

Chapter 173-50 WAC

ACCREDITATION OF ENVIRONMENTAL LABORATORIES

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WAC

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DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

- 173-50-160 Reciprocity. [Statutory Authority: RCW 43.21A.230.
WSR 02-20-090 (Order 01-12), § 173-50-160, filed
10/1/02, effective 11/1/02; WSR 89-10-001 and 90-07-
017 (Order 89-1 and 89-1A), § 173-50-160, filed
4/20/89 and 3/13/90, effective 4/13/90.] Repealed by
WSR 10-17-032 (Order 09-09), filed 8/9/10, effective

9/9/10. Statutory Authority: RCW 43.21A.230,
43.20.050 and 2009 c 564 § 301.

173-50-180 Exemptions. [Statutory Authority: RCW 43.21A.230.
WSR 02-20-090 (Order 01-12), § 173-50-180, filed
10/1/02, effective 11/1/02; WSR 89-10-001 and 90-07-
017 (Order 89-1 and 89-1A), § 173-50-180, filed
4/20/89 and 3/13/90, effective 4/13/90.] Repealed by
WSR 10-17-032 (Order 09-09), filed 8/9/10, effective
9/9/10. Statutory Authority: RCW 43.21A.230,
43.20.050 and 2009 c 564 § 301.

WAC 173-50-010 Purpose. Department of ecology, department
of health, and other entities require persons and organizations
submitting analytical data under the purview of their programs
to use environmental laboratories which are accredited. The
purpose of this chapter is to establish a state program for
accreditation of environmental laboratories which conduct tests
and submit data to the department of ecology, the department of
health, and other entities which require the use of accredited

laboratories. The accreditation program is designed to satisfy the intent of RCW 43.21A.230 and 43.21A.445.

[Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-010, filed 10/1/02, effective 11/1/02; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-010, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-020 Scope. (1) The Washington state environmental laboratory accreditation program (WA ELAP) applies to laboratories which conduct tests for or prepare analytical data for submittal to any entity requiring the use of an accredited laboratory. This includes laboratories that analyze drinking water.

(2) Accreditation in itself does not authorize use of a specific method for any specific program or project. If such authorization is not granted in documentation governing a program or project within which samples are being analyzed, authorization should be obtained from the laboratory's data user.

(3) Accreditation does not guarantee validity of analytical data submitted by the accredited laboratory but rather assures

that the laboratory has demonstrated its capability to reliably generate and report the analytical data (WAC 173-50-040, definition of "accreditation").

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-020, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-020, filed 10/1/02, effective 11/1/02; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-020, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-030 Objectives. Objectives of the WA ELAP are to:

- Assure accredited laboratories have a demonstrated capability to accurately and defensibly analyze environmental samples;
- Assist environmental laboratories in improving their quality assurance/quality control procedures; and
- Foster cooperation between the state departments of ecology and health, local agencies, other users of environmental data, and operators of environmental laboratories.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-030, filed 8/9/10,

effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-030, filed 10/1/02, effective 11/1/02; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-030, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-040 Definitions. Definitions in this section apply throughout this chapter, unless context clearly indicates otherwise.

"Accreditation" - The formal recognition by the department that an environmental laboratory is capable of producing accurate and defensible analytical data. This recognition is signified by issuance of a written certificate accompanied by a scope of accreditation indicating the parameters for which the laboratory is accredited.

- The term "accredit" as used in this chapter is intended to have the same meaning as the term "certify" as used in RCW 43.21A.230.

- Any laboratory accredited under this chapter shall be deemed to have been certified under RCW 43.21A.230.

- The department does not, by accrediting any laboratory pursuant to these rules, vouch for or warrant the accuracy of any particular work done or report issued by that laboratory.

"Accreditation year" - The one-year period as stated on the certificate of accreditation.

"Accuracy" - The degree to which an analytical result corresponds to the true or accepted value for the sample being tested. Accuracy is affected by bias and precision.

