Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Department of General Services, Division of Consolidated Laboratory Services
Virginia Administrative Code (VAC) citation	1VAC30-41 (new) and 1VAC30-40 (repeal)
Regulation title	Certification of Laboratories Analyzing Drinking Water
Action title	Revise regulation to meet current guidance under the federal Safe Drinking Water Act and to update fees
Date this document prepared	September 26, 2013; February 17, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

This action repeals 1VAC30-40 and replaces 1VAC30-40 with 1VAC30-41. 1VAC30-40 is repealed because the required revisions to 1VAC30-40 are extensive.

This proposed action updates the drinking water laboratory certification regulation to incorporate by reference the most recent federal guidance used to certify drinking water laboratories, the Environmental Protection Agency's (EPA's) *Manual for the Certification of Laboratories Analyzing Drinking Water*, Fifth Edition (January 2005) and *Supplement 1* to the Fifth Edition (June 2008). Drinking water laboratories are required to meet this federal guidance.

The proposed action revises the fee provisions. Local, state and federal public laboratories as well as private or commercial laboratories will be required to pay fees under the proposed regulation. DCLS currently waives fees for public laboratories. Requiring all laboratories seeking certification for drinking water to pay a fee creates a more equitable fee system for the program.

The final regulation revises references to federal and Virginia Department of Health requirements, and adds clarity to the provisions where needed.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

The Director of the Department of General Services approved the revised regulations on November 15, 2013. The regulations are entitled Certification of Laboratories Analyzing Drinking Water.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Federal Legal Authority

Under the federal SDWA (42 USC 300f *et seq.*), EPA sets national limits on contaminant levels in drinking water to ensure that the water is safe for human consumption. The federal regulations at 40 CFR 142.10 (b)(3)(i) require the establishment and maintenance of a State program for the certification of laboratories conducting analytical measurements of drinking water contaminants pursuant to the requirements of the State primary drinking water regulations. To determine compliance under the SDWA, EPA at 40 CFR 141.28 requires that the analysis of samples must be made by certified laboratories.

Virginia Legal Authority

Section 2.2-1102 A 1 of the *Code of Virginia* authorizes the Department of General Services to prescribe regulations necessary or incidental to the performance of the Department's duties or execution of powers conferred by the *Code*. The statutory authority to promulgate regulations is discretionary based on whether the proposed regulation is "necessary or incidental to the performance of the Department's duties or execution of powers conferred" by the *Code of Virginia*.

Section 2.2-1102 A 2 of the *Code of Virginia* authorizes the Department of General Services to establish fee schedules that may be collectible from users when general fund appropriations are not applicable to the services rendered.

Section 2.2-1104 A 4 of the *Code of Virginia* authorizes the Division of Consolidated Laboratory Services to establish and conduct programs of inspection and certification of other laboratories in the Commonwealth as mandated by the federal Safe Drinking Water Act and state requirements pursuant to the Act.

Promulgating Entity

The promulgating entity for this regulation is the Division of Consolidated Laboratory Services of the Department of General Services.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Public health is protected when drinking water laboratories meet established federal standards for analyzing drinking water samples.

The SDWA is carried out in Virginia by the Department of Health. The Waterworks Regulation (12VAC5-590) promulgated by the Department of Health sets standards for the maximum permissible level of contaminants in drinking water. The regulation at 12VAC5-590-340 requires all analyses for the purpose of demonstrating compliance with the primary and secondary maximum contaminant levels or action levels be performed by DCLS or by laboratories certified by DCLS for such purposes. 12VAC5-590-440 requires all laboratories that seek certification to perform drinking water analyses to comply with the drinking water laboratory certification regulation promulgated by DCLS. The Department of Health is the agency with the primary enforcement authority (primacy) to carry out the SDWA in Virginia.

The proposed regulatory action is necessary to ensure that current federal requirements are set out in the drinking water laboratory certification regulation. Maintaining primacy for drinking water in Virginia requires the drinking water laboratory certification regulation to incorporate the most current federal guidance and regulatory requirements.

The proposed regulatory action revises the fee provisions to allow DCLS to charge fees to public as well as private laboratories to cover the cost of the certification program. The fees currently charged to the laboratories certified under the regulation do not cover the cost of the program.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The proposed action repeals the current regulation and creates a new regulation. The latest EPA guidance and agency procedures are set out in the proposed new regulation.

