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" - A written procedure for acquiring analytical data.

<u>"Audit" - An inspection and evaluation of laboratory facilities, equipment, records, and staff. This may be on-site or virtual.</u>

"Calibration curve" - A series of standards of known 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
- \bullet Where data ((is)) are 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.

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

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

"Laboratory control sample" or "LCS" (also known as a "laboratory fortified blank" or "LFB") - 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.

<u>"Limit of quantitation"</u> or <u>"LOQ"</u> - The smallest concentration that produces a quantitative result with acceptable precision and accuracy, as required by data quality objectives.

"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.

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

"Matrix spike" or "MS" - An aliquot of environmental samples to which known concentrations of certain target analytes have been added before sample preparation, cleanup, and determinative procedures have been performed.

"Method detection limit" or "MDL" - The minimum concentration of an analyte that can be measured and reported with a 99 percent confidence that the analyte concentration is distinguishable from the method blank results as determined by the procedure set forth in Appendix B of 40 C.F.R. Part 136.

"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 <u>in a specific matrix</u>. Examples of parameters include:

- The analyte alkalinity by method SM 2320 B in nonpotable water;
- The analyte ((zinc)) arsenic by method EPA ((200.7)) 200.8 in drinking water;
- The ((set of analytes called volatile organic compounds (vocs))) analyte benzene by method EPA 8260 in solid and chemical materials; and
- The analyte (($\frac{\text{Total Coli/Ecoli-count}}{\text{count}}$)) $\frac{\text{fecal coliform-count}}{\text{method SM 9222 ((}\frac{\text{B}/9221 \text{ F})}{\text{)}}$) $\frac{\text{D in nonpotable water}}{\text{-}}$. "Principal laboratory" A laboratory designated by the Washing-

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

"Procedural manual" - The <u>most recent version of the</u> Department of Ecology's Procedural Manual for the Environmental Laboratory Accreditation Program (($\frac{1}{2}$

"Proficiency testing (PT)" - ((Evaluation of the results from the)) Analysis of samples in the accredited matrix, 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.

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"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.)) The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

"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.

<u>AMENDATORY SECTION</u> (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

WAC 173-50-050 Responsibilities of the department. (1) The department maintains a procedural manual describing specifics of the accreditation process. ((As)) $\underline{\text{At}}$ 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.

- 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:
- $((\bullet))$ <u>(a)</u> Submit an <u>environmental laboratory accreditation</u> 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);
- ((*)) (c) For laboratories seeking direct accreditation from the department, SOP's for all methods for which the laboratory is seeking accreditation must be submitted;
- $\underline{\text{(d)}}$ Submit an initial set of satisfactory PT sample results (WAC 173-50-070); and
 - $((\bullet))$ <u>(e)</u> Undergo an ((on-site)) audit (WAC 173-50-080).
- (2) For laboratories to be accredited for drinking water parameters, the laboratory must follow requirements designated in the drinking water certification manual.

NEW SECTION

- WAC 173-50-061 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) For parameters where a multilevel calibration is necessary:
- (a) A laboratory must not remove any midpoints from a calibration curve with the exception of consecutive points at either end of the curve. Exceptions can be made if a significant error's cause can be clearly identified, the error is documented, and the calibration point is excluded for all analytes contained in the calibration point.
- (b) Each calibration point must have its value recalculated against the calibration curve. Unless otherwise specified in the method, each calibration point must have its percent error or relative standard error meet the calibration verification acceptance limits from the method; with the exception of calibration points at or below the LOQ, in which case the limit is 50 150 percent error, or percent relative standard error.
- (3) For parameters that require a limit of quantitation and the method does not specify any requirements, laboratories must analyze a standard at their limit of quantitation at least annually. This standard must be between 50 and 150 percent 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;
 - (q) Mass spectrometry;

- (h) Total organic carbon analysis; and
- (i) Any other technology where method detection limits are applicable.
- (4) Matrix spikes are required as specified by the method. Matrix spikes that do not meet their acceptance criteria must be documented for regulated parameters under the federal Safe Drinking Water Act and Clean Water Act. The lab must take corrective action if specified by the method.
- (5) Unless the method specifies otherwise, laboratory control samples must include all analytes of interest in the respective analysis. Matrix spikes should include all analytes of interest in the respective analysis.
- (6) For compliance monitoring samples, if a laboratory control sample is outside of its acceptance criteria for a parameter(s), the data for that parameter(s) should only be reported if the laboratory can demonstrate:
- (a) No source of low bias of that parameter(s) is also present in the sample(s) and/or other related quality control samples;
- (b) Instrument calibration have met method acceptance criteria; and
- (c) The reported samples do not have a detection for any high biased parameter(s).
- (7) Documented resolution of spectral interferences is required for ICP-OES.