"Analyte" - The constituent or property of a sample measured using an analytical method.

"Analytical data" - The recorded qualitative and/or quantitative results of a chemical, physical, biological, microbiological, radiochemical, or other scientific determination.

"Analytical method" or "method" - A written procedure for acquiring analytical data.

"Calibration Curve" - A series of solutions of known analyte concentrations used to determine the relationship between concentration and analytical response.

"Data traceability" or "traceability" - The ability to recreate the final result by means of records. This must be an unbroken trail of accountability for verifying or validating the chain of custody of samples, the data, the documentation of a procedure, or the values of a standard.

"Department" - The state of Washington department of ecology when the term is not followed by another state designation.

"Drinking water certification manual" - The Environmental Protection Agency *Manual for the Certification of Laboratories Analyzing Drinking Water*, 5th Edition, January 2005.

"Ecology accrediting authority" - The supervisor of the lab accreditation unit of the environmental assessment program of the department of ecology.

"Environmental laboratory" or "laboratory" - A facility:

- Under the ownership and technical management of a single entity in a single geographical location or in a self-contained mobile unit;

- Where scientific determinations are performed on samples taken from the environment, including drinking water samples; and

- Where data is submitted to the department of ecology, department of health, or other entity requiring the use of an accredited laboratory under provisions of a regulation, permit, or contractual agreement.

"Lab accreditation unit" - The lab accreditation unit of the department of ecology.

"Instrument" or "instrumentation" - Equipment used to quantitatively measure an analyte.

"Laboratory Control Sample" or "LCS" - An aliquot of analyte-free water or analyte-free solid (e.g., Ottawa sand, anhydrous sodium sulfate, or other purified solid) to which known amounts of the method analytes are added.

"Limit of Quantitation" or "LOQ" - The lowest point of quantitation which, in most cases, is the lowest concentration in the calibration curve.

"Matrix" - The material to be analyzed, including, but not limited to, ground or surface water, wastewater, drinking water,

air, solid waste, soil, tissue, nuclear waste, and hazardous waste. For the purposes of establishing a fee structure (WAC 173-50-190(4)), matrices are grouped as follows:

- Nonpotable water;
- Drinking water;
- Solid and chemical materials; and
- Air and emissions.

"Matrix Spike" or "MS" - Matrix spikes are aliquots of environmental samples to which known concentrations of certain target analytes have been added before sample preparation, cleanup, and determinative procedures have been implemented.

"Method Detection Limit" or "MDL" - The minimum concentration of an analyte that can be measured and reported with a 99% confidence that the analyte concentration is distinguishable from the method blank results as determined by the procedure set forth in Appendix B of 40CFR 136.

"On-site audit" - An on-site inspection and evaluation of laboratory facilities, equipment, records and staff.

"Out-of-state laboratory" - A laboratory that is not located in the state of Washington.

"Parameter" - The combination of one or more analytes determined by a specific analytical method. Examples of parameters include:

- The analyte alkalinity by method SM 2320 B;
- The analyte zinc by method EPA 200.7;
- The set of analytes called volatile organic compounds (VOCs) by method EPA 8260; and
- The analyte Total Coli/Ecoli-count by method SM 9222 B/9221 F.

"Principal laboratory" - A laboratory designated by the Washington department of health to support the drinking water certification program.

"Procedural manual" - The *Department of Ecology's Procedural Manual for the Environmental Laboratory Accreditation Program* dated September 2010.

"Proficiency testing (PT)" - Evaluation of the results from the analysis of samples, the true values of which are known to the supplier of the samples but unknown to the laboratory conducting the analyses. PT samples are provided by a source external to the environmental laboratory.

"Quality assurance (QA)" - Activities intended to assure that a quality control program is effective. A QA program is a totally integrated program for assuring reliability of measurement data.

"Quality assurance (QA) manual" - A written record intended to assure the reliability of measurement data. A QA manual documents policies, organization, objectives, and specific QC and QA activities. Volume and scope of QA manuals vary with complexity of the laboratory mission.