The current drinking water laboratory certification regulation requires laboratories to meet the newest edition of the EPA Manual when published (1VAC30-40-80) while citing the 1992 edition of the EPA Manual for the certification of drinking water laboratories. EPA published the fifth edition of the Manual in June 2005 and a Supplement to the Manual in June 2008. The drinking water laboratories certified under 1VAC30-40 already meet this latest edition of the EPA Manual and the Supplement due to the 1VAC30-40-80 requirement.

Because there were numerous changes to the current regulation, a new 1VAC30-41 is being proposed. The current 1VAC30-40 will be repealed when 1VAC30-41 becomes effective. The revisions made to 1VAC30-40, effective on February 3, 2010, are included in proposed new 1VAC30-41.

The following are the substantive changes to the current regulation. The references are to proposed new 1VAC30-41.

1. Removes the references to outdated versions of the EPA Manual. Lists the most recent version of the EPA Manual and the Supplement in section 1VAC30-41-50 and incorporates these documents by reference.

2. Removes from the regulation the provisions in current Part III through Part V that were included verbatim from outdated versions of the EPA Manual. Replaces these provisions with the requirements from the most recent version of the EPA Manual as incorporated by reference into 1VAC30-41-50. The regulatory provisions refer to the appropriate requirements in the EPA Manual and its Supplement.

3. Deletes the general fee provisions of current 1VAC30-40-60. Adds new fee provisions in 1VAC30-41-270. Public laboratories as well as private laboratories would pay fees.

4. Adds a new provision, 1VAC30-41-30, allowing drinking water laboratories to obtain certification by meeting the requirements of 1VAC30-46, *Accreditation for Commercial Environmental Laboratories*.

5. Revises many of the provisions in Parts I and II of the current regulation. These provisions lacked specificity and a few had out-of-date references. These provisions have been updated and made more specific. These sections cover definitions, application requirements, reciprocal certification, renewal of certification, modification of certification, general quality assurance requirements, on-site assessment, certification type, maintenance of certification status, reporting requirements, reasons to downgrade laboratory to provisionally certified status, procedure to downgrade a laboratory to provisionally certified status, reasons to revoke certification, procedure to revoke certification, appeal, and requesting reinstatement of certification.

6. Adds new provisions where needed to improve the clarity of the regulation or to include necessary requirements where there are none in the current regulation. These new provisions are listed below.

    a. Section 20 defines the laboratories and contaminants that are covered by the regulation.

    b. Section 60 describes the categories for which a laboratory may be certified.

    c. Section 80 describes the requirements laboratories must meet to become certified and provides cross-references to the detailed requirements.

    d. Section 130 establishes the requirements for proficiency testing.

    e. Section 140 requires laboratories to meet the laboratory ethics and fraud detection and deterrence requirements of the Supplement. EPA encourages laboratories to meet these requirements.

    f. Section 170 establishes a one-year term for certification.

    g. Section 200 sets out specific requirements for major changes to personnel and equipment at a laboratory and for a change to laboratory location.

    h. Section 460 sets out the quality assurance requirements for microbiology laboratories.

7. Current 1VAC30-40-85 has been moved to 1VAC30-41-55. This section lists and incorporates by references the *Code of Federal Regulation* requirements for drinking water laboratory test methods and associated requirements.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantage to the public is to maintain an up-to-date regulation governing the certification of laboratories analyzing drinking water. While the drinking water laboratories are already meeting the provisions of the proposed regulation, the current regulation does not contain these provisions. As a result the agency cannot enforce compliance with the most up-to-date federal guidance requirements for the certification of these laboratories. Revising the regulation provides the agency with the ability to enforce these requirements. There are no disadvantages to the general public associated with this regulatory action.

