Chapter 246-390 WAC

DRINKING WATER CERTIFICATION RULES

WAC
246-390-001 Purpose—Objectives. (1) The purpose of this chapter is to establish a state drinking water program for certification of laboratories analyzing public drinking water under RCW 43.20.050. The certification program is designed to satisfy the intent of the primacy agreement with United States Environmental Protection Agency and the state, in compliance with 40 C.F.R. 142.10, 7/1/90.
(2) The department certification program:
(a) Requires laboratories to demonstrate capability to accurately analyze drinking water samples;
(b) Aids laboratories in improving quality assurance;
(c) Offers technical assistance in all drinking water analyses; and
(d) Fosters cooperation between the state department of health, local health agencies, and operators of laboratories.
[Statutory Authority: RCW 43.20.050. WSR 92-15-152 (Order 290B), § 246-390-001, filed 7/22/92, effective 8/22/92.]

WAC 246-390-010 Definitions. Definitions in this section shall apply throughout this chapter, unless clearly indicated otherwise.

(1) "Administrative Procedure Act" means the adjudicative proceedings governed by chapter 34.05 RCW and chapter 246-08 WAC.
(2) "Analytical data" means the recorded qualitative and/or quantitative results of a chemical, physical, biological, microbiological, or radiological determination.
(3) "Certification" means the formal contractual agreement between the department and the certified laboratory indicating a laboratory is capable of producing accurate analytical data and is authorized to test drinking water compliance samples. The department will issue a certificate to the laboratory indicating the contaminants the laboratory is authorized to analyze. Certification does not guarantee validity of analytical data submitted by a certified laboratory.
(4) "Certification authority" means the designated official or a representative of the official authorized by the department as the head of the certification program.
(5) "Certification manual" means the most recent revision of the procedural and technical criteria of the drinking water certification rules. This document, entitled "Certification Manual for Laboratories Analyzing Washington State Drinking Water," is available from the Department of Health, Public Health Laboratory, Drinking Water Certification Program, 1610 NE 150th St., Seattle, Washington 98155-7224.
(6) "Certification official (CO)" means the designated official authorized by the department to certify drinking water laboratories.
(7) "Compliance sample" means a drinking water sample collected in accordance with WAC 246-290-300 and/or 246-290-320 and submitted to a state certified laboratory for analysis.
(8) "Department" means the Washington state department of health.
(9) "EMSL-CI" means the EPA Environmental Monitoring and Support Laboratory, Cincinnati, Ohio.
(10) "EMSL-LV" means the EPA Environmental Monitoring System Laboratory, Las Vegas, Nevada.
(11) "EPA" means United States Environmental Protection Agency.
(12) "Intercomparison studies" means a series of cross check samples sent to radiochemistry laboratories by EPA to compare the results between participating laboratories.
(13) "Laboratory" means any facility under the ownership and technical management of a single entity in a single geographical locale. A laboratory is where scientific examinations are performed on drinking water samples.
(14) "Maximum contaminant level (MCL)" means the maximum permissible level of a contaminant in water the purveyor delivers to any public water system user, measured at the location identified under WAC 246-290-300, Table 4.
(15) "Official methods" means methodologies specified by EPA drinking water regulations under 40 C.F.R. 141.21 - 141.30, 141.41 - 141.42, 7/1/90 and approved by the department.
(16) "Parameter" means a single determination or group of related determinations using a specific written official method.
(17) "Performance evaluation (PE)" means an evaluation of the results of analysis of samples from an external testing source whose true values are unknown to the laboratory conducting the analysis. The external testing service must be approved by the department and/or CO if other than EPA sources are used.
(18) "On-site audit" means an on-site inspection performed by the department to determine a laboratory's capabilities and facilities.
(19) "Quality assurance (QA)" means all those planned and systematic actions necessary to provide confidence that an analysis, measurement, or surveillance program produces data of known and defensible quality.
(20) "Quality controls (QC)" means internal written procedures and routine analyses of laboratory reference materials, samples, and blanks to insure precision and accuracy of methodology, equipment and results.

(11/17/92)
246-390-020  Drinking Water Certification Rules

WAC 246-390-020 Requirement for certification. (1) Certification officers are required to meet EPA requirements for drinking water certification as described in the latest version of the Manual for the Certification of Laboratories Analyzing Drinking Water, EPA/570/9-90/008, 4/90.

(2) Applicants for laboratory certification shall submit to the department:
(a) An application fee as specified in WAC 246-390-990;
(b) A written application which includes one of the following:
(i) A request for first-time certification;
(ii) A request for certification to analyze additional or newly regulated contaminants; or
(iii) A request to reapply for certification after correction of deficiencies which resulted in the downgrading or revocation of certification status, or after lapse of previous contract; and
(c) A QA plan as specified in subsection (6) of this section.

