

CHAPTER 41

**REGULATION FOR THE CERTIFICATION OF LABORATORIES
ANALYZING DRINKING WATER**

**Part I
General Provisions**

1VAC30-41-10. Purpose.

A. This chapter establishes the requirements for certification of drinking water laboratories.

B. The federal Safe Drinking Water Act (SDWA) mandates the establishment of a national drinking water program to protect public health. The U.S. Environmental Protection Agency (EPA) at 40 CFR 141.28 requires that laboratories be certified to analyze samples of drinking water for compliance purposes. EPA at 40 CFR 142.10(b)(3)(i) requires states to establish and maintain programs for the certification of drinking water laboratories.

C. The Virginia Department of Health, Office of Drinking Water (VDH-ODW) maintains primary enforcement responsibility (primacy) under the SDWA and the federal SDWA regulations for the Commonwealth of Virginia. The VDH-ODW at 12VAC5-590-340 requires that all analyses done to demonstrate compliance with primary and secondary maximum contaminant levels or action levels be performed by the Division of Consolidated Laboratory Services of the Department of General Services (DCLS) or by laboratories certified by DCLS. VDH-ODW at 12VAC5-590-440 further requires that laboratories seeking certification to perform drinking water analyses shall comply with this chapter.

1VAC30-41-20. Applicability.

A. This chapter applies to the following:

1. Owners of drinking water laboratories in Virginia.
2. Owners of drinking water laboratories located outside Virginia who seek reciprocal certification under 1VAC30-41-90.

B. Covered contaminants.

1. This chapter covers the contaminants regulated in 40 CFR Parts 141 and 143 as specified in 12VAC5-590, Waterworks Regulations, of the Virginia Department of Health.
2. Laboratory testing for alkalinity, calcium, chlorite, conductivity, disinfectant residual, orthophosphate, pH, silica, temperature, and turbidity for compliance purposes may be performed by laboratories or persons not certified under this chapter but acceptable to VDH-ODW.

1VAC30-41-30. Alternative certification for drinking water laboratories.

Drinking water laboratories may become certified by meeting the requirements for accreditation set out in 1VAC30-46.

1VAC30-41-40. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Analyst" means a chemist, microbiologist, physicist, or technician who actually performs a test. The analyst may carry out the complete test or participate jointly with other analysts.

"Certification officer" means a DCLS employee who has the responsibility for evaluating drinking water laboratories for certification.

"Contaminant" means any objectionable or hazardous physical, chemical, biological, or radiological substance or matter in water. Contaminants are the analytes for which drinking water laboratories test in the drinking water samples they analyze.

"Corrective action" means the action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

"DCLS" means the Division of Consolidated Laboratory Services of the Department of General Services.

"Drinking water laboratory" or "laboratory" means a laboratory that performs analyses to demonstrate compliance with primary or secondary maximum contaminant levels or action levels or any combination of these specified in 12VAC5-590.

"EPA" means the United States Environmental Protection Agency.

"Findings" means factual, objective statements that provide evidence of deficiencies in meeting the requirements of this chapter.

"Laboratory director" or "laboratory supervisor" means the person who directs the operation of the drinking water laboratory on a day-to-day basis.

"Manual" means the EPA Office of Water, Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, Fifth Edition, EPA 815-R-05-004 (January 2005).

"Manual Supplement" means the EPA Office of Water, Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, EPA 815-F-08-006 (June 2008).

"Maximum contaminant level" or "MCL" means the maximum permissible level of a contaminant in pure water that is delivered to any user of a waterworks. MCLs are set as close to

the MCLGs as feasible using the best available treatment technology. Maximum contaminant levels may be either "primary" (PMCL), meaning based on health considerations, or "secondary" (SMCL), meaning based on aesthetic considerations.

"Maximum contaminant level goal" or "MCLG" means the level of a contaminant in drinking water below which there is no known or expected risk to health. MCLGs allow for a margin of safety.

"National Environmental Laboratory Accreditation Program" or "NELAP" means the national program to establish and implement a program for the accreditation of environmental laboratories. NELAP relies on consensus standards representing the best professional practices in the industry to establish the requirements for this program, which is then implemented by state agencies recognized by the NELAC Institute (TNI) as accreditation bodies.

"Owner" means any person who owns, operates, leases, or controls a drinking water laboratory.

"Persistent" means to continue an activity without change in spite of opposition or warning.

"Private laboratory" means a laboratory that is, or is part of, a commercial entity.

"Proficiency testing sample" or "PT sample" means a sample, the composition of which is unknown to both the analyst and the laboratory. The PT sample tests whether the analyst or laboratory or both can produce analytical results within specified acceptance criteria.

"Public laboratory" means a laboratory that is, or is part of, a local, state, or U.S. governmental agency.

"Pure water" means water fit for human consumption and domestic use that is sanitary and normally free of minerals, organic substances, and toxic agents in excess of reasonable amounts for domestic usage in the area served and normally adequate in quantity and quality for the minimum health requirements of the persons served (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia).

"Quality assurance" means an integrated system of management activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

"Quality assurance plan" or "QA plan" means a comprehensive plan detailing the aspects of quality assurance needed to adequately fulfill the data needs of a program.

"Quality control" means:

1. 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.
2. The operational techniques and activities that are used to fulfill requirements for quality.

"SDWA" means the Safe Drinking Water Act (42 USC § 300f et seq.).

"VDH-ODW" means the Virginia Department of Health - Office of Drinking Water.

1VAC30-41-50. Incorporation by reference - EPA guidance documents.

A. The following EPA guidance documents are incorporated by reference into this chapter:

1. Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, Fifth Edition, EPA 815-R-05-004 (January 2005).
2. Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, EPA 815-F-08-006 (June 2008).