There are two primary advantages to the agency and the Commonwealth associated with this regulatory action. The first is the ability to enforce the most up-to-date federal guidance on the certification of drinking water laboratories and therefore to maintain Virginia's primacy for drinking water rather than having primacy relinquished to EPA. The second relates to the fees charged to laboratories for the certification process. Current fees cover only a minimal portion of the cost of the program. No general funds have been allocated to cover the cost of the certification program. The current regulation waives fees for public laboratories. The proposed regulation would eliminate the waiver and charge fees to public laboratories. One-third of the laboratories certified under the program are public laboratories. The cost to the agency of running the program has increased over the almost two decades since DCLS began charging fees. Charging fees to public laboratories as well as to private laboratories will help to recover the cost of the program to the agency. Spreading the cost of the program among all the laboratories certified under the program will be a more equitable approach to fees.

The primary disadvantage of the proposed regulatory action is to the public laboratories in that they will now be charged fees. The revised regulation charges fees to public laboratories as well as to private laboratories.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number (1VAC30-41-)	Requirement at proposed stage	What has changed	Rationale for change
40	Definition of "maximum contaminant level" or "MCL."	The definition of "MCL" has been revised to be consistent with the equivalent definition in 12VAC5-590-10.	The VA Department of Health, Office of Drinking Water revised its definition of "MCL" in September 2010 in response to comments from EPA. The definitions of 1VAC30-41 need to

Section number (1VAC30-41-)	Requirement at proposed stage	What has changed	Rationale for change
			be consistent with the Waterworks Regulation definitions.
40	None	Two definitions have been added to 1VAC30-41-40 to make the revised definition of "MCL" clear. These definitions are "pure water" and "MCLG."	The revised definition of "MCL" is unclear without defining "pure water" and "MCLG" both of which are defined in 12VAC5-590.
40	None	A definition of "National Environmental Laboratory Accreditation Program" or "NELAP" has been added to section 40.	See 90 C below.
55 A	Incorporated by reference 40 CFR 141 and 143 in effect as of July 1, 2011	Revises the federal requirements incorporated by reference to those in effect as of July 1, 2013	This change updates the federal requirements incorporated by reference to include the changes to the CFRs that occurred over the last two years. These include alternative test methods for drinking water.
55 B 3	None	A citation for 40 CFR §141.402(c)(2) has been added to the federal requirements for microbiology incorporated by reference into this section.	The requirements of 40 CFR §141.402(c)(2), were incorporated by reference into 12VAC5-590 in December 2011. DCLS certifies drinking water laboratories to do analyses required under 12VAC5-590.
90 B 5	90 B lists the required materials that laboratories seeking reciprocal certification must send to DCLS.	The language of 90 B 5 has been revised for clarity.	The proposed language incorrectly stated that testing results would be reported to a list rather than to DCLS, the certifying authority. The revision corrects the statement.
90 C	90 C pertains to out-of-state laboratories seeking reciprocal accreditation for drinking water.	The reference to the National Environmental Laboratory Accreditation Conference (NELAC) has been updated to refer to the National Environmental Laboratory Accreditation Program (NELAP). A definition of NELAP has been added to section 40.	The reference needed to be updated.
130 A 4	The proficiency testing requirements laboratories must meet to become certified.	A requirement is added that laboratories must meet the proficiency testing requirements incorporated by reference in 1VAC30-41-55.	There are some Code of Federal Regulation requirements for proficiency testing that are not included in the proposed regulation language. This addition remedies the omission. These are general requirements that are already in the regulation's

Section number (1VAC30-41-)	Requirement at proposed stage	What has changed	Rationale for change
			provisions but not specified for proficiency testing.
190 A and B	Requires drinking water laboratories to meet the public notice requirements under 12VAC5-590-540 to maintain certification	Deletes the public notice requirements under 12VAC5-590-540 for drinking water laboratories.	The change corrects the provision. Only waterworks owners are required to provide public notice under 12VAC5-590-540.
340 B	Lists the analytical methodology requirements of the Manual that chemistry laboratories must meet and the exceptions to these requirements.	The exceptions have been revised to include Table IV-11 of the Manual.	Table IV-11 of the Manual was not included in this provision of the proposal. This addition remedies the omission.
360; 460; and 500 A	Lists the specific quality assurance requirements that chemistry, microbiology, and radiochemistry laboratories must meet.	Adds language to make it clear that drinking water laboratories must meet the quality assurance (QA) and quality control (QC) requirements of both the Manual and the required analytical methods incorporated by reference in 1VAC30-41-55.	While the proposed provisions listed the requirements, there was no general language stating that drinking water laboratories must meet the QA and QC requirements of the Manual and the federally approved analytical requirements. This additional language remedies the omission.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
VDH-ODW	In Section 1VAC30-41-190 Reporting requirements, references to 12VAC5-590-540 should be deleted. The Virginia Department of Health Office of Drinking Water Waterworks Regulations in 12VAC5-590-540 contains the requirements for public notification which only pertains to waterworks owners. Certified drinking water laboratories are not responsible for complying with 12VAC5-590-540.	The revision was made.
Region III, U.S. EPA	Definition of MCL in 1VAC30-41-40 should be revised to be consistent with the definition in Virginia Waterworks Regulations 12VAC5-590-10 (copied below). Virginia Department of Health revised its MCL definition when it published its final Lead and Copper Rule Short Term Revision on September 13, 2010 (Volume 27 Issue 1). The revision was in response to	The revision was made.

