



TECHNICAL ADVISORY

2025-002

Date: February 3, 2025

Subject: Guidance re Determining and Documenting Measurement Uncertainty in Medical Cannabis Testing

Relevant authority: 915 KAR 1:060; 915 KAR 1:110

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Kentucky Office of Medical Cannabis

The purpose of this technical advisory is to provide safety compliance facility licensees with guidance on the Office of Medical Cannabis's interpretation of, and how a licensee may maintain compliance with, KRS Chapter 218B and 915 KAR Chapter 1, with regard to determining and documenting measurement uncertainty in medical cannabis testing.

With respect to measurement uncertainty, Kentucky licensed safety compliance facilities are required to do the following:

- Determine the measurement uncertainty of each test they conduct;
- Document the methods used to determine measurement uncertainty in their respective Standard Operating Procedures; and
- Report measurement uncertainty on all Certificates of Analysis provided to other licensed medical cannabis businesses.

Per Kentucky law and regulation, licensed safety compliance facilities are required to maintain a “certification of accreditation.” See 915 KAR 1:060, Section 1(6)(g)¹; see also, 915 KAR 1:001, Section 1(14) (defining “certification of accreditation”).² The certification of accreditation requires

¹ Licensees are also required to provide a copy of its certification of accreditation to the Office of Medical Cannabis during inspections or upon request. See 915 KAR 1:060, Section 1(6)(g). The accreditation must be in good standing and from an accreditation body. *Id.*

² A “certificate of accreditation” is a document issued by an accreditation body evidencing that a safety compliance facility is in compliance with International Organization for Standardization Standard ISO and IEC 17025 and other requirements relevant to the operation of laboratories conducting tests on medical cannabis and other items used in the growing, processing, or dispensing of medicinal cannabis.

the safety compliance facility be in compliance with International Organization for Standardization Standard ISO and IEC 17025, and other relevant requirements. *Id.*

ISO 17025 provides, among other things, requirements for the evaluation of measurement uncertainty. The term “measurement uncertainty” refers to a parameter, associated with a measurement result, that characterizes the dispersion of values that could reasonably be attributed to the measureand.

The relevant ISO 17025 standards regarding “measurement uncertainty” as of the date of this Technical Advisory are shown below:

7.6 Evaluation of measurement uncertainty

7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

7.6.3 A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.

NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

For more information on requirements for safety compliance facility licensees, please review 915 KAR 1:060.

For more information on medical cannabis testing requirements, please review 915 KAR 1:110.

If you have any questions, please contact the Office’s Division of Enforcement and Compliance at kymedcanreporting@ky.gov.

ISSUED BY:



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Office of Medical Cannabis
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