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Ryan Zboralski Rule Lead Department of Ecology EAPRulemaking@ecy.wa.gov

Re: Accreditation of Cannabis Laboratories Draft Rule - Comments

Dear Mr. Zboralski and the Department of Ecology Cannabis Laboratory Accreditation team:

We have reviewed the proposed draft rule WAC 173-55 and have the following comments:

- 173-55-040 Initial Accreditation Application
 - Sections 2(b)(i) and 2(b)(ii) state that the lab must submit a copy of their standard operating procedures and Quality Assurance Manual. Our manual includes a lot of proprietary information. Will this manual be protected from public records disclosure? We believe that this information is confidential and should not be open to the public.

173-55-050 Accreditation Renewal Application

• Sect 3 states "A laboratory must submit a renewal application to the department 30 days before their accreditation expires." We believe "30 days" should be qualified: "at least 30 days," "30-40 days," etc. The current verbiage implies exactly 30 days.

173-55-090 Proficiency Testing

• Sect 2 states "For full accreditation, proficiency tests for potency, pesticides, and residual solvents must be in cannabis material containing concentrations of cannabinoids representative of products available to consumers." Current PT samples are in hemp matrices due to the DEA Schedule 1 status of THC and the inability to ship samples using standard logistics companies. During the scheduled meetings, DOE did discuss that waivers can be issued if appropriate PT samples are unavailable. We would like to confirm that waivers are how the DOE (or other agency) would handle the lack of availability of PT samples described in this section.



173-55-090 Proficiency Testing (cont'd)

• Sect 5 states "Proficiency tests samples must undergo the identical preparation and analytical process used for routine samples." Instructions to prepare some PT samples are often different from the procedure listed in the laboratory's SOP. For example, the SOP may state to subsample 0.50 g for a pesticide test but the PT may provide approximately 1 g of sample with instructions to extract the entire sample and assume 1.0 g. In cases like this, we would follow the PT instructions and make necessary changes to the preparation/extraction as necessary to bring it as close to our standard SOP. How would the DOE advise the lab to address this discrepancy?

173-55-180 Fee structure

• Sect 2: During the recent webinars, the DOE did provide updated information on the fee structure and it was a reduction from the previous calculations. However, the fee is currently significantly higher than current licensing fees. Furthermore, the highly variable structure makes it challenging for laboratories to budget for this annual fee and determine test pricing accordingly. If passed, this fee is the among the highest fee for testing laboratories in any legal cannabis state. Other states with high licensing fees, such as California, provide a fee structure that is based on the size/revenue of the cannabis laboratory. We believe the proposed significant increase in fees for WA laboratories would negatively impact the industry and affect consumer health and safety.

If the number of accredited laboratories in the state decreases, the fee per laboratory would increase significantly because the remaining labs would be required to absorb the costs. Laboratories already navigate extensive method requirements/regulations and high costs for purchase, maintenance, and servicing of analytical instrumentation; qualified personnel; proficiency testing programs; reference standards; consumables (including expensive columns and compressed gasses); and accreditation/licensing fees (which are currently about 10x lower than the newly proposed fees!) Cannabis is highly taxed and an ideal solution would be for the regulatory agencies to request a portion of these taxes be used to offset the cost of the laboratory accreditation program and limit the maximum percent increase that can be implemented when fees are recalculated, which would result in more predictable accreditation costs. Laboratory testing is an important service to public health and safety when consuming cannabis products; therefore, it is in everyone's best interest to have functional and competent labs with appropriate oversight.

We would also like confirmation that the fee is set for a biennium so will be the same for two consecutive years.

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Sincerely,



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