Commenter	Comment	Agency response
	EPA RIII's comments.	
Region III, U.S. EPA	1VAC30-41-55 Incorporation by reference – Code of Federal Regulations. B.3. Microbiology. Please add a citation to 40 CFR §141.402 (c)(2) referencing E. Coli analytical methods under the Ground Water Rule which was incorporated into 12VAC5-590 on November 7, 2011, effective December 7, 2011.	The revision was made.
Region III, U.S. EPA	1VAC30-41-90. Reciprocity. C. Please note that "NELAC" has been replaced by "NELAP" ("National Environmental Laboratory Accreditation Program"). The requirements for laboratories are based on standards developed by a non-profit organization, The NELAC Institute (TNI) that have been approved and adopted by the State Accreditation Bodies.	The revision was made.
Region III, U.S. EPA	1VAC30-41-130. Proficiency testing. A.1. references the requirements of this section. It is not clear what requirements. A.2. references Chapter III, Section 13.1 of the EPA Laboratory Certification Manual which does not include 40 CFR citation on Performance Testing sample, i.e., 141.131 (b)(2)(i). To ensure full coverage of 40 CFR, DCLS should also include requirements incorporated by reference at 1VAC30-41-55.	A 1. Subdivision A 1 refers to the requirements of "this section." Similar references are made elsewhere in the regulation. These mean simply the section in which the reference is found. No change was made as a result of this comment. A 2. The revision was made.
Region III, U.S. EPA	Part III Chemistry requires drinking water laboratories to follow requirements of Chapter IV of the EPA Manual for analytical methodologies, sample collection, handling and preservations, as well as quality assurance, with the exception of Tables IV-2 through Table IV-10. Where the exceptions are mentioned, additional references (listed below) should be included. If allowed, reference to the EPA's Office of Ground Water and Drinking Water's (OGWDW) web site can also be included as the site provides a comprehensive list of approved drinking water analytical methods (http://water.epa.gov/scitech/drinkingwater/labcert/analyticalmethods.cfm) and additional recently approved alternative testing methods (http://water.epa.gov/scitech/drinkingwater/labcert/analyticalmethods_expedited.cfm) DCLS may wish to add something to the effect that: - In lieu of Tables IV-2 through IV-5, drinking water laboratories shall use approved methodologies incorporated by reference at 1VAC30-41-55 - In lieu of Table IV-6, labs shall follow the requirements incorporated by reference at 1VAC30-41-55 for inorganic compounds and requirements of approved methods for organic compounds.	The final regulation updates the federal requirements incorporated by reference to include the changes to the CFRs that occurred over the last two years. These include alternative test methods for drinking water. Incorporation of federal requirements can be simply and quickly done through an exempt process under Virginia's Administrative Process Act (APA). This is the legal approach to adding federal requirements to Virginia regulations. The exceptions to the analytical methodology requirements of the Manual are the various tables in the Manual that list approved methods. Laboratories are required instead to meet the approved methods incorporated by reference into 1VAC30-41-55. This requirement is already stated in 1VAC30-41-340 A. No change was made as a result

