

641—154.51(124E) Reporting requirements.

154.51(1) *Reporting test results.* The laboratory shall generate a certificate of analysis for each primary sample that it tests and make the certificate of analysis available to the manufacturer and the department.

154.51(2) *Tentatively identified analytes.* A laboratory shall report on the certificate of analysis any tentatively identified analytes detected during the analysis of the primary sample. When a laboratory identifies additional analytes in a primary sample, the laboratory shall:

- a. Notify the department of the additional analytes detected.
- b. Refrain from issuing a final certificate of analysis until given approval to do so by the department.

154.51(3) *Additional reporting requirements.* In addition to the requirements described in rule 641—154.50(124E), the certificate of analysis shall contain, at a minimum, the following information:

- a. All requirements of ISO/IEC 17025 dated 2017;
- b. Date of primary sample collection;
- c. Date the primary sample was received by the laboratory;
- d. Date of each analysis;
- e. The LOQ and action level for each analyte, as applicable;
- f. Whether the primary sample and lot passed or failed laboratory testing; and
- g. A signature by the laboratory quality officer or delegate and the date the certificate of analysis was validated as being accurate by the laboratory quality officer or delegate.

154.51(4) *Measurements.*

- a. Any test result that is not covered under the laboratory's ISO/IEC 17025 scope of accreditation shall be clearly identified on the certificate of analysis.
- b. Measurements below a method's limit of detection shall be reported as "<" (less than) or "not detected" and reference the reportable limit. The reporting of zero concentration is not permitted.
- c. Measurements greater than or equal to LOD but less than LOQ shall be reported as "detected but not quantified."
- d. The number of significant figures reported shall reflect the precision of the analysis.

[ARC 8124C, IAB 7/10/24, effective 8/14/24]