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## 16.02.13 - State of Idaho Drinking Water Laboratory Certification Program

**IDAPA 16,**
**TITLE 02**
**CHAPTER 13**

# 16.02.13 - STATE OF IDAHO DRINKING WATER LABORATORY CERTIFICATION PROGRAM

## 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. Under Section 56-1007, Idaho Code, the Department is authorized to charge and collect fees for services rendered by the Department. (4-7-11)

## 001. TITLE AND SCOPE.

**01. Title**. The title of these rules is IDAPA 16.02.13, "State of Idaho Drinking Water Laboratory Certification Program." (4-7-11)

**02. Scope**. These rules establish a process for certification and standards of operation for laboratories certified by the State of Idaho to test drinking water. (4-7-11)

## 002. WRITTEN INTERPRETATIONS.

The Department may have written statements in the form of guidance and policy documents that pertain to the interpretation of the rules in this chapter. Such written statements may be inspected and copies obtained at the Idaho Bureau of Laboratories, 2220 Old Penitentiary Rd. Boise, ID 83712. (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.

**01. Selected Sections from the Code of Federal Regulations, Title 40, Part 141 -- National Primary Drinking Water Regulations, July 1, 2010 Edition**. 40 CFR 141 and 143 may be accessed in electronic format. The following sections from the Code of Federal Regulations are hereby incorporated by reference: (4-7-11)

**a.** 40 CFR 141.6 (h), effective dates; (4-7-11)

**b.** 40 CFR 141.27, alternate testing program; (4-7-11)

**c.** 40 CFR 141.21(f)(3), total coliform rule; (4-7-11)

**d.** 40 CFR 141.23, inorganic methods; (4-7-11)

**e.** 40 CFR 141.24, organic methods; (4-7-11)

**f.** 40 CFR 141.25, methods for radioactivity; (4-7-11)

**g.** 40 CFR 141.131, disinfection by-products; (4-7-11)

**h.** 40 CFR 141.74(a), surface water treatment rule; (4-7-11)

**i.** 40 CFR 141.89, lead and copper; (4-7-11)

**j.** 40 CFR 141.402(c)(2), ground water; (4-7-11)

**k.** 40 CFR 141.704, long-term surface water treatment rule 2; (4-7-11)

**l.** 40 CFR 141.803, aircraft drinking water rules; (4-7-11)

**m.** 40 CFR 141, Appendix A to Subpart C, expedited method approval; and (4-7-11)

**n.** 40 CFR 143.4, secondary contaminants. (4-7-11)

**02. Manual for the Certification of Laboratories Analyzing Drinking Water EPA 815-R-05-004, Fifth Edition, January 2005**. The Manual for the Certification of Laboratories Analyzing Drinking Water EPA 815-R-05-004, Fifth Edition, January 2005, including Supplement 1 EPA 815-F-08-006, June 2008, is hereby incorporated by reference. It may be accessed in electronic format. (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. (4-7-11)

**b.** The webpage for the Department's Idaho Bureau of Laboratories (IBL). (4-7-11)

## 006. CONFIDENTIALITY OF RECORDS AND PUBLIC RECORD 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 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. (4-7-11)

## 007. -- 009. (RESERVED).

## 010. DEFINITIONS.

**01. Analyst**. A person responsible for testing, quality control, and reporting of analytical results. (4-7-11)

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

**03. Certification Authority for the State of Idaho (CA)**. The CA has signature authority for all

certification decisions as required for primacy in 40 CFR 142.10 (b)(3)(i). The Bureau Chief of the Idaho Bureau of Laboratories is the certification authority for the State of Idaho. (4-7-11)

**04. Certification Officer (CO)**. The CO is the person responsible for on-site evaluations and providing technical support and guidance to a certified drinking water laboratory (CDWL). (4-7-11)

**05. Certified Drinking Water Laboratory (CDWL)**. A facility that examines drinking water for the purpose of identifying or measuring microbiological, chemical, radiological, or physical parameters, and is certified by the State of Idaho. (4-7-11)