Commenter	Comment	Agency response
	- In lieu of Tables IV-7 through IV-10, labs shall follow the requirements incorporated by reference at 1VAC30-41-55 and per the approved methods.	of this comment.
Region III, U.S. EPA	Part III Chemistry does not make Table IV-11 an exception. Please note that Table IV-11 does not include all the approved methods, including alternative testing methods listed in 40 CFR Part141, Appendix A to Subpart C. For example, Table IV-11 includes Method 524.2 Rev. 4.1, but not Method 524.3 Rev. 1.0 which is an alternative method.	The revision was made.
Region III, U.S. EPA	IVAC30-41-360 should clearly state that drinking water laboratories must meet the quality assurance and quality control requirements per the EPA Lab Certification Manual and the mandatory methods.	The revision was made. The same revision was also made to Parts IV and V, microbiology and radiochemistry, respectively.
Jason Barnett	The commenter addressed the incident in Charlottesville when a young woman was taken into custody after buying a case of water. The commenter believes those who arrested the young woman were completely out of control.	This comment is not germane to this regulatory action.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

The new regulation, 1VAC30-41, is replacing the current regulation, 1VAC30-40. 1VAC30-40 will be repealed when 1VAC30-41 becomes effective. Except to update the list of required federal test methods, 1VAC30-40 has not been revised since 1994 and is out-of-date.

1VAC30-41 includes only one section from 1VAC30-40 in its entirety. Many provisions have been revised or replaced in 1VAC30-41. New sections have been added. 1VAC30-41 includes current federal requirements and current DCLS program practice. Laboratories that are currently certified for drinking water already meet both the federal requirements and the DCLS procedural requirements set out in the proposed regulation revisions. Because certified laboratories are currently meeting these requirements, there is no change from current program requirements. The laboratories will see no change to their requirements except for fees.

Section number (1VAC30-41-	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
Part 1 - General Provisions			
10	States the purpose of the regulation	Replaces section -10 of Chapter 40	Revisions were made to this section to enhance clarity of the language.
20	Defines the laboratories and contaminants covered by the regulation. Provides a link to the VDH-	New section	Needed in order for the regulation to be clearly understood.

Section number (1VAC30-41-	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
	ODW waterworks regulation requirements.		
30	Provides that drinking water laboratories may alternatively obtain certification under 1VAC30-46.	New section	EPA allows drinking water laboratories to obtain certification through meeting an approved TNI environmental laboratory accreditation program. This section references 1VAC30-46, the regulation that DCLS implements as an accreditation body under TNI since Nov. 2009. For commercial laboratories that also perform environmental testing, this option provides an efficient and potentially cost-effective approach to obtain certification.
40	Lists the definitions used in the regulation. See NOTE 1 for the specific changes to definitions.	Replaces section -20 of Chapter 40	Uses definitions specific to the regulation, eliminating those no longer in use, revising others to make them current, and adding others to make the regulation clear. The impact of such changes is positive.
50	Incorporates by reference the current EPA Manual for the Certification of Laboratories Analyzing Drinking Water and the Supplement to the Manual.	Replaces section -80 of Chapter 40	Updates the regulation to meet current EPA guidance. Allows DCLS to enforce current guidance for drinking water laboratories.
55	Lists the federal regulations that are incorporated by reference into the regulation. These federal regulations include approved test methods and related testing requirements.	Moves section -85 of Chapter 40 to section -55 of Chapter 41	This section was added to 1VAC30-40 in an exempt action that became effective February 3, 2010. The final regulation at section 55 A updates the federal requirements incorporated by reference to those in effect as of July 1, 2013, instead of those in effect as of July 1, 2011. The final regulation at section 55 B revises the microbiology requirements to add those in 40 CFR §141.402(C)(2). The change was made in response to a comment from EPA.
Part II - Certification of Laboratories - General Requirements			
60	Describes the categories for which a laboratory may be certified	New section	Provided in order for the regulation to be clearly understood.
70	Lists the information and documents laboratories are required to submit to apply initially for certification. Sets out the procedure DCLS uses to review the application.	Replaces section -90 of Chapter 40	Updates the application requirements and includes the current procedure used by DCLS to review the application.
80	Provides a concise list of the requirements laboratories must meet to become certified, providing cross-references to the specific sections where the detailed requirements are set out.	New section	Provides a list of requirements to ensure that laboratories understand what is required for certification.