"Quality control (QC)" - The routine application of statistically based procedures to evaluate and control the accuracy of analytical results.

"Regulatory program" - A program administered by a federal, state, or other regulatory agency.

"Standard Operating Procedure" or "SOP" - A detailed written description of a procedure designed to systematize performance of the procedure.

"Third-party accreditation" - Recognition by the ecology accrediting authority of accreditation granted by another accrediting authority.

"WA ELAP" - Washington state environmental laboratory

accreditation program.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-040, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-040, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-040, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-040, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-040, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-050 Responsibilities of the department. (1)

The department maintains a procedural manual describing specifics of the accreditation process. As a minimum, the procedural manual describes the procedures for:

- Submitting an application and fee;
- Preparing a quality assurance manual;
- Performing proficiency testing;
- Conducting on-site audits;
- Accrediting out-of-state laboratories;

- Granting, denying, suspending, and revoking accreditation; and

- Notifying laboratories and authorized government officials of accreditation actions.

The department will make the procedural manual available to all interested persons.

(2) Department personnel assigned to assess the capability of drinking water laboratories participating in the WA ELAP must meet the experience, education, and training requirements established in the drinking water certification manual.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-050, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-050, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-050, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-050, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-050, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-060 Responsibilities of environmental laboratories. (1) When applying for initial accreditation (see

WAC 173-50-130 for maintaining an existing accreditation),
managers of environmental laboratories must:

- Submit an application (WAC 173-50-063) and required fees (WAC 173-50-190) to the department fiscal officer;
- Submit a copy of the laboratory's quality assurance manual (WAC 173-50-067);
- Submit an initial set of satisfactory PT sample results (WAC 173-50-070); and
- Undergo an on-site audit (WAC 173-50-080).

(2) For laboratories to be accredited for drinking water parameters, the laboratory must be compliant with the current version of the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-060, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-060, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-060, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-060, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-050-061 Required quality control practices.

Laboratories must comply with the following quality control practices:

(1) Have a dedicated SOP for each method listed on their current Washington scope of accreditation.

(2) A laboratory must not remove any midpoints from a calibration curve with the exception of consecutive points at either end of the curve.

(3) Each calibration point must have its value recalculated against the calibration curve. Unless specified in the method, each calibration point must have its percent error meet the calibration verification acceptance limits from the method; with the exception of the lowest point which is 50-150%.

(4) Laboratories must analyze a standard at their limit of quantitation at least annually. This standard must meet 50% of the true value. This applies to the following instrumentation technologies:

(a) Atomic absorption;

(b) Flow-injection analysis;

(c) Gas and liquid chromatography;

(d) Inductively coupled plasma;

(e) Ion chromatography;

(f) Spectrometry;

(g) Total organic carbon analysis; and

(h) Any other technology where method detection limits are applicable

(5) Matrix spikes are required as specified by the method.

Observed matrix issues must be addressed.

(6) Laboratory control samples and matrix spikes must include all analytes of interest in the respective analysis.

(7) Documented resolution of spectral interferences is required for ICP-OES.

WAC 173-50-063 Application. (1) Through the application, laboratory managers:

- Request accreditation for specific parameters;
- Calculate fees due to the department; and

- Provide evidence that sufficient personnel and equipment are available to successfully perform analytical methods as specified in the application.

(2) Through review of the application submitted by the applicant laboratory, the lab accreditation unit determines if:

- Requested parameters are eligible for accreditation;
- The fee calculated by the applicant laboratory is correct; and

- Personnel and equipment are adequate to support successful performance of requested parameters.

(3) Following the review, the lab accreditation unit advises the applicant laboratory of any required changes.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-063, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-063, filed 10/1/02, effective 11/1/02.]

WAC 173-50-067 Quality assurance manual. (1) The lab accreditation unit reviews and approves the laboratory's QA manual prior to the initial on-site audit. The QA manual submitted concurrently with the application must be in detail

and scope commensurate with the size and mission of the laboratory. Guidelines for contents of the QA manual are in the procedural manual.