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

**07. Department of Environmental Quality (DEQ)**. The state agency that has primacy and is primarily responsible for administrating and enforcing regulations related to environmental quality. (4-7-11)

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

**09. Discipline**. Areas of certification for the testing of drinking water, i.e., microbiology, radiochemistry, inorganic chemistry, and organic chemistry. (4-7-11)

**10. Drinking Water Coordinator (DWC)**. The drinking water coordinator is an Environmental Health Specialist at a public health district assigned to monitor public water systems. (4-7-11)

**11. Idaho Bureau of Laboratories (IBL)**. The IBL is a bureau in the Division of Public Health in the Idaho Department of Health and Welfare. (4-7-11)

**12. LIMS**. Laboratory Information Management System. (4-7-11)

**13. Laboratory Supervisor**. A person who directs the day-to-day activities of a CDWL. (4-7-11)

**14. Maximum Contaminant Level (MCL)**. The maximum permissible level of a contaminant in water that is delivered to any user of a public water system. (4-7-11)

**15. On-Site Evaluation**. The physical, quality control, and data audit of a laboratory, including all aspects of operation related to the testing of drinking water samples. (4-7-11)

**16. Primacy**. The responsibility for ensuring that Safe Drinking Water Act (SDWA) laws are implemented and the authority to enforce a law and related regulations (40 CFR 142.2) applicable to public water systems within the state. (4-7-11)

**17. Proficiency Test (or Testing) (PT)**. Sample(s) provided to demonstrate that a laboratory can successfully analyze the sample(s) within the acceptance limits specified in the regulations. The qualitative or quantitative composition of the reference material is unknown to the laboratory at the time of the analysis. (4-7-11)

**18. Public Water System (PWS)**. A system for the provision to the public of water for human consumption through pipes or other constructed conveyances, if such system has at least fifteen (15) service connections, regardless of the number of water sources or configuration of the distribution system, or regularly serves an average of at least twenty-five (25) individuals daily at least sixty (60) days out of the year. (4-7-11)

**19. Quality Assurance (QA)**. An integrated system of management activities that involves planning, quality control, quality assessment, reporting, and quality improvement to ensure a product or service meets defined standards of quality with a stated level of confidence. (4-7-11)

**20. Quality Control (QC)**. The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of the users. QC also includes operational techniques and activities that are used to fulfill the requirement of quality. (4-7-11)

**21. Quality Assurance Plan (QA Plan)**. A comprehensive plan detailing the aspects of quality assurance required to adequately fulfill the needs of a program. This document is required before a laboratory can be certified or reciprocity is granted. (4-7-11)

**22. Reciprocity**. An extension of certification by the CA to an accredited or certified out-of-state laboratory based upon satisfactory review of documentation that demonstrates compliance with these rules. (4-7-11)

**23. Regulatory Agency**. The Idaho Department of Environment Quality (DEQ). (4-7-11)

**24. Regulatory Authority (RA)**. The assigned drinking water Analyst III at a regional DEQ office. (4-7-11)

**25. Standard Operating Procedure (SOP)**. A written document that describes the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and that is officially approved as the method for performing a routine or repetitive test. (4-7-11)

**26. Standard Methods (SM)**. SM refers to a standard method of water testing published in the Standard Methods for the Examination of Water and Wastewater, as incorporated by reference under Section 004 of these rules. (4-7-11)

**27. Subcontracting**. The procedure whereby a laboratory certified by the State of Idaho may send samples to another laboratory that is certified or has been granted reciprocity by the State of Idaho for analysis. (4-7-11)

**011. -- 099. (RESERVED).**

## REQUIREMENTS FOR CERTIFICATION OF DRINKING WATER LABORATORIES (Sections 100-199)

### 100. APPLICATION FOR CERTIFICATION.

**01. Required Information on Application**. An application for first-time certification for microbiology, inorganic chemistry, organic chemistry, or radiochemistry must be submitted to the CA on a form provided by the IBL. The following information must be included: name, location, and contact information of the drinking water laboratory, name of the owner, listing of methods/analytes for which certification is requested, documentation of the education, experience, and training of the laboratory supervisor for each discipline for which certification is being requested. (4-7-11)