B. The federal regulatory requirements incorporated by reference into 1VAC30-41-55 shall govern if a conflict is found between the requirements of the Manual or the Manual Supplement and the requirements incorporated by reference into 1VAC30-41-55.

1VAC30-41-55. Incorporation by reference - Code of Federal Regulations.

A. The sampling, analytical methodology, and laboratory certification requirements of 40 CFR 141 and 143 in effect as of July 1, 2013, are incorporated by reference into this chapter.

B. The specific sampling, analytical methodology, and laboratory certification requirements incorporated by reference are listed as follows by category for information purposes:

1. Inorganic chemistry: 40 CFR 141.23, 40 CFR 141.89, and 40 CFR 141.131.
2. Organic chemistry: 40 CFR 141.24 and 40 CFR 141.131.
3. Microbiology: 40 CFR 141.21, 40 CFR 141.74, 40 CFR 141.174, 40 CFR 141.402(c)(2), 40 CFR 141.704, and 40 CFR 141.705. 40 CFR 136.3(a) for E. coli requirements under 40 CFR 141.704.
4. Radiochemistry: 40 CFR 141.25.
5. Alternative testing methods: 40 CFR Part 141, Subpart C, Appendix A.
6. Test methods specified for secondary maximum contaminant levels: 40 CFR 143.4.

C. The exceptions to the requirements for laboratory certification in 40 CFR 141.28, 40 CFR 141.74(a), 40 CFR 141.89(a)(1), 40 CFR 141.131(b)(3), and 40 CFR 141.131(c)(3) are incorporated by reference into this chapter.

Part II
Certification of Laboratories - General Requirements

1VAC30-41-60. Categories of certification.

A. Laboratories may apply to be certified for inorganic chemistry, organic chemistry,

microbiology, radiochemistry, or any combination of these four categories of certification.

B. Within each category, laboratories may be certified for specific contaminants or contaminant groups and for one or more methods used to determine the levels of these contaminants.

1VAC30-41-70. Initial certification application.

A. Application for initial certification. Drinking water laboratories applying under this chapter shall submit a completed Application for Certification, obtained by contacting the DCLS Laboratory Certification Office. A complete application contains:

1. Specific laboratory information, including name of organization, name of laboratory director, and contact information.
2. Identification of public water systems served by the laboratory.
3. Identification of the drinking water certification contaminants or contaminant groups and related methods for which the laboratory requests certification.
4. A quality assurance plan that meets the requirements of (i) Chapter III, Section 11 of the Manual and (ii) the Manual Supplement to Chapter III, Section 2 as required by 1VAC30-41-120.
5. A satisfactory report of at least one proficiency test performed within the last 12 months for each method and contaminant for which the laboratory seeks certification.
6. Laboratory personnel list.
7. Requested laboratory data, including at a minimum:
 - a. For microbiology applications:
 - (1) Equipment and supply list.
 - (2) Sampling information and test results for at least 20 analyses for each method and contaminant for which the laboratory seeks certification.
 - b. For chemistry applications:
 - (1) Instrumentation and equipment list.
 - (2) Method detection limit (MDL) documentation for each requested method and contaminant for which the laboratory seeks certification.
 - (3) Initial demonstration of capability (IDC) documentation for each requested method and contaminant for which the laboratory seeks certification.
 - c. For radiochemistry applications:

(1) Instrumentation and equipment list.

(2) Minimum detectable activity (MDA) documentation for each requested method and contaminant for which the laboratory seeks certification.

(3) Initial demonstration of capability (IDC) documentation for each requested method and contaminant for which the laboratory seeks certification.

8. Payment of the fee required by 1VAC30-41-270.

B. DCLS review of application submittal.

1. DCLS shall administratively review the application submittal and respond to the applicant laboratory within 60 calendar days.

2. If DCLS finds that the application submittal is complete, a certification officer shall arrange a mutually agreeable time and date with the laboratory for an onsite assessment.

3. If DCLS finds that the application submittal is incomplete, a certification officer shall request the applicant laboratory to submit the additional information or documentation required within 90 days.

4. If the laboratory has not submitted the required additional information within 90 days of the DCLS request for information, DCLS may return the incomplete application and inform the laboratory that the application cannot be processed. The laboratory may then submit a new application.

1VAC30-41-80. Certification requirements.

To become certified, a laboratory shall meet or successfully complete the following:

1. Requirements for a quality assurance plan in 1VAC30-41-120.

2. Analysis of a proficiency testing sample for each contaminant and each method for which certification is sought. Proficiency testing requirements are set out in 1VAC30-41-130.

3. Specific requirements for chemistry, microbiology, or radiochemistry that are pertinent to the specific laboratory's application for certification. These requirements are set out in Part III (1VAC30-41-300 et seq.) through Part V (1VAC30-41-500) of this chapter.

4. Onsite assessment by DCLS certification officers at least once every three years. Onsite assessment requirements are set out in 1VAC30-41-150.

5. The laboratory ethics and fraud detection and deterrence requirements set out in 1VAC30-41-140.

6. Payment of the fee required by 1VAC30-41-270.

1VAC30-41-90. Reciprocity.

A. DCLS may grant reciprocal certification to a drinking water laboratory located outside Virginia, provided the laboratory demonstrates the need to serve customers in Virginia and is certified by EPA or another state under equivalent certification criteria.

B. To be considered for certification, the applicant laboratory shall send DCLS the following:

1. A copy of the certificate and scope of certification issued by the laboratory's primary certifying or accrediting authority.
2. A list of the methods and the contaminants tested under each method for which the laboratory is requesting certification.
3. The most recent proficiency testing report for each method and contaminant combination listed by the laboratory under subdivision 2 of this subsection.
4. The fee required under 1VAC30-41-270.
5. Confirmation that the laboratory's proficiency test provider includes DCLS as a certifying authority to which the laboratory's proficiency test results will be reported.

