641—154.52(124E) Recordkeeping requirements.

154.52(1) *Data package.* A laboratory shall create a data package for each analytical batch of primary samples that the laboratory analyzes. The data package shall contain at minimum the following information:

a. The name and address of the laboratory that performed the analytical procedures;

b. The names, functions, and signatures (electronic or handwritten) of the laboratory personnel who performed the primary sample preparation, analyzed the primary samples, and reviewed and approved the data;

c. All primary sample and analytical batch quality control sample results;

d. Raw data for each primary sample analyzed;

e. Instrument raw data, if any was produced;

f. Instrument test method with parameters;

g. Instrument tune report, if one was created;

h. All instrument standard calibration data;

i. Test-method worksheets or forms used for primary sample identification, characterization, and calculations, including chromatograms, sample-preparation worksheets, and final datasheets;

j. The quality control report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis;

k. The analytical batch sample sequence;

l. The field sample log; and

m. The chain-of-custody form.

154.52(2) *Review of data package.* After the laboratory has compiled a data package, an individual at the laboratory who was not previously involved in the creation of the data package shall:

a. Assess the analytical results for technical correctness and completeness;

b. Verify that the results of each analysis carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively;

c. Verify that the measurements can be traced back; and

d. Approve the measurement results by signing and dating the data package prior to release of the certificate of analysis by the laboratory.

154.52(3) *Data package record retention.* The entire data package shall be stored by a laboratory for a minimum of five years and shall be made available upon request by the department or the requester of the laboratory testing.

154.52(4) *Other records.* A laboratory shall maintain all documents, forms, records, and standard operating procedures associated with the testing of medical cannabidiol.

a. A laboratory shall maintain analytical testing laboratory records in such a manner that the analyst, the date the analysis was performed, the approver of the certificate of analysis, the reviewer and approver of the data package, the test method, and the materials that were used can be determined by the department.

b. Records shall be stored in such a way that the data may be readily retrieved when requested by the department.

c. All testing laboratory records shall be kept for a minimum of five years, unless otherwise noted in these rules.

d. The department shall be allowed access to all electronic data, including standards records, calibration records, extraction logs, and laboratory notebooks.

e. A laboratory shall keep and make available to the department the following records related to the testing of medical cannabidiol:

(1) Personnel qualification, training, and competency documentation, including but not limited to résumés, training records, continuing education records, analytical proficiency testing records, and demonstration of competency records for laboratory work. These records shall be kept current.

(2) Method verification and validation records, including method modification records, method detection limit and quantitation limit determination records, ongoing verification records such as proficiency test records and reference material analysis records.

(3) Quality control and quality assurance records, including the laboratory's quality assurance manual and control charts with control limits.

(4) Chain-of-custody records, including chain-of-custody forms, field sample logs, sample-receipt records, sample-description records, sample-rejection records, laboratory information management system records, sample-storage records, sample-retention records, and disposal records.

(5) Purchasing and supply records, equipment-services records, and other equipment records, including purchase requisition records, packing slips, supplier records, and certificates of analysis.

(6) Laboratory equipment installation records, maintenance records, and calibration records. These records shall include the date and name of the person performing the installation of, calibration of, or maintenance on the equipment, with a description of the work performed, maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records, and daily verification-of-calibration records.

(7) Customer service records, including customer contracts, customer requests, certificates of analysis, customer transactions, customer feedback, records related to the handling of complaints and nonconformities, and corrective action pertaining to complaints.

(8) Nonconforming work and corrective action records, including corrective action, nonconformance, nonconformities resolved by correction, customer notification of nonconformities, internal investigations, implementation of corrective action, and resumption-of-work records.

(9) Internal-audit and external-audit records, including audit checklists, standard operating procedures, and audit observation and findings reports. These records shall include the date and name of the person performing the audit.

(10) Management review records, including technical data review reports and final management-review reports. These records shall include the review date and the name of the reviewer.

(11) Laboratory data reports, data review, and data approval records, including instrument and equipment identification records, records with unique sample identifiers, analysts' laboratory notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data, and test-method raw data. These records shall include the analysis date and the name of the analyst.

(12) Proficiency testing records, including the proficiency test schedule, proficiency tests, data-review records, data-reporting records, nonconforming work and corrective actions, and quality control and quality assurance records related to proficiency testing.

(13) Electronic data, backed up data, records regarding the protection of data, including unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, and authorized personnel records.

(14) Security data, including laboratory-security records and laboratory-access records, surveillance-equipment records, and security-equipment records. These records shall be stored for at least one year.

(15) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' laboratory notebooks and logbooks, supplier records, and certificates of analysis, and all other data-related records.

(16) Laboratory contamination and cleaning records, including autoclave records, acid-wash logs and records, and general laboratory-safety and chemical-hygiene protocols.

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