Section number (1VAC30-41-	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
90	Describes the conditions that laboratories must meet to obtain reciprocal certification in Virginia and the material these applicant labs must submit to be certified.	Replaces section -70 of Chapter 40	Updates the requirements for laboratories applying for reciprocal certification. The final regulation replaces the reference to NELAC with NELAP. A new definition has been added to section -40.
100	Sets out conditions for renewal of certification. Provides that certification will be renewed if lab maintains required standards for certification and pays annual fee.	Replaces section -190 of Chapter 40	Updates the provisions for renewal of certification to reflect the requirements of the Manual and current agency procedure.
110	Provides a procedure to follow if a laboratory wants to add or delete a method or contaminant to its certification. Lists the information the agency needs to evaluate the addition of a method or contaminant to a laboratory's certification.	Replaces section -180 of Chapter 40	Revises and updates the current provision to reflect current procedure to add or delete a method or contaminant.
120	Requires labs to meet the quality assurance plan provisions of the EPA Manual and Supplement.	Replaces section -50 of Chapter 40	Replaces the current provisions with the EPA Manual requirements. The current provisions are out-of-date.
130	Requires labs to meet the requirements of the EPA Manual and Supplement on proficiency testing as well as the specific procedural requirements set out in this section. The section requires an annual proficiency test for each contaminant and method for which the lab wants to become certified. The procedures that DCLS will use to administer the proficiency testing requirements are included.	New section	Adds a new section on the proficiency testing requirements of the program. These requirements are currently in program guidance but not in the regulation. The final regulation adds the proficiency testing requirements incorporated by reference into 1VAC30-41-55. These are general requirements that are already in the regulation's provisions but not specified for proficiency testing.
140	Requires labs to meet the laboratory ethics and fraud detection and deterrence requirements in the EPA Manual Supplement. EPA, in the Supplement, encourages laboratories to have an ethics policy and to implement a fraud detection and deterrence policy or program.	New section	This EPA requirement is intended to minimize fraud and maximize laboratory integrity and data quality.
150	Sets out the requirements for on-site assessment of laboratories. Describes when on-site assessments occur and the procedure DCLS uses before, during, and after the assessment as well as the requirements laboratories must follow.	Replaces section -100 of Chapter 40	Replaces out-of-date provisions with a specific outline of the on-site assessment procedure. The intent is to communicate clearly the on-site assessment procedure for the laboratories.
160	Describes each type of certification: (a)	Replaces	Adds interim certification to the current

Section number (1VAC30-41-	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
	certified, (b) interim certification, (c) provisionally certified, and (d) not certified.	section -110 of Chapter 40	provision's list of certification types. The time limit for provisionally certified laboratories to correct their deficiencies is deleted from this section and is moved to more appropriate locations.
170	Provides that the term of certification is one year.	New section	This new section is provided so that the regulation may be clearly understood.
180	Lists the requirements a laboratory must continue to meet in order to maintain its certification status. Cross-references the detailed requirements.	Replaces section -130 of Chapter 40	The intent is to make the requirements for maintaining certification clear to the laboratories.
190	Lists the reporting requirements that laboratories must meet to maintain certification.	Replaces sections -30 and -40 of Chapter 40	Deletes out-of-date references in the current provisions, listing the correct references to the VDH-ODW reporting requirements. The final regulation limits the reporting requirements to those found in 12VAC5-590-530, in response to comments from VDH-ODW.
200	Sets out specific requirements pertaining to major changes in personnel or equipment or a change of laboratory location from the Manual. Specifies the reporting requirements for these changes. Defines a major change in personnel. Specifies what information laboratories must provide to DCLS when adding new equipment. Provides that DCLS may perform an on-site assessment of a new laboratory location. The section requires laboratories to submit a schedule to DCLS showing how the major change will be incorporated into the laboratory's operation as to not affect the quality of the data produced.	New section	Adds a section to let laboratories know what they must do when major changes in personnel or equipment occur. Specifying what is meant by a major change in personnel is intended to help laboratories understand when they must report this change to DCLS. The intent is to be clear on what DCLS requires of the laboratories under these conditions.
210	Lists the conditions under which DCLS would downgrade a laboratory to provisionally certified status.	Replaces section -140 of Chapter 40	Revises the current list of conditions so that it conforms to the list in the current edition of the EPA Manual.
220	Sets out the procedure DCLS will use to downgrade a lab to provisionally certified status. Provides the actions a laboratory must take in response to the DCLS notice of its intent to downgrade.	Replaces section -160 of Chapter 40	Provides explicit provisions on the procedure to downgrade a laboratory to provisionally certified status. The provisions are intended to set out the process DCLS will use to notify the laboratory of its intention to downgrade its certification status and the laboratory's responsibilities in responding to the notice and subsequent actions.
230	Lists the conditions under which DCLS may revoke a laboratory's certification.	Replaces section -150 of	Revises the current list of conditions so that it conforms to the list in the current