(2) The QA manual must address QA and QC requirements of applicable regulatory programs. For drinking water laboratories, such requirements are found in the drinking water certification manual.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-067, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-067, filed 10/1/02, effective 11/1/02.]

WAC 173-55-069 Data and record traceability.

(1) In order to demonstrate data traceability, laboratories must:

(a) Be able to recreate final sample results by means of records in entirety;

(b) Document proper storage of any chemical used by a method;

(c) Document proper storage of samples as required by the specific method;

(d) Document that all temperature-based equipment such as a refrigerator, oven, or incubator is both within control and checked manually as required by the relevant method; and

(e) Keep logbooks for any and all instruments, including documentation of installation, setup, maintenance, and removal from service.

(2) When records are hand-written, they must be in indelible ink and comply with the relevant method requirements. Incubator temperatures must be handwritten and include the date and time of reading, temperature, and technician's initials.

(3) When records are kept electronically, they must be populated at the time of record, using a fully traceable and secure format. Use of continuous data-loggers is not an acceptable substitute for method-required temperature checks.

WAC 173-50-070 Proficiency testing (PT). (1) The lab accreditation unit advises applying laboratories of specific requirements for participation in proficiency testing (PT) studies for applicable parameters. Proficiency tests conducted under the provisions of other recognized programs may be used to

satisfy these requirements. The lab accreditation unit determines the sufficiency of such proficiency tests.

(2) Accredited laboratories must analyze a minimum of one PT sample per applicable microbiology parameter per year and two PT samples for applicable chemistry parameters per year. For chemistry parameters, after an accredited laboratory submits two satisfactory PT sample results and no unsatisfactory results in an accreditation year, the laboratory is required to submit only one satisfactory PT sample result in subsequent accreditation years. This applies as long as there are no intervening unsatisfactory PT sample results.

(3) The lab accreditation unit may require the laboratory to submit raw data along with the report of analysis of PT samples.

(4) The lab accreditation unit may waive proficiency tests for certain parameters if PT samples are not readily available or for other valid reasons.

(5) Applying laboratories are responsible for obtaining PT samples from vendors approved by the lab accreditation unit. No

fee shall be charged to the department for the purchase or analysis of PT samples.

(6) PTs must undergo the identical preparation and analytical processes that are used for samples.

(7) When two approved PT providers are available for a parameter, the laboratory must analyze and pass a PT to gain or maintain accreditation.

(8) Presence-absence microbiology parameters must pass all ten replicates in their PTs to be considered acceptable.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-070, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-070, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-070, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-070, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-070, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-080 On-site audit. The laboratory must undergo an on-site audit by the department to assess critical elements and areas of recommended practices. The laboratory must

assist/accommodate department of ecology personnel during on-site audits as required.

(1) **Critical elements for accreditation.** Elements of an environmental laboratory's operations which are critical to the consistent generation of accurate and defensible data are critical elements for accreditation. Critical elements are subject to intense scrutiny throughout the accreditation process. The ecology accrediting authority may deny, revoke, or suspend accreditation for deficiencies in critical elements. Functional areas including critical elements are:

(a) **Analytical methods.** The on-site audit seeks to determine if documentation of analytical methods:

- Are present at the laboratory;
- Readily available to analysts; and
- Being implemented. If the laboratory is using a locally developed method, the on-site audit may include an evaluation of the adequacy of that method.

(b) **Equipment and supplies.** The on-site audit seeks to determine if sufficient equipment and supplies as required by analytical methods are:

- Available;
- Being adequately maintained; and
- In a condition to allow successful performance of applicable analytical procedures.

To gain and maintain accreditation, laboratories must demonstrate that equipment and supply requirements of applicable regulatory programs are being met.

(c) **QA and QC records.** The on-site audit includes a review of QA and QC records for programs/projects within which the laboratory is generating analytical data for submission to the data user.