(3) Applicants for routine renewal shall submit to the department at least three months before expiration of the contract:
(a) A renewal fee as specified in WAC 246-390-990;
(b) A written application which includes:
(i) Name and address of each laboratory or testing site;
(ii) Owner's name, address, and contact person;
(iii) List of parameters to be certified;
(iv) Completed personnel training and experience forms;
(v) List of methods used;
(vi) Copy of QA manual; and
(vii) List of equipment;
(c) Verification of the successful performance of PE studies as specified in subsection (4) of this section; and
(d) A QA plan, if changes have been made since the plan was last submitted to the department.

(4) Laboratory approved personnel shall participate in EPA Water Supply, EMSL-CI, EMSL-LV, or other department approved PE studies at least once annually for microbiological and twice annually for chemistry and radiochemistry laboratories as described in the certification manual. Radiochemistry laboratories must also participate in two intercomparison studies per year.

(5) Laboratory directors shall allow on-site audit by the CO as follows:
(a) At least every three years;
(b) Announced or unannounced;
(c) At contract renewal; or
(d) At the discretion of the CO.

(6) Laboratory directors shall submit a QA plan with a section specific to drinking water with initial application; at contract renewal, if changes have been made; or at the discretion of the CO. The QA plan or manual shall follow EPA and state requirements, as described in the certification manual.

(7) Laboratory personnel shall notify the CO in writing within thirty days of major changes to analytical staff management including:
(a) Moving facilities;
(b) Loss or replacement of the laboratory supervisor;
(c) A situation in which a trained and experienced analyst no longer is available to analyze a particular parameter for which certification had been granted;
(d) Loss or replacement of major equipment; and
(e) Any other situation described in the certification manual that would affect laboratory operations.

(8) Laboratories shall meet the following minimum workload requirements for each certified parameter:
(a) Microbiological laboratories to analyze a minimum of fifteen water samples per quarter that are positive for both total and fecal coliform.
(b) Chemistry and radiochemistry laboratories to analyze five water samples per quarter. These workload requirements shall not include PE samples. Laboratories must assure the CO that proper QA/QC was followed, and official drinking water methods were used. See certification manual for further explanation.

(9) Laboratory personnel shall follow official EPA methods, or EPA approved alternate analytical techniques, as described in the certification manual.

(10) Laboratory personnel shall accurately report analytical results of compliance samples in a timely manner as described in the certification manual using:
(a) The department specified format; and
(b) Electronic or hard copy transmission.

(11) Laboratories shall follow the standard of quality requirements as described in the certification manual.

[Statutory Authority: RCW 43.20.050. WSR 92-15-152 (Order 290B), § 246-390-020, filed 7/22/92, effective 8/22/92.]

WAC 246-390-030 Certification. (1) The department may grant certification to a laboratory after conducting a complete assessment of the laboratory's capabilities, including:
(a) Submission of a completed application;
(b) Submission of the proper fees;
(c) Satisfactory performance on PE studies, and intercomparison samples where necessary;
(d) Submission of an updated QA plan; and
(e) Successful completion of an on-site inspection.

(2) The department may grant less than full certification based on terms and conditions incorporated in the contractual agreement between the laboratory and the department.

[Statutory Authority: RCW 43.20.050. WSR 92-15-152 (Order 290B), § 246-390-030, filed 7/22/92, effective 8/22/92.]

WAC 246-390-040 Provisional certification. Laboratories which have deficiencies requiring corrective action but which can produce valid analytical data as determined by the CO may be given provisional certification. The department may downgrade a laboratory to provisional certification for failure to:

(1) Analyze a PE sample and/or an intercomparison sample, or any other unknown test sample within the acceptance
limits established by the EPA and/or the department. Failure on a mandatory PE sample is defined as a failure on any concentration provided, unless otherwise specified by the EPA and/or the department. The laboratory shall be given an opportunity to request a make-up PE or QC sample before the CO takes action.

(2) Notify the CO in writing within thirty days of major change impairing analytical capability, such as personnel, equipment, or location.

(3) Demonstrate that the laboratory maintains the required standard of quality, based upon an on-site evaluation. See certification manual for minimum standard of quality requirements.

(4) Promptly send reports of analysis to the department as described in the certification manual.

(5) Promptly notify the public water system by the end of the business day, or the department if the public water system cannot be notified, of results exceeding MCL or SAL. For all results exceeding MCL or SAL the laboratory must notify the department as soon as possible.

[Statutory Authority: RCW 43.20.050. WSR 92-15-152 (Order 290B), § 246-390-040, filed 7/22/92, effective 8/22/92.]