**02. Time Frame for Renewal of Application for Reciprocity**. Applications for renewal of reciprocity must be received by the IBL at least thirty (30) days before the current certificate expires. (4-7-11)

**03. Reapplication for Additional Analytes or to Change Methods**. An in-state laboratory seeking to change methods or to add analytes utilizing the same method for which the laboratory is currently certified must submit a written application requesting the change in certification and include a copy of the SOP with QC requirements specific to the method. (4-7-11)

**04. Reapplication for Certification**. A laboratory that has been downgraded to provisional or has been decertified for an analyte or method, or both, must provide written documentation to the CO of the corrective actions within the specified period. A laboratory that has been decertified in entirety must re-apply following the same procedure as a laboratory applying for first-time certification. (4-7-11)

**05. Reciprocity for Out-State-Laboratories**. Each out-of state laboratory seeking reciprocity with Idaho must submit the same information as an in-state drinking water laboratory applying for first-time certification. (4-7-11)

### 101. CERTIFICATION FEES.

**01. Annual Base Fee**. All CDWLs must pay an annual base fee of fifty dollars ($50) per discipline and twenty dollars ($20) per analyte per method for which certification is requested. Certification is valid for one (1) year from the date of issuance. (4-7-11)

**02. Non-Refundable Application Fee**. Each new laboratory that is seeking certification or reciprocity must include a non-refundable application fee of two hundred dollars ($200) per discipline with the application. (4-7-11)

**102. TYPES OF CERTIFICATION.**

**01. Certified**. A certified laboratory meets the regulatory performance criteria described in these rules. (4-7-11)

**02. Provisionally Certified**. A provisionally certified laboratory has deficiencies, but demonstrates the ability to consistently produce valid data within the acceptance limits in these rules. (4-7-11)

**03. Not Certified**. A laboratory with the status of "not certified" can not produce consistently valid data, or is not following method protocol, or both. Such laboratories cannot analyze compliance samples. (4-7-11)

**04. Interim Certification**. The CA may grant interim certification to a laboratory if the laboratory has appropriate instrumentation, is using approved methods, has adequately trained personnel to perform the analyses, and has satisfactorily analyzed PT samples for the contaminants involved. The CO will review the laboratory's quality control data before granting this type of certification and will conduct an on-site evaluation as soon as possible. (4-7-11)

**05. Reciprocity**. Reciprocity may be granted by the CA to out-of-state laboratories if such laboratories are certified or accredited by an approved regulatory agency and meet the regulatory performance criteria described in these rules. (4-7-11)

**103. SUBCONTRACTING.**

**01. List of Subcontractors**. Laboratories who subcontract work must maintain a list of subcontractors and documentation of the subcontracting laboratories' certification or reciprocity with the State of Idaho. (4-7-11)

**02. Identification Requirements for Subcontracting Laboratory**. The laboratory performing the subcontracted analysis must be identified by name and EPA identification number on the final report. (4-7-11)

**03. Availability of the Report from the Subcontracting Laboratory**. The report from the subcontracting laboratory must be available to the client upon request. (4-7-11)

**04. Availability of all Subcontracting Laboratory Records**. All subcontracting laboratory records must be available to the COs. (4-7-11)

**104. -- 109. (RESERVED).**

**110. ON-SITE EVALUATION.**

**01. On-Site Audits and Evaluations**. COs will perform audits of the premises and operations of new laboratories or laboratories requesting continuing certification for the purpose of determining if there is enough security to maintain the integrity of the samples and data. The frequency of the on-site evaluation is at the discretion of the CA or a minimum of every three (3) years. In addition, the CO will evaluate the: (4-7-11)