(d) **Sample management.** The on-site audit includes a review of applicable procedures for receipt, preservation, transportation, and storage of samples. The laboratory is responsible only for those elements of sample management over which it has direct control. To gain and maintain accreditation, laboratories must demonstrate that sample management requirements of applicable regulatory programs are being met.

(e) **Data management.** The on-site audit includes a review of activities necessary to assure accurate management of laboratory data including:

- Raw data;
- Calculations; and
- Transcription, computer data entry, reports of analytical results.

To gain and maintain accreditation, laboratories must demonstrate that data management requirements of applicable regulatory programs are being met.

(2) **Recommended practices.** Recommended practices are those elements of laboratory operations which might affect efficiency, safety, and other administrative functions, but do not normally affect quality of analytical data. Normally these practices would not be the basis for denial or revocation of accreditation status. Functional areas within which recommended practices may be noted are:

(a) **Personnel.** The department seeks to determine if managerial, supervisory, and technical personnel have adequate training and experience to allow satisfactory completion of

analytical procedures and compilation of reliable, accurate data. Minimum recommended education and experience criteria for laboratory personnel are specified in the procedural manual.

(b) **Facilities.** The department seeks to determine if laboratory facilities allow efficient generation of reliable, accurate data in a safe environment.

(c) **Safety.** The department may refer serious safety deficiencies to appropriate state or federal agencies.

(3) **Drinking water laboratory requirements.** For laboratories applying for accreditation of drinking water parameters, on-site audit requirements are those designated in the drinking water certification manual. If such a standard is more stringent than the corresponding standard in this chapter, the drinking water certification manual applies.

(4) **Documentation requests.** Laboratories must submit requested documentation at least two weeks prior to the scheduled start date of an audit. At a minimum this includes:

(a) Standard Operating Procedures for all methods being audited;

(b) Analytical data for each method being audited; and

(c) Additional documentation as requested by the
department.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-080, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-080, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-080, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-080, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-080, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-090 Evaluation and issuance of certificate.

(1) After preliminary requirements (WAC 173-50-060 through 173-50-080) have been met, the lab accreditation unit submits a report to the affected laboratory concerning the results of the overall accreditation process. The report may:

- List findings;
- Assess the importance of each finding; and
- Make recommendations concerning actions necessary to assure resolution of problems.

(2) After completing the accreditation review, the ecology accrediting authority decides whether accreditation should be granted.

(a) If accreditation is warranted, the department issues a certificate and accompanying scope of accreditation. The certificate remains the property of the department and must be surrendered to the department upon revocation or voluntary termination of accreditation status.

(b) If accreditation is not warranted, the department issues a report specifying areas of deficiency and steps necessary to upgrade the laboratory to accredited status. In such cases, the laboratory must provide documentation that the specified deficiencies have been corrected. Based on such documentation the ecology accrediting authority decides whether to grant or deny accreditation.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-090, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-090, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-090, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-090, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and

90-07-017 (Order 89-1 and 89-1A), § 173-50-090, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-100 Interim accreditation. If the department is unable to complete the accreditation process through no fault of the laboratory, the ecology accrediting authority may grant interim accreditation. To be considered for interim accreditation, the laboratory must:

- Submit an application and applicable fees;
- Successfully complete applicable proficiency tests; and
- Submit a QA manual that meets the requirements of WAC

173-050-067.

The lab accreditation unit may also require the laboratory to submit an analytical data package as evidence of analytical capability.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-100, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-100, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-100, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-100, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and

90-07-017 (Order 89-1 and 89-1A), § 173-50-100, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-110 Provisional accreditation. (1) The ecology accrediting authority may grant provisional accreditation to laboratories which can consistently produce valid analytical data but have deficiencies requiring corrective action. When the laboratory has corrected such deficiencies, it must provide evidence of correction to the lab accreditation unit, or request a follow-up on-site audit, as appropriate. If the lab accreditation unit determines the deficiencies have been corrected, the ecology accrediting authority awards full accreditation as in WAC 173-50-090.