C. Out-of-state laboratories holding National Environmental Laboratory Accreditation Program (NELAP) accreditation for drinking water that seek reciprocal accreditation for drinking water in Virginia shall apply for that accreditation under 1VAC30-46.

1VAC30-41-100. Renewal of certification.

DCLS shall renew the certification for a drinking water laboratory if the laboratory maintains its certified status as required by 1VAC30-41-180, and pays the annual fee as required by 1VAC30-41-270.

1VAC30-41-110. Modification of certification.

A. To request the addition of contaminants or methods to its certification, the drinking water laboratory shall submit the following to DCLS:

1. A completed DCLS drinking water certification application form.
2. An acceptable proficiency testing report for each requested method and contaminant, performed within the last 12 months.
3. The standard operating procedures for the requested methods.
4. The current quality assurance plan, if requested.
5. For chemistry:

a. Method detection limit (MDL) documentation for each requested method and contaminant for which the laboratory seeks certification.

b. Initial demonstration of capability (IDC) documentation for each requested method and contaminant for which the laboratory seeks certification.

6. For microbiology, sampling information and test results for at least 20 analyses by the requested method and contaminant combination.

7. Applicable fees as required by 1VAC30-41-270.

B. To drop a contaminant or a method from the laboratory's certification, the laboratory shall submit a request in writing to the DCLS Laboratory Certification Office.

1VAC30-41-120. Quality assurance plan.

A drinking water laboratory shall develop and maintain a quality assurance plan that meets the requirements of (i) Chapter III, Section 11 of the Manual and (ii) the Manual Supplement to Chapter III, Section 2.

1VAC30-41-130. Proficiency testing.

A. A drinking water laboratory shall meet the following requirements pertaining to proficiency testing (PT):

1. The requirements of this section.

2. The requirements of Chapter III, Section 13.1 of the Manual.

3. The specific requirements of the Manual for chemistry in Chapter IV, Section 7.2.1; for microbiology in Chapter V, Section 7.2; and for radiochemistry in Chapter VI, Section 7.4 that are pertinent to the laboratory.

4. Proficiency testing requirements incorporated by reference in 1VAC30-41-55.

B. A drinking water laboratory shall successfully participate in at least one water supply (WS) PT study per calendar year for each contaminant and by each method for which the laboratory seeks or wants to maintain certification.

C. Drinking water laboratories shall obtain WS PT studies from PT providers approved by the American Association for Laboratory Accreditation utilizing the National Standards for Water Proficiency Testing Studies.

D. Drinking water laboratories shall instruct the PT providers to send the results of the WS PT studies to the DCLS Laboratory Certification Office.

E. WS PT study results.

1. DCLS shall certify or maintain certification for a drinking water laboratory for which WS PT study results are reported by the proficiency test provider as "acceptable."

2. A drinking water laboratory for which some or all WS PT study results are reported as "not acceptable" shall follow the procedure in subsection F of this section.

F. Procedure and requirements for "not acceptable" PT study results.

1. When a laboratory receives a PT study result of "not acceptable," the laboratory shall perform and document corrective action. The corrective action documentation shall be submitted to DCLS within 30 days of receiving the "not acceptable" PT study result.

2. Upon completion of the corrective action, the laboratory shall perform another PT study for each contaminant that had a "not acceptable" initial PT study result.

3. If the result of the laboratory's makeup PT study is "acceptable," DCLS shall not downgrade the laboratory.

4. If the laboratory fails the makeup PT study, DCLS shall downgrade the laboratory to provisionally certified status for the contaminant or contaminants for which the PT study was "not acceptable."

5. When DCLS becomes aware of a failure to comply with PT study requirements, DCLS shall notify the laboratory of its downgraded status within 14 days of the downgrade. DCLS shall send the notification by certified mail or an equivalent mailing service.

6. The laboratory shall correct the problems that caused the downgrade and satisfactorily analyze another PT study within three months. A laboratory may not be provisionally certified for more than three months.

7. If the result of the second makeup PT study is "acceptable," the laboratory can request DCLS in writing to restore its certified status.

8. If the result of the second makeup PT is "not acceptable," DCLS shall revoke certification for the contaminant or contaminants for which the PT study was unsuccessful.

9. DCLS shall follow the provisions of 1VAC30-41-240 in revoking the laboratory's certification.

1VAC30-41-140. Laboratory ethics and fraud detection and deterrence.

Drinking water laboratories shall meet the requirements of the Manual Supplement to Chapter III of the Manual concerning laboratory ethics and fraud detection and deterrence.

1VAC30-41-150. Onsite laboratory assessment.

A. Frequency of onsite laboratory assessments.

1. DCLS shall assess a drinking water laboratory when the laboratory owner initially applies for certification and at least once every three years after initial certification is granted.

2. DCLS may perform an onsite assessment if major changes in personnel or equipment occur at the laboratory or if the location of the laboratory changes.
3. DCLS may perform interim onsite assessments to confirm that a laboratory has carried out a corrective action plan.
4. DCLS may perform unannounced onsite assessments.

B. Action prior to a scheduled onsite assessment.

1. DCLS shall arrange a mutually agreeable date and time for the onsite assessment with the drinking water laboratory's management.
2. Prior to the onsite audit, DCLS shall request and the laboratory shall provide current records and information that are necessary to evaluate the laboratory. These records and information may include the following:
 - a. Quality manual.
 - b. Personnel list.
 - c. Instrument list or equipment list or both.
 - d. Standard operating procedure (SOP) for each method to be evaluated.
 - e. A data package specified by the certification officer.
 - f. For chemistry, the most recent method detection limit (MDL) study for each regulated contaminant to which the MDL requirement applies.

