Website [appropriate] and Public Records. The standard provisions regarding Administrative Appeals and Confidential Records have been moved over from the existing chapter and redesignated. The chapter rewrite does not have any Criminal History and Background Check provisions.

B. Definitions

The term "laboratory director" is substituted for "laboratory supervisor" throughout the chapter rewrite. The definition for "laboratory or clinical laboratory" is essentially the same under both the existing chapter and the chapter rewrite, except that the chapter rewrite excludes

the various types of laboratories ("hospital laboratory," "independent laboratory," "private laboratory," and "other laboratory") that are individually defined in the existing chapter at section 003.01. The chapter rewrites also eliminates definitions for "clinical laboratory technologist" and "clinical laboratory technician." The chapter rewrite specifically provides that a pathologist be licensed in accordance with Board of Medicine rule on the licensure to practice medicine and surgery and osteopathic medicine and surgery.

C. Regulatory Provisions

The chapter rewrite (section 100) removes some specific information that the existing rule (section 011) requires be included on the registration form (name of laboratory owner; education, experience and training of the person(s) actually performing the laboratory examinations and services; and annual volume of laboratory work performed).

The exclusions from rule compliance under the chapter rewrite also exhibit changes. Removed from these exclusions by the chapter rewrite is physicians performing tests on their own patients found under existing chapter. Existing chapter, section 012.01. Added to the list of agencies that can certify a laboratory, and thus exempting the laboratory from compliance with the chapter rewrite (except for registration and proficiency testing requirements), are the Centers for Medicare and Medicaid Services (CMS), Clinical Laboratory Improvement Amendment certification program and agencies approved by CMS as accreditation organizations. Chapter rewrite, sections 110.01.a and c. Not carried forward into the chapter rewrite as other certifying agencies are the Centers for Disease Control and Medicare Title XVIII standards. Existing chapter, section 012.02.a and c.

Each laboratory must maintain suitable record of each test result for at lest two years under the chapter rewrite, section 130.02.b, compared to three years under the existing chapter, section 014.02.b.. Under the chapter rewrite, the laboratory director must furnish proficiency testing results to the Laboratory Improvement Section, rather than to the Department's Director. Compare chapter rewrite, section 200.02, with existing chapter, section 022.02.

The chapter rewrite does not provide that laboratories may be approved for performance of tests in one or more of the categories of urinalysis, hematology, clinical chemistry, serology, immunohematology, histology and cytology, and microbiology. Compare chapter rewrite, section 220, with existing chapter, section 024. The chapter rewrite also does not include failure to utilize appropriate personnel with qualifications for the test being performed as grounds for denial of approval. Compare chapter rewrite, section 230, with existing chapter, section 025.05.

Under the chapter rewrite, it is the failure to pass two consecutive or two out of three proficiency testing "events" that constitute an unacceptable result. Chapter rewrite, section 240.01. The existing chapter uses the term, "unknown proficiency testing samples." Existing chapter, section 026.01. The chapter rewrite requires the Chief of the Bureau of Laboratories to make determinations on renewal of approval of tests or disapproved tests, section 250, rather

than the Department's Director, existing rule, section 027.

Finally, the chapter rewrite does not require that the list of approved laboratories include the name of the owner of the laboratory, that annual list of approved laboratories be sent to specified locations, or that the Department keep owners and supervisors of approved laboratories informed regarding any discrepancies that might lead to revocation of approval. Compare chapter rewrite, section 370, with existing chapter, section 029.

SUMMARY

The Department's new chapter to be authorized under section 56-1003, Idaho Code.

cc: Department of Health and Welfare
Tamara Prisock & David Eisentrager

IDAPA 16 - DEPARTMENT OF HEALTH AND WELFARE

16.02.06 - RULES GOVERNING QUALITY ASSURANCE FOR IDAHO CLINICAL LABORATORIES

DOCKET NO. 16-0206-1001 (CHAPTER REPEAL)

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 56-1003, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than August 18, 2010.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

Since the last major update of these rules in 1987, there have been significant technological changes that render much of the language in this chapter obsolete and outdated. Further, the rules do not reflect more recent changes in federal regulations, in the organizational structure of the Department's Bureau of Laboratories, and in the Bureau's current practices.

As a result, this chapter of rules is being repealed under this docket and rewritten in this Bulletin under companion Docket No. 16-0206-1002.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

FISCAL IMPACT: The following is a specific description, if applicable, of any fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year:

There is no anticipated fiscal impact to state general funds related to this rulemaking. The functions administered under these rules are 100% federally-funded under the CLIA (Clinical Laboratory Improvement Amendments of 1988) grant.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the May 5, 2010, Idaho Administrative Bulletin, Volume 10-5, page 25.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact David Eisentrager at (208) 334-2235 x245.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before August 25, 2010.