**a.** Physical set up of the laboratory; (4-7-11)

**b.** Quality assurance program; (4-7-11)

**c.** Personnel qualifications; (4-7-11)

**d.** Equipment considerations; and (4-7-11)

**e.** Adequacy of data handling. (4-7-11)

**02. Written Report of Findings from the On-Site Evaluation**. The CO will generate a written report of findings from the on-site evaluation. The report will detail areas requiring a written response and specify the length of time the laboratory has to respond. The length of time for the laboratory to respond will be proportional the number and severity of deviations. If the conditions observed during an on-site evaluation are such that an immediate down grade or decertification is warranted the laboratory will be notified by certified mail within thirty (30) days by the CA. (4-7-11)

**111. -- 119. (RESERVED).**

**120. PERSONNEL QUALIFICATIONS.**

**01. General Supervisor Qualifications**. (4-7-11)

**a.** A supervisor must be on-site frequently enough to satisfactorily perform the required duties outlined below. The CO must be notified if the supervisor is unable to be on-site for a period greater than three (3) consecutive weeks. (4-7-11)

**b.** Supervisors are responsible for ensuring that all laboratory personnel have demonstrated proficiency for assigned functions and that all data reported by the laboratory meet the required quality assurance criteria and regulatory requirements. (4-7-11)

**c.** If a formal complaint is received from the regulatory agency, then the CO will notify the responsible laboratory supervisor and request a report describing the incident, the probable cause, and the corrective action to be taken to ensure the situation is resolved. The incident report must be received by the CA within thirty (30) days of the laboratory being notified of the problem. The CO in conjunction with the CA will evaluate the response and if found to be acceptable, no further action will be required of the laboratory. If the response is incomplete, the CO will provide in writing the additional steps that must be completed for certification status to remain uninterrupted. (4-7-11)

**d.** No drinking water supervisor will be responsible for the supervision of more than two (2) certified drinking water laboratories unless specifically approved by the CA. (4-7-11)

**e.** If a microbiology supervisor is not available, a consultant having the same qualifications may be utilized. The laboratory must submit the academic qualifications and work experience of the potential consultant to the CA. In addition, the laboratory must define and submit a list of the specific functions the consultant will be performing along with a schedule of routine visits. If the information is found to be acceptable, the CA will notify the laboratory director or owner in writing. A record of all consultant visits and communications must be maintained and be available for review during the on-site evaluation. The record must include a brief description of on-site findings and include any telephone or electronic consultation. Each entry must be dated and signed by the consultant. (4-7-11)

**02. Supervisor Qualifications by Discipline**. (4-7-11)

**a.** The supervisor of a microbiology laboratory must have a bachelor's degree from an accredited college in microbiology, biology, or equivalent. Supervisors who have a degree in a subject other than microbiology must have had at least two (2) college-level microbiology courses in which environmental microbiology was part of the curriculum. In addition, the supervisor must have a minimum of two (2) weeks training at a federal agency, state agency, or academic institution in the microbiological analysis of drinking water or eighty (80) hours of on-the-job-training in water microbiology at a certified laboratory, or other comparable training acceptable to the CA. (4-7-11)

**b.** The supervisor of a chemistry laboratory must have at least a bachelor's degree from an accredited college with a major in chemistry or equivalent and at least one (1) year of experience in the analysis of drinking

water. In addition, the supervisor must have a working knowledge of quality assurance principles. (4-7-11)

**c.** The supervisor of a radiochemistry laboratory must have at least a bachelor's degree from an accredited college with a major in chemistry, or equivalent, and should have at least one (1) year of experience in the measurement of radioactive analytes in drinking water. In addition, the supervisor must have a working knowledge of QA and QC principles as applied to all radiochemical practices and procedures conducted in the laboratory. (4-7-11)