C. Opening conference. The DCLS onsite assessor or team shall begin the process of the onsite assessment by holding a conference to state the purpose of the assessment, identify the assessment team, and set out the tasks to be done during the assessment.

D. Assessment process.

1. The DCLS onsite assessment team shall evaluate laboratory personnel qualifications and training, operations, equipment, supplies, general laboratory practices, sample handling procedures, methodology, written procedures, and records. The team shall perform the assessment for those specific methods and contaminants for which the laboratory has requested certification.
2. DCLS may require a laboratory to demonstrate drinking water testing methods during the assessment.
3. The DCLS onsite assessment team shall perform a data audit on at least one sample and on one PT sample for at least one method.

4. The DCLS onsite assessment team shall discuss observed deviations at the time such deviations are observed.

5. Findings or deviations are considered preliminary until the final report is issued.

E. Closing conference.

1. The onsite assessment team shall conduct a closing conference to review the results of the assessment with laboratory staff and management.

2. The onsite assessment team shall discuss the following:

a. Any deviations in the observed procedures and records.

b. The time frame for any corrective actions needed and the response.

c. Recommendations, if necessary, for changes in equipment and supplies, staffing, and facility.

F. Notification. Within 30 calendar days after the onsite assessment, DCLS shall notify the laboratory of its certification status and send the laboratory the final onsite assessment report.

G. Final report. In its final onsite report, DCLS:

1. Shall list the certification status for each contaminant or, if applicable, each class of contaminants evaluated as determined by DCLS as a result of the onsite assessment.

2. Shall list and describe each finding, providing a reference to the underlying requirement.

3. May recommend changes to correct the problems described in the findings that have resulted in the laboratory not obtaining certification for a particular contaminant.

4. May recommend improvements to laboratory operation, recognize outstanding performance, and provide other information of use to the laboratory.

H. Results of the onsite assessment.

1. DCLS shall certify the laboratory when the onsite assessment shows that the laboratory has established or is maintaining the standards of quality required under this chapter.

2. When DCLS finds during the onsite assessment that the laboratory is not maintaining the standards of quality required under this chapter, the laboratory shall follow the procedure in subsection I of this section.

I. Procedures and requirements when findings are reported.

1. The laboratory shall respond with a corrective action plan for all findings issued in the report within 60 calendar days. This corrective action plan shall specify what immediate corrective actions are being taken and any proposed actions that need the concurrence of

DCLS.

2. DCLS shall review the corrective action plan. If DCLS finds that any aspect of the laboratory's corrective action plan is inadequate, it shall notify the laboratory director in writing by certified mail or other equivalent mailing service of its intent to downgrade the laboratory.

3. The laboratory director shall respond within 30 calendar days with an additional corrective action plan. If the additional corrective action plan is still deficient, DCLS shall not issue a certificate for the initial application or shall downgrade the laboratory to provisionally certified status.

4. DCLS shall respond within 14 days of determining the laboratory's letter and corrective action plan are deficient.

5. The laboratory shall correct the problems cited in the initial notification letter within three months of the date the laboratory was downgraded.

6. If within three months the laboratory has not corrected the problems for which DCLS downgraded the laboratory to provisionally certified status, DCLS shall revoke the laboratory's certification status.

7. DCLS shall revoke certification only for the contaminants and methods for which the laboratory was initially cited.

8. DCLS shall follow the provisions of 1VAC30-41-240 in revoking the laboratory's certification.

9. When DCLS reports a finding that had been identified in the previous triannual onsite assessment where the laboratory had not implemented corrective action, DCLS shall downgrade the laboratory to provisionally certified.

10. A provisionally certified laboratory may continue to analyze samples for compliance purposes but shall notify its clients in writing of its downgraded status and shall indicate its downgraded status in writing on any report.

1VAC30-41-160. Levels of certification.

A. Certified. DCLS shall certify a laboratory that meets the criteria set out in this chapter.

B. Interim certification. DCLS may issue an interim certification when it finds that performing an onsite assessment is unnecessary or when the onsite assessment cannot be scheduled within a reasonable time. This may occur when DCLS reviews a laboratory application for an addition to its certification status or when a laboratory notifies DCLS that its location is changing. The laboratory shall maintain the requirements for certification while awaiting the onsite assessment. DCLS shall perform the onsite assessment as soon as possible. Interim certification status is equivalent to certified status.

C. Provisionally certified. DCLS shall provisionally certify a laboratory that has deficiencies as

a preliminary stage prior to revocation. A provisionally certified laboratory may continue to analyze drinking water samples for compliance purposes. The laboratory shall notify its clients of the downgraded status in writing and indicate the status on reports. A laboratory may not be provisionally certified for more than three months.

D. Not certified. DCLS shall not certify a laboratory that possesses deficiencies and, in the opinion of DCLS, cannot consistently produce valid data. A laboratory that has had its certification revoked in whole or in part shall notify its clients of its revoked status in writing.

1VAC30-41-170. Term of certification.

DCLS shall certify drinking water laboratories for a period of one year.

1VAC30-41-180. Maintenance of certified status.

To maintain its certified status, a laboratory shall:

1. Continue to meet the requirements for certification listed in 1VAC30-41-80.
2. Successfully pass water supply proficiency testing studies annually as required by 1VAC30-41-130.
3. Notify DCLS in writing within 30 calendar days of major changes in personnel, equipment, or laboratory location as specified in 1VAC30-41-200.
4. Use approved methodology as required by this chapter and incorporated by reference into 1VAC30-41-55.
5. Comply with the reporting requirements specified in 1VAC30-41-190.