(2) The ecology accrediting authority may renew a provisional accreditation for a subsequent accreditation period if laboratory management has demonstrated that all reasonable measures to correct deficiencies have been exhausted.

(3) For drinking water laboratories, specific conditions warranting provisional accreditation and specific actions required of the laboratory when provisional accreditation is granted are found in the drinking water certification manual.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-110, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-110, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-110, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-110, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-120 Accreditation categories. (1)

Environmental laboratories are accredited within one or more of the matrix groups defined in WAC 173-50-040. Within each matrix group, accreditation is granted within the following broad categories:

- General chemistry;
- Trace metals;
- Organics I;
- Organics II (Category II methods use mass spectrometer detectors);
- Microbiology;
- Radiochemistry;
- Bioassay;

- Immunoassay; and
- Physical.

Within these categories, laboratories are specifically accredited for well-defined parameters, such as, but not limited to, those suggested in the procedural manual, using specific analytical methods or sampling techniques chosen by the applying laboratory.

(2) The scope of accreditation accompanying the accreditation certificate indicates the parameters for which the laboratory is accredited, and any applicable qualifications, such as interim or provisional accreditation.

(3) The scope of accreditation also indicates the matrix groups within which each parameter applies. Those matrix groups may include, but are not limited to:

- Nonpotable water;
- Drinking water;
- Solid and chemical materials; and
- Air and emissions.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-120, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-

20-090 (Order 01-12), § 173-50-120, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-120, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-120, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-120, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-130 Requirements for maintaining accreditation

status. (1) Accreditation is granted for a one-year period (the accreditation year) and expires one year after the effective date of accreditation.

(2) Renewal requires the laboratory to submit:

- An application and appropriate fees;
- An update of the laboratory's QA manual if applicable;
- Evidence of accreditation by a third party when

appropriate; and

- Successful completion of proficiency testing requirements.

(3) For laboratories accredited for drinking water parameters, on-site audits are required at periods not to exceed three years from the previous on-site audit.

(4) For laboratories not accredited for drinking water parameters, the schedule of on-site audits will be determined by the ecology accrediting authority.

(5) For laboratories planning to change their location, the department must be notified 30 days prior to the need for accreditation at the new location. At the time of the laboratory move, all accredited parameters are placed into interim status pending successful completion of an audit. For instrumental analysis methods laboratories must take the following actions after a move:

(a) Conduct new MDL studies for all parameters at the new location;

(b) Pass a PT for all parameters at the new location;

(c) Update SOPs for all changed parameters, if there are any revisions to the SOPs due to the laboratory move; and

(d) Update third-party scope(s), if applicable.

(6) If the laboratory move includes a merger with another accredited laboratory, the department must be notified sixty days prior to the need for accreditation.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-130, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-130, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-130, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-130, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-130, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-140 Denying accreditation. (1) The ecology accrediting authority may deny accreditation if the applicant laboratory:

- Fails to comply with standards for critical elements of the on-site audit;
- Misrepresents itself to the department;
- Fails to disclose pertinent information in the application;
- Falsifies reports of analysis including proficiency testing results;
- Engages in unethical or fraudulent practices concerning generation of analytical data;

- Is deficient in its ability to provide accurate and defensible analytical data; or

- Fails to render applicable fees.

(2) A laboratory may be denied accreditation for a specific parameter for unsatisfactory proficiency testing results.

(3) Laboratories denied accreditation may appeal under the provisions of WAC 173-50-200. If an appeal does not result in action favorable to the laboratory, and following correction of deficiencies, laboratories denied accreditation may reapply for accreditation to include payment of appropriate fees as determined in WAC 173-50-190.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-140, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-140, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-140, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-140, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-150 Revoking or suspending accreditation. (1)

Revocation of accreditation is the withdrawal of a previously

granted accreditation. Revocation may involve the entire laboratory or one or more individual parameters.