- WAC 173-50-063 Application. (1) Through ((the)) a department environmental laboratory accreditation application, laboratory managers:
 - ((-)) <u>(a)</u> Request accreditation for specific parameters;
 - ((*)) (b) Calculate fees due to the department; and
- ((-)) <u>(c)</u> Provide evidence that sufficient <u>and capable</u> 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:
 - ((+)) <u>(a)</u> Requested parameters are eligible for accreditation;
- ((-)) (b) The fee calculated by the applicant laboratory is correct; and
- $((\bullet))$ <u>(c)</u> 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.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

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)) a department environmental laboratory accreditation 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)) can be found in the drinking water certification manual and/or approved method.

NEW SECTION

- WAC 173-50-069 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, reagent, and/or media used by an analytical method;
- (c) Document proper storage of samples and samples extracts as required by the specific analytical method and/or regulation;
- (d) Document that all temperature-based equipment such as a refrigerator, oven, or incubator is within control. When electronic record keeping equipment is used, these records must be appropriately monitored by lab personnel to verify that temperatures meet relevant method and regulatory requirements;
- (e) Keep a log for any and all instruments, including documentation of installation, setup, maintenance, and removal from service; and
- (f) Document proper preparation and QC of chemicals, reagents, and media used in support of the analyses.
- (2) When records are handwritten, they must be in indelible ink and comply with the relevant method requirements and include the date and time(s) of reading, temperature(s), and technician's initials.
- (3) Unmonitored use of continuous data-loggers is not an acceptable substitute when methods and/or regulations require temperature checks. Use of electronic record keeping equipment is allowed when:
- (a) The equipment can demonstrate the accuracy and precision required by the applicable method and/or regulations;
- (b) It includes the date and time the record was captured, using a fully traceable and secure format; and
- (c) It is not being used on an incubator used for analysis of samples for microbiology parameters.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

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)) two PT samples 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. For bioassay parameters, only one acceptable PT sample is required per parameter per year.
- (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 or more approved PT providers make available a PT sample for a parameter in an appropriate matrix, the laboratory must analyze and pass a PT to gain or maintain accreditation, unless an exception is approved by the department.
- (8) Presence-absence microbiology parameters must pass all 10 replicates in their PTs to be considered acceptable.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- WAC 173-50-080 ((On-site)) <u>Audits</u>. The laboratory must undergo an ((on-site)) audit by the department, or their primary accreditation authority (in cases of third party recognition), to assess critical elements and areas of recommended practices. <u>All directly accredited laboratories will be audited on a triennial basis</u>. The laboratory must assist/accommodate department of ecology personnel during ((on-site)) audits as required. <u>The department will determine if the audit will be on-site</u>.
- (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)) By conducting audits the department determines if SOPs and other documentation of analytical methods:
 - ((-)) <u>(i)</u> Are present at the laboratory;
 - ((♠)) (ii) Are approved for regulatory use, if applicable;
 - (iii) Readily available to analysts; and

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- $((\bullet))$ <u>(iv)</u> 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:
 - ((♣)) <u>(i)</u> Available;
 - ((♠)) (ii) Being adequately maintained; and
- $((\bullet))$ <u>(iii)</u> 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) ${\tt Data\ management.}$ The ((${\tt on-site}$)) audit includes a review of activities necessary to assure accurate management of laboratory data including:
 - ((-)) (i) Raw data;
 - ((♣)) (ii) Calculations; and
- $((\stackrel{\bullet}{\bullet}))$ $\underline{(iii)}$ 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.

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- (4) **Documentation requests.** Laboratories must submit requested documentation to the department at least two weeks prior to the scheduled start date of an audit. At a minimum the documents submitted must include:
 - (a) Standard operating procedures for all methods being audited;
 - (b) Analytical data for each method being audited; and
- (c) Additional documentation deemed necessary by the department to conduct the audit.

- WAC 173-50-100 Interim accreditation. (1) 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:
 - ((-)) <u>(a)</u> Submit an application and applicable fees;
 - ((+)) (b) Successfully complete applicable proficiency tests; and
- ((-)) (c) Submit a QA manual <u>and applicable SOP's</u> that meet((-s)) the requirements of WAC 173-050-067.
- $\underline{(2)}$ The lab accreditation unit may also require the laboratory to submit an analytical data package as evidence of analytical capability.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- 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.