1VAC30-41-190. Reporting requirements.

A. To maintain certification, drinking water laboratories shall comply with the reporting requirements for compliance, monitoring, and exceedances set out in the VDH-ODW regulations in 12VAC5-590-530.

B. Drinking water laboratories shall report the results of analyses to the VDH-ODW within three days of completion unless 12VAC5-590-530 requires a different time limit.

1VAC30-41-200. Major changes in personnel or equipment or a change of laboratory location.

A. Major change in personnel.

1. The drinking water laboratory shall notify DCLS of a major change in the laboratory's personnel in writing within 30 calendar days of the change.
2. A "major change in personnel" is defined as (i) the loss or replacement of the laboratory director or laboratory supervisor or (ii) the loss of all the trained and experienced analysts

who had been available to analyze a particular contaminant for which certification has been granted.

3. DCLS shall follow the procedure in 1VAC30-41-220 to downgrade the laboratory to provisionally certified status if the laboratory fails to notify DCLS within 30 calendar days of a major change in personnel.

B. Change of laboratory location.

1. The laboratory shall notify DCLS of a change in the laboratory's location in writing at least 30 calendar days prior to the location change.

2. DCLS may perform an onsite assessment of the new facility when a laboratory changes location.

3. DCLS shall follow the procedure in 1VAC30-41-220 to downgrade the laboratory to provisionally certified status if the laboratory fails to notify DCLS of a change in the laboratory's location at least 30 days prior to the location change.

C. Equipment.

1. A drinking water laboratory shall notify DCLS in writing within 30 calendar days of a major change in equipment.

2. A drinking water laboratory shall provide the following information to DCLS about new equipment:

- a. Make and model of the new instrument.
- b. Date of installation and training.
- c. Initial demonstration of capability (IDC) and minimum detection limit (MDL).
- d. Updated standard operating procedure (SOP).
- e. Methods and contaminants for which the instrument will be used.
- f. Successful proficiency testing analyzed on the new instrument.
- g. Date the instrument was put into service analyzing compliance samples.

3. DCLS shall follow the procedure in 1VAC30-41-220 to downgrade the laboratory to provisionally certified status if the laboratory fails to notify DCLS within 30 calendar days of any major change in equipment.

D. Laboratory action to address major changes to personnel or equipment or a change of location.

1. When a major change to laboratory personnel or equipment or a change of location

occurs, the laboratory shall establish a schedule to address the change and provide the schedule in writing to DCLS. The laboratory shall submit the schedule to DCLS along with the notification of the change.

2. If DCLS determines that the laboratory can no longer produce valid data because of the major change in personnel or equipment or the change of location, DCLS shall follow the procedure in 1VAC30-41-240 to revoke certification for the contaminants in question.

1VAC30-41-210. Downgrading to provisionally certified status.

DCLS shall downgrade a certified drinking water laboratory's status to provisionally certified for each contaminant and by each method for any of the following reasons:

1. Failure to analyze a PT sample each calendar year during the period defined by DCLS and within the acceptance limits specified in the regulations incorporated by reference in 1VAC30-41-55.

2. Failure to successfully analyze a PT sample for a contaminant after participating in two successive PT studies.

3. Failure to notify DCLS within 30 calendar days of major changes in personnel or equipment or a change in laboratory location as required by 1VAC30-41-200.

4. Failure to satisfy DCLS that the laboratory is maintaining the required standard of quality based upon the onsite assessment requirements in 1VAC30-41-150.

5. Failure to comply with the reporting requirements of 1VAC30-41-190 in a timely manner.

1VAC30-41-220. Procedure to downgrade to provisionally certified status.

A. DCLS shall notify the laboratory director in writing that DCLS intends to downgrade the laboratory to provisionally certified status. DCLS shall send this notification within 14 days of becoming aware of the cause for the downgrade. DCLS shall send the notification by certified mail or other equivalent mailing service.

B. The laboratory director shall review the problems cited in the notice. Within 30 days of receiving the notice, the laboratory director shall send DCLS a letter specifying what immediate corrective actions are being taken and any proposed action that needs the concurrence of DCLS.

C. DCLS shall consider the adequacy of the laboratory's response and notify the laboratory director in writing by certified mail or other equivalent mailing service of the laboratory's certification status. DCLS shall respond within 14 days of receiving the laboratory's letter and corrective action plan.

D. The laboratory shall correct the problems cited in the initial notification letter from DCLS within three months of the date of the DCLS response to the laboratory's corrective action plan.

E. If within three months the laboratory has not corrected the problems for which DCLS

downgraded the laboratory to provisionally certified status, DCLS shall revoke the laboratory's certification status. This revocation shall apply only to the contaminants and methods for which the laboratory was initially cited in the DCLS downgrade notification.

F. DCLS shall follow the provisions of 1VAC30-41-240 in revoking the laboratory's certification.

G. A provisionally certified laboratory may continue to analyze samples for compliance purposes but shall notify its clients in writing of its downgraded status and shall indicate its downgraded status in writing on any report.

1VAC30-41-230. Revocation of certified status.

DCLS shall downgrade a drinking water laboratory's status to not certified from certified or provisionally certified or interim certified status for each contaminant and by each method for any of the following reasons:

1. Falsification of data or use of other deceptive practices.
2. Reporting proficiency testing data from another laboratory as its own.
3. Failure to use the federally-approved methods incorporated by reference into this chapter at 1VAC30-41-55.
4. Refusal to participate in an onsite assessment conducted by DCLS.
5. Failure to pay the annual fee to DCLS.
6. For provisionally certified laboratories, failure to successfully analyze a PT sample or any other unknown test sample for a particular contaminant within the specified acceptance limits.
7. For provisionally certified laboratories, failure to satisfy DCLS that the laboratory has corrected identified deficiencies based on an onsite assessment.
8. For provisionally certified laboratories, persistent failure to comply with the reporting requirements specified in 1VAC30-41-190.