**03. Analyst or Equivalent Job Title**. (4-7-11)

**a.** An analyst performing microbiological testing must have a minimum of a high school education or equivalent, at least three (3) months of bench experience in environmental microbiological testing, and thirty (30) days on-the-job training in drinking water microbiology under the direction of an experienced analyst. If an analyst has a bachelor's degree in microbiology, or related field, the three- (3) month bench training may be shortened to thirty (30) hours at the discretion of the laboratory supervisor. Before analyzing compliance samples, the analyst must demonstrate competency by successfully completing a PT. (4-7-11)

**b.** Analysts in each of the chemical disciplines should have at least a bachelor's degree with a major in chemistry, or equivalent, and at least one (1) year of experience in the analysis of drinking water for the discipline in which they are working. If the analyst is responsible for the operation of analytical instrumentation, he or she must have completed specialized training offered by the manufacturer or another qualified training facility or have successfully served an apprenticeship under an experienced analyst. The duration of this apprenticeship should be proportional to the sophistication of the instrument. Data produced by analysts and instrument operators while in the process of obtaining the required training or experience are acceptable only when reviewed and validated by a fully qualified analyst or the laboratory supervisor. Documentation of training must be maintained for each analyst and available for evaluation by the CO. (4-7-11)

**04. Chemistry Technician**. Technicians in each of the chemical disciplines must have at least a high school diploma or equivalent, have completed a method-training program under an experience analyst, and have six (6) months bench experience in the analysis of drinking water. The method-training record for each analyst should be recorded in a training file and available for evaluation by the CO. (4-7-11)

**121. -- 129. (RESERVED).**

**130. REPORTING, NOTIFICATION, AND DISTRIBUTION OF LABORATORY RESULTS.**

**01. Submission of Test Results in Approved Format**. The drinking water supervisor in each of the disciplines of certification is responsible for submission of all test results performed on samples submitted by PWSs, including subcontracted samples, in a format approved by the DEQ Drinking Water Program. Reports must be submitted to the appropriate regulatory authority or drinking water coordinator in a timely manner not to exceed ten (10) business days after the completion of testing or upon receipt of results from subcontract laboratories. (4-7-11)

**02. Notification of High Contaminant Levels**. The chemistry supervisor or designee must notify the appropriate regulatory agency or drinking water coordinator by phone as soon as feasible of any nitrate and nitrite level exceeding the current MCL including subcontracted samples. Notification must also be made when any other regulated chemical or radiological contaminant exceeds four (4) times the MCL. (4-7-11)

**03. Notification of Positive Microbiological Results**. The microbiological supervisor or designee is responsible for an immediate telephone notification to the appropriate regulatory agency in the case of a positive result for a microbiological test. If the RA or DWC is not available, the results must be given to the person designated by the RA or DWC to take the information. (4-7-11)

**131. -- 139. (RESERVED).**

**140. LABORATORY QUALITY ASSURANCE.**

**01. The QA Plan**. Each laboratory certified or having reciprocity with the State of Idaho must have and adhere to a QA plan. Laboratories seeking certification will be required to submit such a plan for review as part

of the application process. (4-7-11)

**02. Required Items for the QA Plan**. The EPA Manual for the Certification of Laboratories Analyzing Drinking Water lists the items that must be included: (4-7-11)

**a.** Laboratory organization and responsibility; (4-7-11)

**b.** SOPs with dates of last revision; (4-7-11)

**c.** Laboratory sample receipt and handling procedure; (4-7-11)

**d.** Instrument calibration procedures; (4-7-11)

**e.** Analytical procedures; (4-7-11)

**f.** Data reduction, validation, reporting and verification; (4-7-11)

**g.** Type of quality control (QC) checks and frequency of use; (4-7-11)

**h.** List of schedules of internal and external system and data quality audits and inter laboratory comparisons; (4-7-11)

**i.** Preventive maintenance procedures and schedules; (4-7-11)

**j.** Corrective action contingencies; and (4-7-11)

**k.** Record-keeping procedures. (4-7-11)

**03. Chain-of-Custody Procedures**. Each laboratory must have a procedure in place in the event the submitter requires an evidence chain-of-custody. (4-7-11)