Section number (1VAC30-41-	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
		Chapter 40	edition of the EPA Manual.
240	Sets out the procedure DCLS will use to revoke a laboratory's certification. Provides the actions a laboratory must take in response to the DCLS notice of its intent to revoke certification.	Replaces section -160 of Chapter 40	Provides explicit provisions on the procedure to revoke a laboratory's certification. The provisions are intended to set out the process DCLS will use to notify the laboratory of its intention to revoke certification and the laboratory's responsibilities in responding to the notice.
250	Sets out the procedure a laboratory must use to appeal a DCLS notification of intent to revoke a laboratory's certification status.	Replaces section -120 of Chapter 40	Provides explicit procedures that a laboratory should use to appeal a DCLS notice of intent to revoke laboratory certification.
260	Sets out the process that a laboratory must use to request reinstatement of certification. Describes how DCLS will handle the request.	Replaces section -170 of Chapter 40	Rewrites the current provisions and adds that the laboratory requesting reinstatement would have to pay a fee if an on-site assessment is necessary.
270	Sets out the provisions concerning fees. The fees listed are to be paid initially and annually. Additional fees are charged for certain actions. The calculation of these additional fees is described.	Replaces section -60 of Chapter 40	This revised section on fees specifies when fees are due and the specific fees due. The section includes fees for the first year of the program after the regulation becomes effective and a formula to increase fees annually using the CPI-Urban, a common inflation indicator. Additional fees are charged under specified circumstances.
Part III - Chemistry			
300	Requires chemistry laboratories to meet the personnel requirements of Chapter III, Section 10 and Chapter IV, Section 1 of the EPA Manual.	Replaces section -200 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement.
310	Requires chemistry laboratories to meet the laboratory facility requirements of Chapter IV, Section 2 of the EPA Manual.	Replaces section -210 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement.
320	Requires chemistry laboratories to meet the laboratory equipment and instrumentation requirements of Chapter IV, Section 3 of the EPA Manual and the related requirements set out in federally-approved test methods.	Replaces section -220 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations.
330	Requires chemistry laboratories to meet the general laboratory practices requirements of Chapter IV, Section 4 of the EPA Manual and the related requirements set out in federally-approved test methods.	Replaces section -230 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations.
340	Requires chemistry laboratories to meet the analytical methodology requirements set out in federally-	Replaces section -240 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well

Section number (1VAC30-41-	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
	approved test methods and the requirements of Chapter IV, Subsection 5.1 of the EPA Manual. Minimum performance requirements are also stated.		as federal regulations. The final regulation adds Table IV-11 to the list of the Manual requirements for chemistry that are exempted from the provisions of Part III. This corrects an omission made in the proposed regulation and is in response to a comment from EPA.
350	Requires chemistry laboratories to meet the sample collection, handling, and preservation requirements set out in federally-approved test methods and the requirements of Chapter IV, Section 6 of the EPA Manual.	Replaces section -250 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations.
360	Requires chemistry laboratories to meet the quality assurance requirements set out in federally-approved test methods and the requirements of Chapter III, Section 11 and Chapter IV, Section 7 of the EPA Manual.	Replaces section -260 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations. The final regulation adds general language to the specific list of quality assurance (QA) and quality control (QC) requirements. The purpose of this addition is to ensure that laboratories meet the QA/QC requirements of the mandatory methods and the Manual. This change was made in response to comments from EPA.
370	Requires chemistry laboratories to meet the records and data reporting requirements set out in federally-approved test methods and the requirements of Chapter IV, Section 8 of the EPA Manual.	Replaces section -270 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations.
380	Requires chemistry laboratories to meet the action response to laboratory results requirements of Chapter IV, Section 9 of the EPA Manual and the reporting requirements of 1VAC30-41-190.	Replaces section -280 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as VDH-ODW reporting requirements.
Part IV - Microbiology			
400	Requires microbiology laboratories to meet the personnel requirements of Chapter III, Section 10 and Chapter V, Section 1 of the EPA Manual.	Replaces section -290 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement.
410	Requires microbiology laboratories to meet the laboratory facility requirements of Chapter V, Section 2 of the EPA Manual. Additional clarification is provided.	Replaces section -300 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement.
420	Requires microbiology laboratories to meet the laboratory equipment and	Replaces section -310 of	Revises the regulation to require laboratories to meet the current EPA