1VAC30-41-240. Procedure to revoke certification.

A. DCLS shall notify the laboratory owner in writing of its intent to revoke certification. DCLS shall describe in detail the reasons and circumstances that form the basis for revoking certified status in this notice. DCLS shall send the notification by certified mail or an equivalent mailing service.

B. DCLS shall provide an opportunity for an informal fact-finding conference pursuant to § 2.2-4019 of the Code of Virginia prior to making a final decision to revoke certification.

C. A drinking water laboratory that has had its certification revoked for methods and

contaminants under the methods shall do the following:

1. Stop analyzing SDWA compliance samples for these contaminants and methods.
2. Send the samples to a laboratory that is certified to perform the analyses.
3. Notify its clients of its revoked status in writing.

1VAC30-41-250. Appeal procedure.

A laboratory may appeal a final decision to revoke certification by DCLS pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

1VAC30-41-260. Reinstatement of certification.

A. A drinking water laboratory may request in writing to have its certification status upgraded or reinstated.

B. DCLS shall upgrade or reinstate certification when the laboratory can demonstrate that it has corrected the deficiencies that produced the downgrading or revocation of certified status.

C. DCLS may require an onsite assessment or successful completion of a water supply proficiency testing study or both before upgrading or reinstating a drinking water laboratory. If the onsite assessment is necessary, the laboratory shall pay the fees set out in 1VAC30-41-270 H.

1VAC30-41-270. Fees.

A. DCLS shall charge a fee to certify drinking water laboratories. This fee shall be limited to the cost of administering the certification program.

B. Required fees.

1. Drinking water laboratories shall submit payment of the fee with the initial applications for certification.
2. Drinking water laboratories located out-of-state and applying for reciprocal certification shall submit payment of the fee with the initial applications.
3. Once certified under this chapter, drinking water laboratories shall pay the fee annually. DCLS shall send an invoice to the certified drinking water laboratory.
4. Additional fees may apply under subsection K of this section when changes to the laboratory's certification require DCLS staff time to administer the change.

C. DCLS shall not consider an application to be complete until the applicant laboratory submits payment of the certification fee.

D. All incomplete payments shall be deemed as nonpayment. Nonpayment of fees shall result in denial or revocation of certification.

E. Payment of fees shall be nonrefundable.

F. DCLS, under 1VAC30-41-230, may revoke the certification of any certified laboratory that does not pay its annual fee.

G. Fee computation.

1. Fees for certification of drinking water laboratories shall be applied on an annual basis.
2. Drinking water laboratories shall pay the total of the base year fees as required by subsections H and J of this section for the first 12 months following May 1, 2014.
3. Beginning May 1, 2015, drinking water laboratories shall pay the total of the base year fees required by subsection H and Table 1 of subsection J of this section as adjusted by the method set out in subsection I of this section.

H. Calculation of fees - base year fees May 1, 2014 - April 30, 2015.

1. DCLS charges a fee for the review and certification of the drinking water laboratory's quality system. This includes a review of the test methods for which the drinking water laboratory requests or holds certification. The fees are based on the number of test methods for which the laboratory would be certified within each of the six testing categories set out in Table 1 of subsection J of this section.
2. DCLS shall calculate a laboratory's fees by adding the fees for the number of test methods in each category as set out in Table 1 of subsection J of this section for which the laboratory applies or is certified.
3. For example, a laboratory may be certified for three microbiological methods (\$700); five inorganic chemistry, nonmetals methods (\$850); two inorganic chemistry, metals methods (\$1000); and two organic chemistry methods (\$1050). The total annual fee would be \$3600.

I. Calculation of fees - fees beginning May 1, 2015.

1. DCLS shall revise the base year fees after the first 12 months following May 1, 2014, and every 12-month period thereafter.
2. DCLS shall increase or decrease the fees set out in Table 1 of subsection J of this section using the Consumer Price Index-Urban (CPI-U) percentage change, average-average for the previous calendar year. (The CPI-U for all urban consumers is published by the U.S. Department of Labor, Bureau of Labor Statistics.)
3. DCLS shall revise each previous year's Table 1 of subsection J of this section so that the revisions will be cumulative, reflecting the changes in the CPI-U over time.
4. DCLS shall round the revised fees to the nearest whole dollar.

5. DCLS shall publish the revised fee table annually on its website for drinking water laboratory certification. This website can be found by going to the DCLS page of the Department of General Services' website at <http://dgs.virginia.gov>.

J. Fee tables.

1. Fees are calculated using the base year fees in Table 1.

Table 1 - Base Year Fees

Testing Category	Fee (\$)
Microbiological testing	
1 - 2 methods	600
3 - 5 methods	700
6+ methods	800
Inorganic chemistry, nonmetals testing	
1 - 2 methods	650
3 - 5 methods	850
6 - 8 methods	1050
9+ methods	1250
Inorganic chemistry, metals testing	
1 - 2 methods	1000
3 - 5 methods	1200
6+ methods	1400
Organic chemistry	
1 - 2 methods	1050
3 - 5 methods	1250
6 - 8 methods	1450
9+ methods	1650
Radiochemistry	
1 - 2 methods	1100
3 - 5 methods	1300
6+ methods	1500
Asbestos	
1 - 2 methods	900
3 - 5 methods	1100
6+ methods	1300

2. Table 2 shows the relationship between the testing categories for fees and the drinking water laboratory certification categories.