**04. Maintenance of Records**. (4-7-11)

**a.** Each laboratory must maintain a record keeping system that allows the history of the sample and associated data to be readily understood through documentation. This would include access to LIMS, both present and prior systems, all electronic data including backup, QC documents and all associated calculations, maintenance records including replacement history of instruments, submission forms, submission forms to subcontracting laboratories, final reports from subcontracting laboratories, and final reports generated by the certified laboratory. (4-7-11)

**b.** The laboratory must retain all records for a minimum of five (5) years from generation of the last entry in the records. (4-7-11)

**c.** A laboratory must notify public water system clients before disposing of records. (4-7-11)

**d.** Laboratories must be aware of and adhere to specific record retention as required for specific analytes or disciplines. (4-7-11)

**05. Proficiency Testing (PT)**. Proficiency test samples must be successfully analyzed annually per analyte per method for which the laboratory is certified. All PT samples must be obtained from an approved supplier, and must be analyzed in the same manner as routine samples by the primary analyst assigned to the specific analysis. If testing is rotated among a number of analysts the supervisor will be responsible for determining who completes the PT. Records must include the name of the analyst who completed the testing. The results of the PT must be sent directly from the supplier to the CO. The methods listed on the laboratory's certificate must be the methods used for PT samples. (4-7-11)

**141. -- 149. (RESERVED).**

**150. EVALUATION.**

**01. Documentation of Corrective Action**. If a CDWL is found to be noncompliant, it will be notified in writing by the CA of the number and seriousness of the deviations. The noncompliant laboratory will be required to submit documentation of correction to the CA or his designee within the time limit specified by the CA. (4-7-11)

**02. Adequacy of Corrective Action**. Upon receipt of documentation of corrective action, the CO in conjunction with the CA will review the response to determine the adequacy of the corrective action taken. The laboratory will be eligible for certification if the response is found to be complete. If the response is incomplete or inadequate, the laboratory will be notified in writing of the additional changes required along with a specified time for completion. (4-7-11)

**03. Unacceptable PT Result**. In the event of an unacceptable PT, the laboratory must submit an incident report to the CO that includes a description of the incident and corrective action taken. A second PT must be completed within sixty (60) days of the laboratory being notified of the failure. If the second PT is successfully analyzed no further action will be taken. If a second PT is not analyzed or if the second PT is also unacceptable, the laboratory will be downgraded in accordance with Section 210 of these rules. (4-7-11)

**04. Continued Certification of Other Tests**. A CDWL that has an unacceptable PT result per analyte per method may remain certified for performance of all tests for which satisfactory performance has been demonstrated through the annual successful PT testing. (4-7-11)

**151. -- 199. (RESERVED).**

## REQUIREMENTS FOR DRINKING WATER LABORATORIES TO MAINTAIN, DOWNGRADE, OR REVOKE CERTIFICATION
## (Sections 200-299)

**200. MAINTENANCE OF CERTIFICATION.**
In order to maintain certification, drinking water laboratories must be able to demonstrate they continue to meet all of the following requirements. (4-7-11)

**01. Successful Completion of PT Samples**. Each year, each laboratory must successfully complete a PT per analyte per method for which the laboratory is seeking to maintain certification. (4-7-11)

**02. Use of Specified Methods**. Each laboratory must be able to demonstrate it is using the methods specified in the drinking water regulations. (4-7-11)

**03. Maintain Required Standard of Quality**. The CO must be satisfied the laboratory is maintaining the required standard of quality for certification. This is based on the results of the PT testing, on-site evaluations, and any feedback from regulatory agencies. (4-7-11)

**04. Notification of Major Changes**. The laboratory must notify the CA in writing within thirty (30) days of major changes that could affect the accuracy and precision of testing. A major change includes but is not limited to the loss of a laboratory supervisor, equipment failure or breakdown, or change in location or ownership. (4-7-11)