WAC 246-390-050 Revoking or denying certification. Action shall be taken consistent with the contract, with 40 C.F.R. 142.10 7/1/90, EPA Manual, RCW 43.20.050, and chapter 246-08 WAC. The department may immediately downgrade laboratories from certified or provisionally certified to not certified, or may deny certification for a particular contaminant analysis or group of contaminants, for the following reasons:

(1) Two consecutive failures to analyze a PE sample or intercomparison sample or any other unknown test sample for a particular contaminant within the acceptance limits established by EPA and/or the department. The laboratory shall be given an opportunity to request a make-up PE or QC sample before the CO takes final action. The decision to revoke certification shall be made at the discretion of the CO after examination of all information.

(2) Failure to demonstrate to the CO that the laboratory has corrected deficiencies identified during an on-site evaluation within:

(a) Three months to correct a procedural or administrative deficiency; and
(b) Six months to correct an equipment deficiency. If the equipment or instrument involved is the only instrument available for a particular analysis, certification may be downgraded immediately, at the discretion of the CO.

(3) Submission of a PE sample to another laboratory for analysis and reporting data as its own.

(4) Failure to use analytical methodology specified in the certification manual.

(5) Failure to submit an appropriate application and associated fees to the department.

(6) Failure to pass a re-audit and correct deficiencies if the laboratory is found deficient in its ability to provide accurate analytical data.

(7) Justifiable evidence of falsification of data or any other practice considered deceptive by the department.

(8) Failure to comply with other provisions of the contractual agreement between the department and the laboratory.

(9) Failure to correct deficiencies quoted in a revoked certificate before reapplying for certification.

(10) Failure to permit entry of a CO or CO's representative for an on-site audit to examine methods, facilities, equipment, and analytical data.

[Statutory Authority: RCW 43.20.050. WSR 92-15-152 (Order 290B), § 246-390-050, filed 7/22/92, effective 8/22/92.]

WAC 246-390-060 Reciprocity. The department may recognize certification of an out-of-state laboratory by another primacy state with which the department has an established mutual reciprocity agreement. The laboratory shall submit an application and a fee as specified in WAC 246-390-990; perform approved PE studies; follow the workload requirements; and follow drinking water methods per WAC 246-390-020. A laboratory accepted under the reciprocity agreement shall enter into a contract with the department.

[Statutory Authority: RCW 43.20.050. WSR 92-15-152 (Order 290B), § 246-390-060, filed 7/22/92, effective 8/22/92.]

WAC 246-390-070 Third-party certification. The department shall recognize only the certification officials authorized and approved by the department. See certification manual for recognized and approved certification officials. Laboratories requesting third party certification shall submit an application; perform approved PE studies; follow the workload requirements; and follow drinking water methods per WAC 246-390-020.

[Statutory Authority: RCW 43.20.050. WSR 92-15-152 (Order 290B), § 246-390-070, filed 7/22/92, effective 8/22/92.]

WAC 246-390-100 Appeals. A laboratory manager may appeal any certification action such as denial and revocation in writing to the CO. If the question is not satisfactorily resolved, the laboratory manager may appeal in writing by certified mail to the certification authority within thirty days of the decision of the CO. Decisions of the certification authority may be appealed to the secretary of the department within thirty days of notification of final action. The adjudication procedure is governed by the Administrative Procedure Act, this chapter, and chapter 246-08 WAC. Laboratories may be allowed to maintain certification during the appeal process.

[Statutory Authority: RCW 43.20.050. WSR 92-15-152 (Order 290B), § 246-390-100, filed 7/22/92, effective 8/22/92.]

WAC 246-390-990 Fees. The fees in this section are established in accordance with RCW 43.70.250 to defray the department's costs associated with certifying laboratories. The department shall review the fee structure annually and may modify the fees as necessary to reflect current administrative costs.

(1) On-site inspections shall not be conducted nor shall provisional or other certifications be granted until appropriate fees have been received by the department.

(11/17/92)
(2) Out-of-state laboratories requesting reciprocity shall pay a fee of one hundred dollars.

(3) Out-of-state laboratories in states which have not established a reciprocity agreement with Washington shall follow the fee schedule in this section and pay all travel costs for the CO for any necessary on-site inspections.

(4) The following fees are due upon application and at the time of each renewal:

**BASE FEE OF $100 PLUS THE FOLLOWING SCHEDULE**

<table>
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<tr>
<th>Category</th>
<th>Parameter</th>
<th>Fee/Parameter</th>
<th>Max. Fee per Category</th>
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<td>Physical Characteristics</td>
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<td>Residual Disinfection</td>
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<td>Organic Contaminants (Insecticides)</td>
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[Statutory Authority: RCW 43.20.050. WSR 92-23-060 (Order 313), § 246-390-990, filed 11/17/92, effective 12/18/92.]