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To: Current and Prospective Marijuana Testing Facility Licensees
From: Director Erik Gundersen, Office of Marijuana Policy
Date: Tuesday, May 18, 2021
Subject: Guidance for Reporting Testing Results Using Laboratory Uncertainty

Background

The Office of Marijuana Policy (OMP) previously released a [guidance document](#)¹ providing a response to a frequently asked question concerning whether the use of laboratory uncertainty is permitted in determining if a sample falls below the 10 mg/serving and 100 mg/package potency threshold. In the time since this guidance was offered, OMP has received additional questions from adult use Marijuana Testing Facilities (MTF) and the Maine Center for Disease Control and Prevention asking for further clarification on this topic.

Section 6.6(C) of 18-691 C.M.R., ch. 5, Rules for the Certification of Marijuana Testing Facilities, states: “When determining whether a sample of marijuana product exceeds the 10 mg/serving and 100 mg/package limits required by 28-B M.R.S. § 703, the marijuana testing facility must account for laboratory uncertainty.”

OMP is providing the following guidance in response to inquiries on this topic.

Frequently Asked Questions

Question: Is there a limit to the extent that laboratory uncertainty can be extended for potency analysis?

Answer: Yes. While laboratory uncertainty can and should be used to determine whether a laboratory result exceeds the upper limits given for potency analyses, there is a reasonable limit to how this can be used. Simply allowing an unlimited degree of uncertainty to be applied could potentially encourage MTFs to tolerate higher than necessary levels of uncertainty in their method. In addition, this may create confusion for customers and regulators when different MTFs pass or fail potency levels that appear to be the same.

To eliminate this confusion between MTFs and the possible tendency toward accepting increasing levels of uncertainty, OMP sets the upper limit of calculated laboratory uncertainty that can be used in determination of potency at 5 percent. **This translates into maximum upper limits of 10.5 mg/serving and 105 mg/package potency thresholds.**

Additionally, the laboratory uncertainty for the MTF must be included on each Certificate of Analysis.

¹ Marijuana Testing Facility Frequently Asked Questions (rev. September 3, 2020)

Q: Can laboratory uncertainty be applied to other analyses beyond potency determination?

A: No. While laboratory uncertainty can be applied to potency analysis, it cannot be applied to any other required adult use marijuana sample testing results. The concentration limits given for solvents, heavy metals, pesticides, microbiological impurities, and water activity may not be surpassed without failing the sample.

These limits have been developed by agencies such as the American Herbal Pharmacopoeia or the United States Pharmacopeia (USP) and are based on safety and toxicological studies which must be adhered to for the protection of consumer health.

Q: Can potency results be reported at greater than 100 percent for potency components in samples of pure extracts?

A: Yes. This question is related to the use of laboratory uncertainty for reporting potency results. When very high purity samples are tested in the MTF, the potency of the main component, such as THC, may result in a value that is greater than 100 percent. While this may seem counterintuitive, the existence of laboratory uncertainty makes this a possibility. In the pharmaceutical industry, assay values of pure drugs exceeding 100 percent are not uncommon² and are often reported as an acceptance range, such as pure Ibuprofen being accepted by the USP as being between 97 and 103 percent pure.³

As with the aforementioned potency threshold determination, the maximum uncertainty limit that can be used by the MTF for this determination is ± 5 percent.

² CBD Results over 100% Purity, Botanacor; <https://www.botanacor.com/science/cbd-results-over-100-purity/> (accessed: March 26, 2021)

³ *Official Monographs/Ibuprofen*, USP 31, United States Pharmacopeia; https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/errata467Ibuprofen.pdf (accessed: March 26, 2021)