Section number (1VAC30-41-	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
	supplies requirements of Chapter V, Section 3 of the EPA Manual and the related requirements set out in federally-approved test methods.	Chapter 40	Manual and Manual Supplement as well as federal regulations.
430	Requires microbiology laboratories to meet the general laboratory practices requirements of Chapter V, Section 4 of the EPA Manual and the related requirements set out in federally-approved test methods.	Replaces section -320 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations.
440	Requires microbiology laboratories to meet the analytical methodology requirements set out in federally-approved test methods and the requirements of Chapter V, Section 5 of the EPA Manual. Minimum performance requirements are also stated.	Replaces section -330 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations.
450	Requires microbiology laboratories to meet the sample collection, handling, and preservation requirements set out in federally-approved test methods and the requirements of Chapter V, Section 6 of the EPA Manual. Additional clarification is provided.	Replaces section -340 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations.
460	Requires microbiology laboratories to meet the quality assurance requirements set out in federally-approved test methods and the requirements of Chapter III, Section 11 and Chapter V, Section 7 of the EPA Manual and the Manual Supplement to Chapter III, Section 2.	New section	Adds quality assurance requirements for microbiology laboratories in a separate section. The current 1VAC30-40 includes some quality control requirements in related microbiology provisions. These are out-of-date. The intent is to require the laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations. The final regulation adds general language to the specific list of quality assurance (QA) and quality control (QC) requirements. The purpose of this addition is to ensure that laboratories meet the QA/QC requirements of the mandatory methods and the Manual.
470	Requires microbiology laboratories to meet the records and data reporting requirements set out in federally-approved test methods and the requirements of Chapter V, Section 8 of the EPA Manual.	Replaces section -350 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations.
480	Requires microbiology laboratories to meet the action response to laboratory results requirements of Chapter V,	Replaces section -360 of Chapter 40	Replaces current section -360 with the requirements for action response to laboratory results for microbiology in the

Section number (1VAC30-41-	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
	Section 9 of the EPA Manual and the reporting requirements of 1VAC30-41-190.		EPA Manual and the VDH-ODW reporting requirements. The intent is to require the laboratories to meet the current EPA Manual and Manual Supplement as well as VDH-ODW reporting requirements.
Part V - Radiochemistry			
500	Requires radiochemistry laboratories to meet the sampling and analytical methodology requirements set out in federally-approved test methods. Requires radiochemistry laboratories to meet the specific requirements in the EPA Manual for the following: personnel; laboratory facilities; laboratory equipment and instrumentation; general laboratory practices; analytical methods; sample collection, handling, and preservation; quality assurance; records and data reporting; and action response to laboratory results.	Replaces section -370 of Chapter 40	Revises the regulation to require laboratories to meet the current EPA Manual and Manual Supplement as well as federal regulations. The final regulation adds general language to the specific list of quality assurance (QA) and quality control (QC) requirements. The purpose of this addition is to ensure that laboratories meet the QA/QC requirements of the mandatory methods and the Manual.

NOTE 1: The following definitions were deleted: certifying team, CFR, compliance sample, EMSL-LV, minimum requirements, NPDWR, performance evaluation sample, primary enforcement responsibility (primacy), TTHM, and Virginia laboratory officer. The following definitions were revised: MCL, USEPA, DGS-DCLS, and quality assurance (QA) plan. The following definitions were added: certification officer, contaminant, corrective action, drinking water laboratory, findings, laboratory director, Manual, Manual supplement, MCLG, NELAP, owner, persistent, private laboratory, proficiency test (PT) sample, public laboratory, pure water, and quality control.