PROPOSED CHANGE TO AUDIT TESTING RULE

OLCC COMMISSION MEETING

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WHAT IS THE PROPOSED RULE CHANGE?

- OLCC has had audit testing authority since the inception of the marijuana program
  - But major gaps included lack of clarity on:
    - What happens if a discrepancy between original test and audit test exists
    - Whether OLCC can require licensed labs to provide samples directly for testing
- Proposed rule change resolves these gaps by:
  1) Requiring labs to retain samples for a minimum period of time, and to provide to OLCC for audit testing if requested
  2) Creating structure related to how big of a difference in potency testing is "big enough," and what happens as a result

WHY DO WE NEED A RULE?

- The current market conditions create a *very* competitive environment, and THC potency numbers are critical to getting shelf space
- There has been a significant uptick in complaints (from labs about other labs, and from producers/processors about other producers/processors) related to "gaming" of potency testing
- Fidelity of testing is a major feature of the legal, regulated market – consumers should pay for what they're getting, and have confidence in its accuracy
- This new rule is a tool *in addition to*, not instead of, existing compliance tools to hold labs and other licensees accountable on sampling & testing

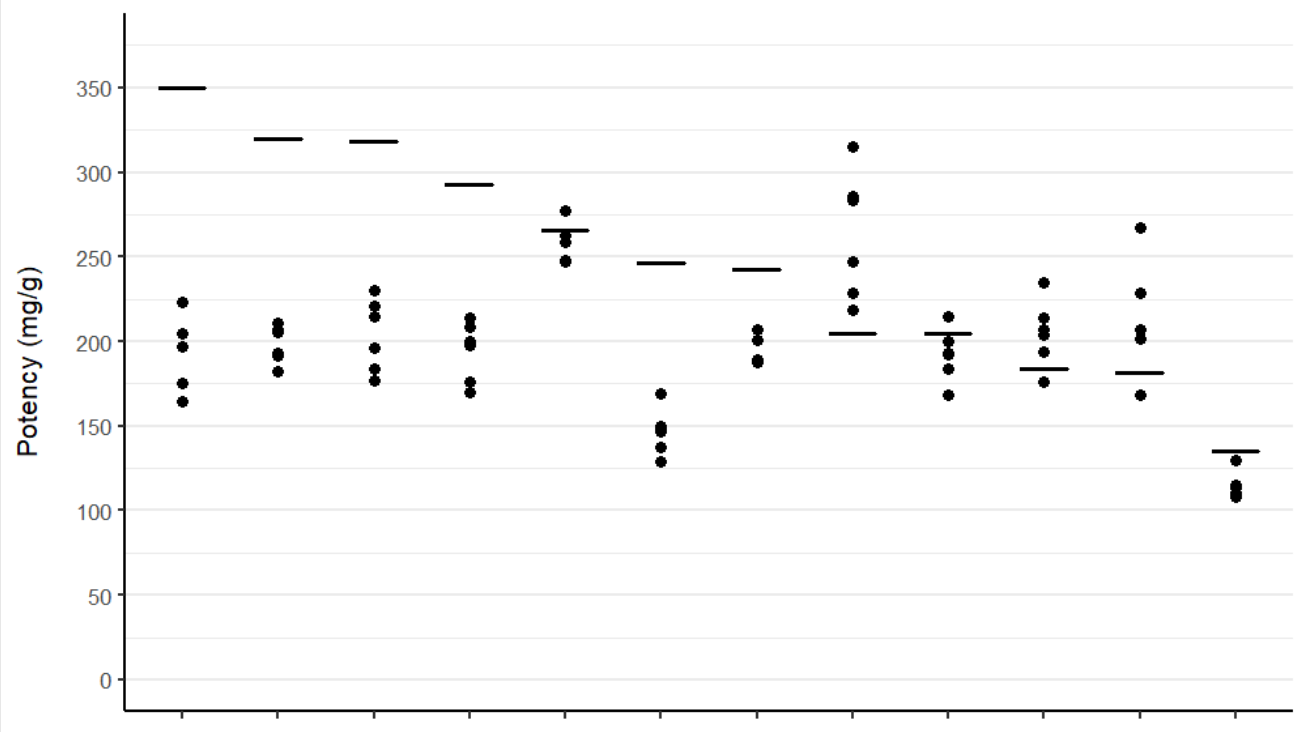
WHY DON'T CURRENT RULES SOLVE THE PROBLEM?

- ORELAP accreditation ensures technical proficiency, but not an adequate tool to prevent compliance issues
  - Labs undergo proficiency testing to prove they can detect required analytes – but they know when they are being tested

- Very difficult cases to prove, including who is at fault; multiple ways potency can be "gamed"
  - Fundamental problem is the incentive structure and licensees "voting with their feet" – labs getting the most business are those with the *highest* numbers, regardless of accuracy

WHAT HAS OLCC SEEN?

Recent "round robin" audit testing of usable marijuana found concerning results – highest original tests had the largest audit testing "drop off" (solid line = original compliance test, dots = round robin results)



DETAILS OF THE RULE CHANGE

- New proposed rules (OAR 845-025-5760) would establish a round robin testing program
- Round robin testing could not begin until after Jan 1, 2023 (when rules become effective), but all compliance tests done on/after **Dec 1, 2022** would be eligible to be checked under this program
- Audit testing that results in statistically significant difference compared to original compliance test could be required to be relabeled by OLCC
- No penalty or violation associated with "failing" the audit testing
  - If evidence of fraud or non-compliance is found (by either lab or client licensee), violations could be pursued – this program is in addition to, not instead of, current rules
- Goal is to flip the incentive structure from "get the highest result possible" to "get the most accurate result possible"

WHAT IS A T-TEST?

- T-test is a statistical method to determine when a difference between two groups is "real" vs. due to random variation
- Proposed rule establishes a threshold of 99% statistical confidence – in other words, *if* the compliance test was accurate and representative of the true mean potency value, only 1% of samples would have that large of a difference
  - 99% confidence interval means it's *much more likely* that the original compliance test does not reflect the true mean potency of the batch
- T-test is calculated based on
  1) The size of the difference between the original potency test and the "round robin" average
  2) The variation ("spread") between the labs participating in the round robin

HOW DO YOU CALCULATE A T-TEST?

Example 1: significant difference between round robin and original compliance test (two-sided one-sample t-test where the original compliance test is "mu," the known specific value)

Round Robin Results	Original Compliance Result		
23%	35%	Round Robin Avg:	25%
24%		Round Robin Std Dev:	2.2%
26%		Number of Round Robin Results:	4
28%		Std Error of Mean	1.1%
		df:	3
		t-statistic:	-8.79426
		p-value:	0.003098
		Significant Difference at 99% level	

HOW DO YOU CALCULATE A T-TEST?

Example 2: ***not*** a significant difference between round robin and original compliance test

Round Robin Results	Original Compliance Result		
31%	35%	Round Robin Avg:	25%
27%		Round Robin Std Dev:	5.1%
19%		Number of Round Robin Results:	4
24%		Std Error of Mean	2.5%
		df:	3
		t-statistic:	-3.85528
		p-value:	0.030831
		NOT a significant difference