WAC 16-309-250 Method approvals. (1) Laboratories must use an agency approved method for cannabinoid concentration, pesticides, residual solvents, and heavy metals testing. A list of approved analytical and preparative methods are available on the agency's website (https://agr.wa.gov/departments/cannabis/cannabis-lab-analysis-program). If a laboratory wants to use a method not currently on the approved agency list of methods, the lab can submit a method for approval.

(2) Laboratories must, at a minimum, do the following for a new method approval:

(a) Laboratories must submit a method approval form with their required method documentation and method validation data emailed to the department at cannabis@agr.wa.gov.

(b) Receive written approval from the department of the validated method for use on customer samples.

(3) The initial method review and approval may take 30 days. The department may request revisions, clarifications, and/or additional data to review the method.

(4) Laboratories will receive notification via email about the status of the method. Approved methods will be added to the agency website for public access.

(5) Laboratories with denied methods will be provided with a detailed synopsis of why the method was insufficient.

(6) Methods submitted to the WSDA for approval must include a standard operating procedure that documents the following:

(a) A title that indicates the type of procedure being conducted (i.e., pesticides, residual solvents, cannabinoid concentration, or heavy metals).

(b) A document control number, date, and revision number.

(c) Approval signatory and date.

(d) A table of contents and page numbering.

(e) A section that documents the revision history for the method.

(f) A definitions section that includes a definition of terms, acronyms, and abbreviations used in the methods.

(g) A section that outlines the purpose, range, limitations (including limit of quantitation and limit of detection), intended use of the method, and target analytes.

(h) A summary section that includes an overview of the method procedure and quality assurance.

(i) An interference section that identifies known or potential interferences that may occur during use of the method and describes ways to reduce or eliminate these interferences.

(j) A safety section that describes special precautions needed to ensure personnel safety during the performance of the method.

(k) A section for equipment, supplies, reagents, and standards that are required to perform the method.

(l) A section that provides requirements and instructions for collecting, preserving, and storing samples.

(m) A quality control section that cites the procedures and analyses required to document the quality of data generated by the method and includes corrective actions for out-of-control data. This section must also describe how to assess data for acceptance based on quality control measures.

(n) A calibration and standardization section that describes the method or instrument calibration and standardization process and the required calibration verification.

(o) A procedure section that describes the sample processing and instrumental analysis steps of the method and provides detailed instructions to analysts.

(p) A section that provides instructions for analyzing data, equations, and definitions of constants used to calculate final sample analysis results.

(q) A method performance section that provides method performance criteria, including precision or bias statements regarding detection limits and sources or limitations of data produced using the method.

(r) A pollution prevention and waste management section that describes aspects of the method that minimizes or prevents pollution and the minimization and proper disposal of waste and samples.

(s) A section for references that lists source documents and publications that contain ancillary information.

(t) A section that contains all the tables, figures, diagrams, example forms for data recording, and flowcharts. This section may also contain validation data references in the body of the method.

(7) Methods must be validated and laboratories must submit method validation documentation as detailed in WAC 16-309-260.

(8) Should the department determine a method has become obsolete or invalid, it may retire the approved method after providing six months notice.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-250, filed 4/17/24, effective 5/18/24.]