Table 2 - Drinking Water Laboratory Certification Categories

Fee Testing Category	Laboratory Certification Category
Microbiological testing	Microbiology (includes coliform, E. coli, heterotrophic bacteria)
Inorganic chemistry, nonmetals testing	Physical/inorganic: aggregate properties (includes turbidity, alkalinity, total dissolved solids, conductivity, pH)

	Wet chemistry (includes fluoride, nitrate/nitrite, cyanide, sulfate, orthophosphate, pH) Organic aggregate properties (includes DOC, TOC, UV254, Surfactants/SUVA)
Inorganic chemistry, metals testing	Trace metals (includes lead, copper, chromium, beryllium, mercury, barium, cadmium)
Organic chemistry, trace	Organic chemistry (includes pesticides, herbicides, SOC, PCB, THM, VOC, HAA5, carbamates, fumigants)
Radiochemistry	Radiochemistry (includes alpha, beta, radium, gamma, uranium, strontium-89)
Asbestos	Asbestos

K. Additional fees.

1. An additional fee shall be charged to a laboratory:

- a. Applying for modification of certification under 1VAC30-41-110.
- b. Moving its location when the move requires DCLS to perform an onsite assessment.
- c. Requesting reinstatement of certification when DCLS requires an onsite assessment.

2. The fee charged shall be the sum of the total hourly charges for all reviewers plus any onsite assessment cost incurred.

- a. An hourly charge per reviewer shall be \$61 as of May 1, 2014. DCLS shall revise the hourly charge after the first 12 months following May 1, 2014, and every 12-month period thereafter. The hourly charge shall increase or decrease using the Consumer Price Index-Urban (CPI-U) percentage change, average-average for the previous calendar year.
- b. The charge per reviewer shall be determined by multiplying the number of hours expended in the review by the reviewer's hourly charge.
- c. If an onsite review is required, travel time and onsite review time shall be charged at the same hourly charge per reviewer, and any travel expenses shall be added.

L. Method of payment. Fees shall be paid by check, draft, or postal money order payable to the Treasurer, Commonwealth of Virginia, or submitted electronically, if available, and must be in U.S. currency, except that agencies and institutions of the Commonwealth of Virginia may submit interagency transfers for the amount of the fee. All fees shall be sent to the following address, or submitted electronically, if available: DCLS, Attn: Lab Certification, 600 North 5th Street, Richmond, VA 23219. Laboratories may also pay fees using credit cards. Laboratories shall fill out the DCLS Fee Payment Form for Virginia Laboratory Certification Programs and send the completed form with the fee.

1VAC30-41-280. (Reserved)

1VAC30-41-290. (Reserved)

Part III Chemistry

1VAC30-41-300. Personnel.

Drinking water laboratories shall meet the requirements of Chapter III, Section 10 and Chapter IV, Section 1 of the Manual.

1VAC30-41-310. Laboratory facilities.

Drinking water laboratories shall meet the requirements of Chapter IV, Section 2 of the Manual.

1VAC30-41-320. Laboratory equipment and instrumentation.

A. Drinking water laboratories shall meet the requirements set out in the approved methods incorporated by reference into 1VAC30-41-55 and in use by the laboratory.

B. Drinking water laboratories shall meet the requirements of Chapter IV, Section 3 of the Manual.

1VAC30-41-330. General laboratory practices.

A. Drinking water laboratories shall meet the requirements set out in the approved methods incorporated by reference into 1VAC30-41-55 and in use by the laboratory.

B. Drinking water laboratories shall meet the requirements of Chapter IV, Section 4 of the Manual with the exception of Table IV-1.

1VAC30-41-340. Analytical methodology.

A. Laboratories shall meet the sampling and analytical methodology requirements incorporated by reference at 1VAC30-41-55 for primary inorganic chemical contaminants, primary organic chemical contaminants, alternative testing methods for chemistry, and secondary maximum contaminant levels.

B. Laboratories shall meet the requirements of Chapter IV, Section 5.1 of the Manual with the exception of Tables IV-2 through IV-5 and Table IV-11.

C. A drinking water laboratory shall perform a minimum of five water analyses monthly for each chemical contaminant for which the laboratory is certified in order to maintain certification status or qualify for initial certification.

D. Exceptions to laboratory certification requirements of 1VAC30-41-20 B 2.

1. Laboratory testing for alkalinity, calcium, chlorite, conductivity, disinfectant residual, orthophosphate, pH, silica, temperature, and turbidity for compliance purposes may be performed by laboratories or persons not certified under this chapter but acceptable to VDH-ODW.

2. This testing shall be performed using approved sampling and analytical methodology as incorporated by reference into 1VAC30-41-55 C.

3. Laboratories performing this testing shall meet the requirements of Chapter IV, Section 5.2 of the Manual, with the exception of Tables IV-2 through IV-5.

1VAC30-41-350. Sample collection, handling, and preservation.

A. Drinking water laboratories shall meet the sample container, required preservation, and maximum holding time requirements incorporated by reference at 1VAC30-41-55 for primary inorganic chemical contaminants, primary organic chemical contaminants, alternative testing methods for chemistry, and secondary maximum contaminant levels.

B. Drinking water laboratories shall meet the requirements of Chapter IV, Section 6 of the Manual with the exception of Table IV-6, and the Manual Supplement to Chapter IV, Section 6 of the Manual.

C. Drinking water laboratories shall reject any sample not meeting the criteria of this section and notify the system or individual requesting the analyses.

D. The laboratory shall have a written sample rejection policy covering samples that do not meet sampling requirements.

1VAC30-41-360. Quality assurance.

Drinking water laboratories shall meet the quality assurance and quality control requirements of both the Manual and the required analytical methods incorporated by reference into 1VAC30-41-55. These requirements include the following:

1. The approved test methods and associated quality assurance and quality control requirements incorporated by reference into 1VAC30-41-55.