**201. -- 209. (RESERVED).**

**210. CRITERIA AND PROCEDURES FOR DOWNGRADING OR REVOKING CERTIFICATION STATUS.**

**01. Reasons a Laboratory May be Downgraded to Provisionally Certified Status**. A laboratory may be downgraded to provisionally certified status for an analyte or method for any of the following reasons: (4-7-11)

**a.** Failure to analyze a PT annually within acceptance limits specified in the regulations as demonstrated by a failure of a second PT; (4-7-11)

**b.** Failure to submit an incident report after failing a PT or to analyze a second PT; (4-7-11)

**c.** Failure to notify the CA within thirty (30) days of major changes; (4-7-11)

**d.** Failure to maintain the required standard of quality based upon observations made by the CO during an on-site evaluation; or (4-7-11)

**e.** Failure to report compliance data to the regulatory agency in a timely manner. (4-7-11)

**02. Procedure for Downgrading to Provisionally Certified Status**. (4-7-11)

**a.** The CA will notify the laboratory director or owner by certified mail of the intent to downgrade the laboratory to provisional certification per analyte per method within thirty (30) days of learning of any of the items listed under Subsection 210.01 of this rule. The laboratory will be given be given thirty (30) days from the date of receipt to develop a written corrective action plan and submit it with all supporting documentation to the CA. This information will be reviewed and evaluated for adequacy. The laboratory will be notified by certified mail if the response is acceptable or if additional corrective action must be taken. The CO will document that the corrective action plan has been implemented during the next on-site evaluation. (4-7-11)

**b.** If a laboratory fails a second PT, the CA will downgrade the laboratory to provisionally certified status for that analyte or method and notify the laboratory by certified mail. (4-7-11)

**c.** A provisionally certified laboratory has three (3) months to correct the problem in a manner that is acceptable to the CA. If the downgrading of certification is based on the results of PT testing, the reason for the error must be identified and corrected. A third PT must be successfully analyzed. A provisionally certified laboratory may continue to analyze samples for compliance purposes, but must notify its clients of the downgraded status of certification and provide that information in writing on all reports. (4-7-11)

**d.** An out-of-state laboratory that has reciprocity with Idaho and is downgraded to provisional status by either the accreditation agency or certification authority of the home state must notify the CA of the change within thirty (30) days of the downgrade. (4-7-11)

**03. Criteria for Revoking Certification Status**. (4-7-11)

**a.** A laboratory must be downgraded from certified, provisionally certified, or interim certified status to "not certified" for a particular analyte or method for the following reasons: (4-7-11)

i. Reporting PT data from another laboratory as its own; (4-7-11)

ii. Falsification of data or other deceptive practices; (4-7-11)

iii. Failure to use the analytical methodology specified in the regulations; and (4-7-11)

iv. For provisionally certified laboratories, failure to correct the identified deficiencies that lead to the downgrading of certification status. (4-7-11)

**b.** Reciprocity of out-of-state laboratories who do not notify the CA of any changes in the status of certification or accreditation will automatically be revoked. (4-7-11)

**04. Procedure for Revocation**. (4-7-11)

**a.** The CA will notify the laboratory in writing of the intent to revoke certification. The laboratory will have thirty (30) days from the time of the notification to provide a written response. (4-7-11)

**b.** If the laboratory responds with an acceptable written corrective action plan, including documentation of implementation, the revocation will be suspended. (4-7-11)

**c.** If the response is unacceptable, incomplete, or both, certification will be revoked. If the laboratory does not respond, certification will be revoked. The laboratory will be notified in writing of the revocation. (4-7-11)

**05. Upgrading or Reinstatement of Certification**. A laboratory seeking an upgrade of certification must request this change in writing and provide documentation that the deficiencies which led to the provisional certification have been corrected. In addition, an on-site evaluation and successful completion of an additional PT may be required. A laboratory seeking certification after a revocation must follow the same procedure as a new laboratory seeking initial certification. (4-7-11)

**211. -- 999. (RESERVED).**

# Subject Index