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- WAC 173-50-130 Requirements for maintaining accreditation sta-(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:
 - ((*)) (a) An application and appropriate fees;
 - ((*)) (b) An update of the laboratory's QA manual if applicable;
- ((+)) <u>(c)</u> Evidence of accreditation by a third party when appropriate; ((and
- +)) (d) Successful completion of proficiency testing requirements; and
- (e) Any other documents specifically requested by the department needed to renew accreditation.
- (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 a laboratory planning to permanently change their location, the laboratory must notify the department at least 30 days prior to the need for accreditation at the new location. At the time of the laboratory move, the department places all accredited parameters 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 laboratory must notify the department at <u>least 60 days prior to the need for accreditation.</u>
- (7) Temporary and/or emergency laboratory moves will be handled on a case-by-case basis. The laboratory must contact the department before any sample analysis can resume.
- (8) For a laboratory to be accredited for drinking water parameters, the laboratory must comply with requirements under WAC 246-390-055, 246-390-065, and 246-390-075 and 40 C.F.R. Part 141.

- WAC 173-50-140 Denying accreditation. (1) The ecology accrediting authority may deny accreditation if the applicant laboratory:
- ((-)) <u>(a)</u> Fails to comply with standards for critical elements of the ((on-site)) audit;
 - ((+)) <u>(b)</u> Misrepresents itself to the department;

- ((*)) (c) Fails to disclose pertinent information in ((the)) their environmental laboratory accreditation application;
- ((-)) (d) Falsifies reports of analysis including proficiency testing results;
- $((\bullet))$ <u>(e)</u> Engages in unethical or fraudulent practices concerning generation of analytical data;
- ((-)) (f) Is deficient in its ability to provide accurate and defensible analytical data; or
 - ((*)) (g) Fails to render applicable fees.
- (2) A laboratory may be denied accreditation for a specific parameter for ((unsatisfactory)) unacceptable 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.

- WAC 173-50-150 Revoking or suspending accreditation. (1) Revocation of accreditation is the <u>department's</u> 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:
- $((\bullet))$ <u>(a)</u> Fails to comply with standards for critical elements of an ((on-site)) audit;
- ((-)) (b) Violates a state rule <u>and/or federal law</u> relative to the analytical procedures for which it is accredited;
 - $((\bullet))$ <u>(c)</u> Misrepresents itself to the department;
- ((-)) (d) Falsifies reports of analysis including proficiency testing results;
- ((*)) <u>(e)</u> Engages in unethical or fraudulent practices concerning generation of analytical data;
- ((-)) Is deficient in its ability to provide accurate and defensible analytical data;
- $((\bullet))$ $\underline{(g)}$ Refuses to permit entry for enforcement purposes (WAC 173-50-210);
 - ((♠)) (h) Fails to render applicable fees;
 - ((♠)) (i) Fails to maintain third-party accreditation; or
- ((-)) (j) 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.

- 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:
 - ((+)) <u>(a)</u> An application and associated fee (WAC 173-50-190(7));
 - ((*)) (b) A copy of the third party's certificate;
 - ((+)) (c) A copy of the third party's scope of accreditation;
- $((\bullet))$ <u>(d)</u> A copy of the third party's most recent ((on-site)) audit report;
- $((\bullet))$ <u>(e)</u> 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.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

- 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)) The department shall assess fees for each parameter or method within each matrix, except as noted in subsection (3) of this section. Laboratories are charged using the fee structure of the fiscal year covering the effective date the department issues a determination on a laboratory's accreditation application, renewal of its accreditation, or a revision of a laboratory's scope of accreditation. The fee schedule per parameter or method for each category((, and the maximum fee per category where applicable,)) are identified in ((Table 1.)):
 - (a) Table 1 Fee schedule through June 30, 2024.
- (b) Table 2 Fee schedule from July 1, 2024, through June 30, 2025.

- (c) Table 3 Fee schedule from July 1, 2025, through June 30, 2026.
- (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 METHOD	MAX FEE PER CATEGORY
General Chemistry	\$80	_	\$1,600
Trace Metals	_	\$400	_
Organies I	_	\$200	_
Organies II	_	\$500	_
Microbiology	\$200	_	_
Radiochemistry	\$250	_	_
Bioassay	\$300	_	\$3,000
Immunoassay	\$80	_	_
Physical	\$80	_	—))

Table 1 - Fee Schedule through June 30, 2024

Category	Fee Per Parameter	Fee Per Method	Max Fee Per Category
General Chemistry	\$80	=	<u>\$1,600</u>
Trace Metals	Ξ.	<u>\$400</u>	Ξ
Organics I	Ξ.	<u>\$200</u>	Ξ
Organics II	=	<u>\$500</u>	Ξ
Microbiology	<u>\$200</u>	Ξ.	Ξ
Radiochemistry	<u>\$250</u>	<u>=</u>	Ξ
Bioassay	<u>\$300</u>	Ξ	<u>\$3,000</u>
<u>Immunoassay</u>	<u>\$80</u>	<u>=</u>	Ξ
Physical	<u>\$80</u>	<u>=</u>	Ξ