(2) Suspension of accreditation is for a specified period during which the affected laboratory corrects deficiencies that led to the suspension. Suspension may involve the entire laboratory, or one or more individual parameters.

(3) The ecology accrediting authority may suspend or revoke accreditation if the accredited laboratory:

- Fails to comply with standards for critical elements of an on-site audit;
- Violates a state rule relative to the analytical procedures for which it is accredited;
- Misrepresents itself to the department;
- Falsifies reports of analysis including proficiency testing results;
- Engages in unethical or fraudulent practices concerning generation of analytical data;
- Is deficient in its ability to provide accurate and defensible analytical data;

- Refuses to permit entry for enforcement purposes (WAC 173-50-210);

- Fails to render applicable fees;
- Fails to maintain third-party accreditation; or
- Reports two consecutive unsatisfactory PT sample results.

(4) A laboratory having had its accreditation suspended or revoked may appeal under the provisions of WAC 173-50-200. If an appeal does not result in action favorable to the laboratory, and following correction of deficiencies, a laboratory having had its accreditation revoked may reapply for accreditation to include payment of appropriate fees as determined in WAC 173-50-190.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-150, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-150, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-150, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-150, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-170 Third-party accreditation. (1) The department may recognize accreditation (or certification, registration, licensure, approval) of a laboratory by a third party when the accreditation process is determined to be equivalent to that described in this chapter.

(2) Laboratories applying for recognition of a third party's accreditation submit:

- An application and associated fee (WAC 173-50-190(7));
- A copy of the third party's certificate;
- A copy of the third party's scope of accreditation;
- A copy of the third party's most recent on-site audit report;
- A copy of the laboratory's corrective action report relative to the on-site audit, if applicable; and
- Recent, satisfactory proficiency test results for the applicable parameters.

(3) In consideration of a request to recognize a third party's accreditation as the basis for accreditation by the ecology accrediting authority, the lab accreditation unit reviews the application and supporting documentation to assure

compliance with minimum accreditation requirements as stated in this chapter. If the review is favorable, a certificate and scope of accreditation are granted as in WAC 173-50-090.

(4) Laboratories granted third-party accreditation must notify the laboratory accreditation unit immediately of changes in the status of their third-party accreditation.

(5) Washington laboratories accredited or applying for accreditation in recognition of a third party's accreditation must notify the lab accreditation unit of on-site audits scheduled by the third party and allow a department observer to attend such on-site audits.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-170, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-170, filed 10/1/02, effective 11/1/02; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-170, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-190 Fee structure. (1) Fees in this chapter are in U.S. dollars and are established to cover costs of administering the WA ELAP. Fees shall be assessed for each parameter or method within each matrix, except as noted in

subsection (3) of this section. The fee per parameter or method for each category, ~~and the maximum fee per category where applicable,~~ are identified in Table 1.

(2) Examples of parameters or methods for each category are published in the procedural manual. Accreditation may be requested for parameters in addition to those listed in the procedural manual.

(3) When a fee is assessed for a specific drinking water parameter or method, the laboratory may be accredited for the same parameter or method in nonpotable water without paying an additional fee.

TABLE 1 - FEE SCHEDULE

CATEGORY	FEE PER PARAMETER	FEE PER PARAMETER ADD FEE TO EXISTING METHOD	MAX FEE PER CATEGORY METHOD
General Chemistry	\$80 <u>\$245</u>	—	\$1,600
Trace Metals	—	\$400 <u>\$60</u>	\$1,230
Organics I	—	\$200 <u>\$35</u>	\$615
Organics II	—	\$500 <u>\$70</u>	\$1,540
Microbiology	\$200 <u>\$615</u>	—	—
Radiochemistry	\$250 <u>\$770</u>	—	—
Bioassay	\$300 <u>\$925</u>	—	\$3,000
Immunoassay	\$80 <u>\$245</u>	—	—
Physical	\$80 <u>\$245</u>	—	—

(4) The minimum fee for accreditation, either direct or through recognition of a third-party accreditation, is ~~three~~ five hundred dollars.