DATED this 9th day of July, 2010.

Tamara Prisock
DHW - Administrative Procedures Section
450 W. State Street - 10th Floor
P.O. Box 83720
Boise, ID 83720-0036
phone: (208) 334-5564; fax: (208) 334-6558
e-mail: dhwrules@dhw.idaho.gov

IDAPA 16 - DEPARTMENT OF HEALTH AND WELFARE

16.02.06 - QUALITY ASSURANCE FOR IDAHO CLINICAL LABORATORIES

DOCKET NO. 16-0206-1002 (CHAPTER REWRITE)

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 56-1003, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than August 18, 2010.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

Since the last major update of these rules in 1987, there have been significant technological changes that render much of the language in this chapter obsolete and outdated. Further, the rules do not reflect more recent changes in federal regulations, in the organizational structure of the Department's Bureau of Laboratories, and in the Bureau's current practices.

As a result, this chapter of rules is being completely rewritten in order to simplify, clarify, update, and modernize the content, and to revise the chapter to reflect current practice of the Department's Bureau of Laboratories. The current chapter is being repealed in this Bulletin under companion Docket No. 16-0206-1001.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

FISCAL IMPACT: The following is a specific description, if applicable, of any fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year:

There is no anticipated fiscal impact to state general funds related to this rulemaking. The functions administered under these rules are 100% federally-funded under the CLIA (Clinical Laboratory Improvement Amendments of 1988) grant.

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DATED this 9th day of July, 2010.

Tamara Prisock, DHW - Administrative Procedures Section
450 W. State Street - 10th Floor
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phone: (208) 334-5564; fax: (208) 334-6558
e-mail: dhwrules@dhw.idaho.gov

THE FOLLOWING IS THE PROPOSED TEXT FOR DOCKET NO. 16-0206-1002

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. ( )

001. TITLE AND SCOPE.

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

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. ( )

002. WRITTEN INTERPRETATIONS.
There are no written interpretations of these rules. ( )

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

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

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. ( )

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. ( )

03. Street Address. ( )

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

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

04. Telephone. ( )

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

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

05. Internet Website. ( )

a. The Department's internet website is found at http://www.healthandwelfare.idaho.gov. ( )

b. The webpage for the Department's Idaho Bureau of Laboratories (IBL) is found at http://www.statelab.idaho.gov. ( )

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." ( )

02. Public Records. The Department will comply with Sections 9-337 through 9-350, 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. ( )

007. -- 009. (RESERVED).

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

01. Board. The Idaho Board of Health and Welfare. ( )

02. Department. The Idaho Department of Health and Welfare. ( )

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

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. ( )

05. Laboratory Director. The person under whose supervision the laboratory is operating. ( )

06. Pathologist. A physician who is: ( )

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 ( )

b. Board certified by the American Board of Anatomic and Clinical Pathology. ( )

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. ( )

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. ( )

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. ( )

011. -- 099. (RESERVED).

100. REGISTRATION REQUIREMENTS FOR CLINICAL LABORATORIES.

01. Registration Timeframes. ( )

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. ( )

b. Existing laboratories must submit a completed laboratory registration form every two (2) years and indicate any changes in laboratory operations. ( )

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: ( )

a. Name and location of the laboratory; ( )

b. Name of the laboratory director; ( )

c. Types of laboratory tests performed in the laboratory; and ( )

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

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: ( )

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

b. College of American Pathologists; ( )

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; ( )

d. Laboratories located in hospitals approved by the Joint Commission (http://www.jointcommission.org/AccreditationPrograms/LaboratoryServices/lab_facts.htm); and ( )

e. Other certification programs approved by the Department. ( )

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

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

b. Prosthetic dental laboratories; and ( )

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

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. ( )

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. ( )

02. Records. ( )

a. Laboratory records must identify the person responsible for performing the procedure. ( )

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. ( )

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

131. -- 149. (RESERVED).

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

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

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

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

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. ( )

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. ( )

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. ( )

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. ( )

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

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

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

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

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

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. ( )

221. -- 229. (RESERVED).

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

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

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

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. ( )

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

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. ( )

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. ( )

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. ( )

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

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

241. -- 249. (RESERVED).

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

01. Renewal Granted. ( )

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. ( )

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

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

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. ( )

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. ( )

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. ( )

301. -- 999. (RESERVED).