Table 2 - Fee Schedule from July 1, 2024, through June 30, 2025

	<u>Per Parameter</u>		
Category	Fee Per Parameter	Addition Fee	Fee Per Method
General Chemistry	<u>\$150</u>	Ξ.	Ξ
<u>Trace Metals</u>	Ξ	<u>\$30</u>	<u>\$745</u>
Organics I	Ξ	<u>\$15</u>	<u>\$375</u>
Organics II	Ξ	<u>\$35</u>	<u>\$930</u>
Microbiology	<u>\$375</u>	Ξ	Ξ
Radiochemistry	<u>\$555</u>	<u>=</u>	Ξ
Bioassay	Ξ	<u>\$15</u>	<u>\$375</u>
<u>Immunoassay</u>	<u>\$150</u>	Ξ	Ξ
<u>Physical</u>	<u>\$150</u>	Ē	=

Table 3 - Fee Schedule from July 1, 2025, through June 30, 2026

<u>Category</u>	Fee Per Parameter	Per Parameter Addition Fee	Fee Per Method
General Chemistry	\$220	<u> </u>	=
Trace Metals	Ξ	<u>\$55</u>	<u>\$1,085</u>
Organics I	Ξ	<u>\$30</u>	<u>\$545</u>
Organics II	Ξ	<u>\$70</u>	<u>\$1,355</u>

<u>Category</u>	Fee Per Parameter	<u>Per Parameter</u> <u>Addition Fee</u>	Fee Per Method
Microbiology	<u>\$545</u>	=	=
Radiochemistry	<u>\$680</u>	Ξ	Ξ
Bioassay	Ξ	<u>\$25</u>	<u>\$445</u>
<u>Immunoassay</u>	<u>\$220</u>	Ξ	=
<u>Physical</u>	<u>\$220</u>	Ξ	Ξ

(4) <u>Starting July 1, 2026, Equation 1 below will be used to calculate the fees:</u>

Equation 1

 $\underline{\text{Fee}}_2 \equiv \underline{\text{Fee}}_1 \times (1 + \text{FGF})$

Where:

 $\underline{\text{Fee}}_1 = \underline{\text{The current fiscal year fees for each category.}}$

Fee2 = The fee for each category for the fiscal year following the fiscal year in which Fee1 was in effect, rounded up to the nearest whole \$5 increment. The updated fee table is then posted on the department's website.

<u>FGF</u> = An annual fiscal growth factor expressed as a percentage, as determined under chapter 43.135 RCW.

- (a) Fiscal year begins July 1st and ends June 30th of the following calendar year. For example, fiscal year 2027 is July 1, 2026, through June 30, 2027.
- (b) Ecology will provide annual notice of the next fiscal year's fees by March 31st.
- $\underline{(5)}$ The minimum fee for accreditation, either direct or through recognition of a third-party accreditation, is ((three hundred dollars)) $\underline{\$500}$.
- $((\frac{5}{}))$ (6) In addition to paying the fee indicated in Table 1, Table 2, Table 3, or as updated by Equation 1: Out-of-state laboratories must pay the department 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) The laboratory must pay applicable fees before:)) (7) For laboratories that have not been accredited for any parameter by the department in the previous 12 months, the laboratory must pay a processing fee of \$300 before:
- ((-)) (a) Its quality assurance manual $((\frac{is}{s}))$ and applicable SOP's are reviewed by the department;
 - ((+)) (b) The ((on-site)) audit is conducted if applicable; and
 - ((+)) <u>(c)</u> Interim, provisional, or full accreditation is granted. The application fee is not refundable.
- ((+7)) (8) Once accreditation is granted the laboratory will be invoiced annually by the department for the requested parameters.
- (9) When a laboratory applies for renewal of their accreditation, an application fee is not required. The applicable accreditation fees per Table 1, Table 2, Table 3, or as updated by Equation 1 do not need to be payed prior to processing of the application.
- (10) The fee for recognition of a third-party accreditation (WAC 173-50-170) is three-fourths (75((%)) percent) of the fee indicated in Table 1, Table 2, Table 3, or as updated by Equation 1.
- ((8) 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.))

- (11) If a laboratory requests to add or reinstate a parameter to an existing method on their scope of accreditation outside of their initial application or renewal process, the laboratory will be invoiced a fee based on the type and number of requested parameters according to the "Per Parameter Addition Fee" column of Table 1, Table 2, Table 3, or as updated by Equation 1.
- (12) 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.
- $\frac{(10)}{(13)}$ 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.

- WAC 173-50-210 ((Enforcement)) Compliance inspections and access. (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.

AMENDATORY SECTION (Amending WSR 10-17-032, filed 8/9/10, effective 9/9/10)

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.