WAC 16-310-120 Audits. (1) A laboratory must undergo an audit by the department to assess critical elements and areas of required standard practices.

(a) All accredited laboratories will be audited on an annual basis. The laboratory must assist or accommodate department personnel and auditors during audits as necessary.

(b) Audits will be performed on-site.

(c) Off-site audits will only be available at the discretion of the department.

(2) The laboratory must successfully show that they meet the minimum standards for each of the critical elements. Critical elements of accreditation are components of a cannabis laboratory's operations which are critical to the consistent generation of accurate and defensible data and keep the laboratory compliant with regulations.

(3) Critical elements include:

(a) Analytical methods. The laboratory must demonstrate that documentation of analytical methods the laboratory employs:

(i) Are present at the laboratory;

(ii) Are approved by the scientific director;

(iii) Are readily available to analysts; and

(iv) Have been validated and implemented before testing customer samples.

(b) Equipment and supplies. The laboratory must demonstrate that sufficient equipment and supplies as required by analytical methods are:

(i) Available at the laboratory;

(ii) Being adequately maintained;

(iii) Have been validated before placing into service; and

(iv) In a condition to allow successful performance of applicable analytical procedures.

(c) QA and QC records. The laboratory must maintain and make available QA and QC records. QA and QC records must monitor laboratory testing and functions to demonstrate analytical performance and compliance requirements.

(d) Sample management. The laboratory must demonstrate that its procedures for sample receipt, analysis, storage, and disposal are sufficient to meet regulatory requirements.

(e) Data management. The laboratory must demonstrate that data management requirements are being met. The audit includes a review of activities necessary to assure accurate management of laboratory data including:

(i) Raw data;

(ii) Calculations;

(iii) Transcription;

(iv) Computer data entry; and

(v) Reports of analytical results.

The department may deny, revoke, or suspend accreditation for deficiencies in critical elements.

(4) The laboratory must successfully show that they meet the minimal requirements of required standard practices. Standard practices are those elements of laboratory operations which might affect efficiency, safety, and other administrative functions, but may not affect quality of analytical data. Typically, deficiencies to standard practices are not grounds for significant accreditation actions but can be if a specific finding directly affects the laboratory's ability to meet a critical element for accreditation or presents a significant safety concern. Standard practices include:

(a) Personnel. The laboratory must demonstrate that its managerial, supervisory, and technical personnel have adequate training and experience to allow satisfactory completion of analytical procedures and compilation of reliable, accurate data. Minimum personnel requirements are set forth in chapter 16-309 WAC.

(b) Facilities. The laboratory must demonstrate that it allows for the efficient generation of reliable, accurate data in a safe environment.

(c) Safety. The laboratory must demonstrate that it has met the minimum safety requirements as stipulated in chapter 16-309 WAC. If the department determines the laboratory has a significant safety deficiency, the department may refer the deficiencies to appropriate state or federal agencies.

[Statutory Authority: RCW 69.50.348. WSR 24-13-102, § 16-310-120, filed 6/18/24, effective 7/1/24.]