2. Chapter III, Section 11 of the Manual.

3. Chapter IV, Section 7 of the Manual with the exception of Tables IV-7 through IV-10.

4. The Manual Supplement to Chapter III, Section 2 of the Manual.

1VAC30-41-370. Recordkeeping and data reporting.

Drinking water laboratories shall meet the recordkeeping and data reporting requirements of the following:

1. The approved test methods incorporated by reference into 1VAC30-41-55.

2. Chapter IV, Section 8 of the Manual.

1VAC30-41-380. Action response to laboratory results.

Drinking water laboratories shall meet the action response requirement of Chapter IV, Section 9 of the Manual and the requirements of 1VAC30-41-190.

1VAC30-41-390. (Reserved)

**Part IV
Microbiology**

1VAC30-41-400. Personnel.

Drinking water laboratories shall meet the requirements of Chapter III, Section 10 and Chapter V, Section 1 of the Manual.

1VAC30-41-410. Laboratory facilities.

A. Drinking water laboratories shall meet the requirements of Chapter V, Section 2 of the Manual.

B. The laboratory facilities shall include sufficient space to process and examine samples proportionate with the total work load.

C. The laboratory shall have provisions for decontamination and disposal of microbiological waste.

D. Office areas for clerical work and recordkeeping shall be segregated from laboratory work areas.

1VAC30-41-420. Laboratory equipment and supplies.

Drinking water laboratories shall meet the following requirements:

1. The requirements set out in the approved methods incorporated by reference into 1VAC30-41-55 and in use by the laboratory.
2. The requirements of Chapter V, Section 3 of the Manual.

1VAC30-41-430. General laboratory practices.

Drinking water laboratories shall meet general laboratory practices of the following:

1. The requirements set out in the approved methods incorporated by reference into 1VAC30-41-55 and in use by the laboratory.
2. The requirements of Chapter V, Section 4 of the Manual.

1VAC30-41-440. Analytical methodology.

A. Drinking water laboratories shall meet the sampling and analytical methodology requirements incorporated by reference into 1VAC30-41-55 for microbiology and alternative testing methods for microbiology.

B. Drinking water laboratories shall meet the requirements of Chapter V, Section 5 of the Manual and the Manual Supplement to Chapter V, Section 5 of the Manual unless these requirements conflict with the requirements specified in subsection A of this section.

C. A drinking water laboratory shall perform a minimum of 20 coliform analyses monthly by each coliform method for which it is certified in order to maintain certification status or qualify for initial certification. The minimum number of coliform analyses (20) may be performed on a variety of water sample types collected from different stages of the water treatment process, raw source water, and surface or ground water, as well as drinking water samples collected from a distribution system or private wells.

1VAC30-41-450. Sample collection, handling, and preservation.

A. Laboratories that perform sampling shall meet the sample container, required preservation, and maximum holding time requirements incorporated by reference at 1VAC30-41-55 for microbiology and alternative testing methods for microbiology.

B. Laboratories that perform sampling shall meet the requirements of Chapter V, Section 6 of the Manual and the Manual Supplement to Chapter V, Section 6 of the Manual unless these requirements conflict with the requirements specified in subsection A of this section.

C. Drinking water laboratories shall reject any sample not meeting the sampling criteria of this section and notify the system or individual requesting the analyses.

D. The laboratory shall have a written sample rejection policy covering samples that do not meet sampling requirements.

1VAC30-41-460. Quality assurance.

Drinking water laboratories shall meet the quality assurance and quality control requirements of both the Manual and the required analytical methods incorporated by reference into 1VAC30-41-55. These requirements include the following:

1. The approved test methods and associated quality assurance and quality control requirements incorporated by reference into 1VAC30-41-55.
2. Chapter III, Section 11 and Chapter V, Section 7 of the Manual.
3. The Manual Supplement to Chapter III, Section 2 of the Manual.

1VAC30-41-470. Recordkeeping and data reporting.

Laboratories shall meet the recordkeeping and data reporting requirements of the following:

1. The approved test methods incorporated by reference into 1VAC30-41-55.
2. Chapter V, Section 8 of the Manual.

1VAC30-41-480. Action response to laboratory results.

Drinking water laboratories shall meet the requirements of Chapter V, Section 9 of the Manual and the requirements of 1VAC30-41-190.

1VAC30-41-490. (Reserved)

**Part V
Radiochemistry**

1VAC30-41-500. Radiochemistry.

A. Drinking water laboratories shall meet the sampling and analytical methodology requirements including the quality assurance and quality control requirements incorporated by reference into 1VAC30-41-55 for radiochemistry and alternative testing methods for radiochemistry.

B. Drinking water laboratories shall meet the requirements of Chapters III and VI of the Manual as follows:

1. Personnel: Chapter III, Section 10 and Chapter VI, Section 1.
2. Laboratory facilities: Chapter VI, Section 2.
3. Laboratory equipment and instrumentation: Chapter VI, Section 3.
4. General laboratory practices: Chapter VI, Section 4.
5. Analytical methods: Chapter VI, Section 5, with the exception of Table VI-1.
6. Sample collection, handling, and preservation: Chapter VI, Section 6, with the exception of Table VI-2.
7. Quality assurance: Chapter III, Section 11 and Chapter VI, Section 7.
8. Recordkeeping and data reporting: Chapter VI, Section 8.
9. Action response to laboratory results: Chapter VI, Section 9 and the requirements of 1VAC30-41-190.

STATUTORY AUTHORITY

§§ 2.2-1102 and 2.2-1105 of the Code of Virginia; 42 USC § 300f et seq.

HISTORICAL NOTES

Derived from Virginia Register Volume 30, Issue 14, eff. May 1, 2014.