(5) In addition to paying the fee indicated in Table 1, out-of-state laboratories must pay for the actual cost of travel associated with on-site audits. The department invoices the laboratory for such costs after completion of the on-site audit.

(6) For laboratories that have not been accredited for any parameter by the department in the previous twelve months, ~~the~~ laboratory must pay an application fee of three hundred dollars ~~applicable fees~~ before:

- Its quality assurance manual is reviewed by the department;
- The on-site audit is conducted if applicable; and
- Interim, provisional, or full accreditation is granted.

The application fee is not refundable.

(7) Once accreditation is granted the laboratory will be invoiced for the requested parameters.

(8) When a laboratory applies for renewal of their accreditation, an application fee is not required. The

applicable accreditation fees per Table 1, do not need to be rendered prior to processing of the application.

(97) The fee for recognition of a third-party accreditation (WAC 173-50-170) is three-fourths (75%) of the fee indicated in Table 1.

(10) If a laboratory requests to add or re-instate a parameter to their scope of accreditation outside of their initial application or renewal process, the laboratory will be invoiced a fee based on the number of parameters, per Table 1.

~~(118) If a laboratory withdraws from the accreditation process after the application has been processed, but before accreditation is granted, the fee is refundable, less an amount up to three hundred dollars as reimbursement for costs of processing the application. If a laboratory withdraws from the accreditation process after the on-site audit has been completed, the department may retain the entire fee including reimbursement of travel costs if applicable.~~

~~(9) Dollar amounts listed in Table 1 and subsections (4) and (8) of this section may be decreased at any time the department determines they are higher than needed to meet~~

~~accreditation program requirements. The department notifies affected parties of any fee adjustment at least thirty days prior to the effective date of the adjusted fee.~~

(~~1210~~) Accreditation fees are waived for laboratories operated by the Washington state departments of ecology and health. Accreditation fees are also waived for drinking water parameters certified by EPA Region 10 at designated principal laboratories.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-190, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-190, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-190, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-190, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-190, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-200 Appeals. An environmental laboratory manager may appeal final accreditation actions within thirty days of notification of final action in accordance with chapter 43.21B RCW.

[Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-200, filed 10/1/02, effective 11/1/02; WSR 93-20-011 (Order 92-53), § 173-50-200, filed 9/22/93, effective 10/23/93; WSR 90-21-090 (Order 90-21), § 173-50-200, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-200, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-210 Enforcement. (1) For the purpose of conducting on-site audits or inspections to ensure compliance with this chapter, the department may, during regular business hours, enter business premises in which analytical data pertaining to accreditation under the provisions of this chapter are generated or stored.

(2) Refusal to permit entry for such purposes may result in denial or revocation of accreditation.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-210, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-210, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-210, filed 10/19/90, effective 11/19/90; WSR 89-10-001 and 90-07-017 (Order 89-1 and 89-1A), § 173-50-210, filed 4/20/89 and 3/13/90, effective 4/13/90.]

WAC 173-50-220 Assistance to laboratories. Laboratories scheduled to undergo an on-site audit may request a training session be conducted by department staff in conjunction with that audit. Accredited laboratories may also request on-site assistance at times other than the on-site audit. Whether requested as part of the on-site audit or otherwise, the department will provide such assistance to the extent allowed by staff resources available at the time.

[Statutory Authority: RCW 43.21A.230, 43.20.050 and 2009 c 564 § 301. WSR 10-17-032 (Order 09-09), § 173-50-220, filed 8/9/10, effective 9/9/10. Statutory Authority: RCW 43.21A.230. WSR 02-20-090 (Order 01-12), § 173-50-220, filed 10/1/02, effective 11/1/02; WSR 90-21-090 (Order 90-21), § 173-50-220, filed 10/19/90, effective 11/19/90.]