

WAC 173-50-080 Audits. The laboratory must undergo an audit by the department, or their primary accreditation authority (in cases of third party recognition), to assess critical elements and areas of recommended practices. All directly accredited laboratories will be audited on a triennial basis. The laboratory must assist/accommodate department of ecology personnel during audits as required. The department will determine if the audit will be on-site.

(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.** By conducting audits the department determines if SOPs and other documentation of analytical methods:

- (i) Are present at the laboratory;
- (ii) Are approved for regulatory use, if applicable;
- (iii) Readily available to analysts; and
- (iv) Being implemented. If the laboratory is using a locally developed method, the audit may include an evaluation of the adequacy of that method.

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

- (i) Available;
- (ii) Being adequately maintained; and
- (iii) 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 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 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 audit includes a review of activities necessary to assure accurate management of laboratory data including:

- (i) Raw data;
- (ii) Calculations; and
- (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 expe-

rience 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, 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 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.

[Statutory Authority: RCW 43.21A.230. WSR 23-18-059 (Order 22-07), § 173-50-080, filed 9/1/23, effective 10/2/23. 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.]