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To: Current and Prospective Adult Use Cannabis Licensees  
From: Director Erik Gundersen, Office of Cannabis Policy  
Date: October 7, 2022  
Subject: Guidance for Reporting Testing Results Using Laboratory Uncertainty

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### Background

The Office of Cannabis Policy (OCP) is issuing this guidance provide information to all adult use cannabis licensees regarding the use of “laboratory uncertainty” by cannabis testing facilities (CTFs) when determining whether samples of edible cannabis products pass or fail mandatory testing for potency. The Office of Cannabis Policy (OCP) previously released a [guidance document](#) 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 that guidance was issued, OCP received additional questions from CTFs requesting for further clarification on this topic. OCP subsequently issued [an additional guidance document](#) with answers to more frequently asked questions related to the consideration of lab uncertainty in determining whether samples of edible cannabis products pass or fail mandatory testing for potency.

Subsequent to the issuance of this guidance, [changes have been made](#)<sup>1</sup> to the *Cannabis Legalization Act*, Title 28-B, ch. 1, subch. 6 which impact the determination by a testing facility as to whether a sample of edible cannabis products passes or fails mandatory testing for potency. Those changes were incorporated into OCP’s most recent revision of the *Adult Use Cannabis Program Rule*, 18-691 CMR, ch. 1, that went into effect September 8, 2022. [OCP issued guidance](#) regarding these changes, which focused on a new statutory allowable variance for licensees manufacturing edible cannabis products.

Since that time, OCP has received numerous inquiries from products manufacturing facility licensees regarding the consideration of lab uncertainty in calculating whether the edible cannabis products manufactured by those licensees pass or fail mandatory testing for potency. OCP is issuing this guidance to address these questions.

### Guidance

“Laboratory uncertainty” is a term of art used by scientists to account for the inherent uncertainty or variability in scientific analyses. It is used to account for variability in a wide array of

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<sup>1</sup> P.L. 2021, ch. 558, *An Act To Allow for a Variance Rate in the Amount and Potency of Cannabinoids in Adult Use Edible Marijuana Products*.

statistical and scientific analyses. In the adult use cannabis program, CTFs are permitted to use lab uncertainty, up to +/- 5%, to determine whether a sample of edible cannabis products passes or fails mandatory testing for potency. It is critical to understand, however, that lab uncertainty is a dynamic value that can vary from analytic batch to analytic batch within and between testing facilities and over time. For that reason, it is inadvisable for adult use products manufacturing facility licensees to depend on testing facility uncertainty when manufacturing edible cannabis products.

Licensees are reminded that the changes made pursuant to P.L. 2021, ch. 558, were intended to give products manufacturing facility licensees greater flexibility when attempting to manufacture “maximum potency” edible cannabis products of 10 mg/serving and 100 mg/package. Those changes *were not* intended push products manufacture licensees to produce higher and higher potency edible cannabis products, but instead to avoid situations where products manufacturers were forced to remediate or destroy maximum potency edibles for being slightly over the statutorily defined edible cannabis product potency limits.

### Conclusion

Laboratory uncertainty is a dynamic value that can vary from analytic batch to analytic batch and should not be depended upon by products manufacturing facility licensees when formulating and manufacturing edible cannabis products.