Steep Hill Pennsylvania

April 3, 2021

John J. Collins, Director, Office of Medical Marijuana
Department of Health
Room 628, Health and Welfare Building
625 Forster Street
Harrisburg, PA 17120

RE: Regulation #10-219-Medical Marijuana

Dear Director Collins:

Thank you for providing the opportunity to submit public comments. Steep Hill Pennsylvania has been ISO/ IEC 17025 accredited and approved by the Department of Health to test Medical Marijuana in the Commonwealth of Pennsylvania since May of 2018. We are writing to you today to provide comments on the proposed permanent Regulation #10-219.

Specifically, we are requesting the proposed change underlined below should be **removed** from the regulations as it does not meet the criteria contained in the Regulatory Review Act.

§ 1171a.29. Testing requirements.

"(c) At a minimum, testing, as prescribed by the Department, shall be performed as follows:

(1) An approved laboratory shall test samples from a harvest batch or harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product.

(2) An approved laboratory other than the one that tested the harvest batch or harvest lot shall test samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization."

The proposed change does not meet the criteria contained in the regulatory review act because it is **not consistent with the statute which the regulation implements** for the following reasons:

1. There may be an unintended consequence of laboratories seeking to partner to control market share. This is counter to state regulations that stipulate the importance of laboratory independence.
2. Laboratories must meet and maintain the stringent standards of ISO/IEC 17025 accreditation, which provides ample checks and balances. This regulatory change will challenge the lab's existing regulatory structure implemented by ISO/IEC 17025:2017. Some of the many ways in which ISO/IEC 17025 accreditation provides ample checks and balances are as follows:
    a. ISO/IEC 17025:2017 4.1 and 8.5: These sections require a laboratory to identify and mitigate risks.
    b. ISO/IEC 17025:2017 6.2: This requires a laboratory to hire competent staff, then train and deem them to be competent. Ongoing demonstration of competency is also required.

c. ISO/IEC 17025:2017 6.5: This requires a laboratory to utilize equipment that is calibrated by a competent provider using traceable reference standards and materials.

d. ISO/IEC 17025:2017 6.6: This requires a laboratory to utilize competent providers for their equipment, consumables, service, and subcontracting needs.

e. ISO/IEC 17025:2017 7.2: This requires a laboratory to utilize a method that has been approved by a reputable organization or validate a method that is developed inhouse.

f. ISO/IEC 17025:2017 7.3: This requires a laboratory to utilize a sampling method that is statistically valid.

g. ISO/IEC 17025:2017 7.5: This requires a laboratory to keep records to trace the life of a sample from the time it arrives at the lab to the time it is destroyed.

h. ISO/IEC 17025:2017 7.7: This requires a laboratory to monitor their results to ensure that they are valid, including mandatory participation in interlaboratory comparison studies.

i. ISO/IEC 17025:2017 7.9 and 8.6: These sections require a laboratory to seek feedback and address any complaints.

j. ISO/IEC 17025:2017 7.10: This requires a laboratory to address any instances of work not conforming to their own procedures and/or processes.

k. ISO/IEC 17025:2017 8.7: This requires a laboratory to investigate deficient and non-conforming areas.

l. ISO/IEC 17025:2017 8.8: This requires a laboratory to audit their procedures and processes to ensure compliance.

m. In addition to routine assessments, laboratories are required to demonstrate ongoing performance through participation in rigorous proficiency testing twice a year, annual reviews, and scrutiny of scope expansion requests. Inter-laboratory comparison proficiency testing (ILC/PT) studies are conducted by ISO/IEC 17043 accredited providers such as NSI or Absolute Standards. These trusted providers conduct ILC/PT studies for a span of industries outside of cannabis. Results are compared to provider assigned values and laboratories receive “acceptable/not acceptable” scores for their submitted data. A redacted report of all submitted laboratory data is also provided to the laboratory participants, allowing for inter-laboratory comparison. Laboratories must report their PT reports to the accreditation body, who requires remediation in the event of “not acceptable” analyte scores. Should a laboratory fail to correct a “not acceptable” result and pass a subsequent ILC/PT, the accreditation may be revoked. Repeated “not acceptable” results from a laboratory may also put a laboratory’s accreditation in danger of revocation by the laboratory’s accreditation body. Recent ILC/PT studies included upward of 40 participating laboratories nationwide for the Fall 2020 series for cannabinoid potency and pesticide residues. Raw data, Z-scores, percent recovery, and Gaussian distribution are used for the inter-laboratory comparison. These results promote accurate testing and call out outlying numbers and bias among the laboratories. We are confident that the laboratories of Pennsylvania are participating in and passing the ILC/PT as part of ISO/IEC 17025 accreditation.

3. The proposed regulations risk violation of the laboratory’s accreditation and the spirit of established international standards. Decoupling the harvest and process testing as proposed could put laboratories in a vulnerable position regarding their legislatively mandated ISO/IEC 17025 accreditation. ISO/IEC 17025 is an international standard for laboratory accreditation and all independent testing laboratories must meet the criteria of ISO/IEC 17025.

    a. ISO/IEC 17025:2017 4.1.3: This section requires a laboratory to act with impartiality and to be free of pressures that could compromise impartiality. The proposed change puts laboratories at risk of compromising impartiality when discrepancies arise in data points

since it would represent a competitive disadvantage to have erroneous results or inferior testing capabilities exposed to customers in this manner.

b. ISO/IEC 17025:2017 5.6: This section requires laboratories to identify and prevent deviations. The proposed change would decrease the ability to identify and minimize deviations between the harvest and final product data, as the laboratories are prohibited from exchanging confidential information with one another.

c. ISO/IEC 17025:2017 7.1.7: This section requires laboratories to cooperate with their customers. The ability to cooperate with customers would be at risk when they would need laboratories to share confidential information, which they are restricted from sharing. Any deviation would force G/Ps to make their data public for the laboratories to participate in any cooperative 'checks and balance' system. Any inter-laboratory cooperation would also be in contradictory to § 1171a.31 (b):

d. "…[results] shall be entered into the electronic tracking system and shall only be accessible to the grower/processor submitting the sample and to the Department."

e. ISO/IEC 17025:2017 4.1.5 requires laboratories to identify and mitigate risks. The proposed change would decrease the laboratory's ability to detect as well as minimize, or eliminate, those risks without violating data confidentiality.

f. ISO/IEC 17025:2017 8.5 & 8.6 requires laboratories to identify risks, opportunities, and improvements. The proposed change would impede laboratory's ability to do so without violating impartiality and confidentiality, therefore decreasing the effectiveness of the laboratory's quality management system.

The proposed change does not meet the criteria contained in the regulatory review act because of **the economic and fiscal impact of the regulation** that will result in the following:

3. The disruption to operations across the industry will result in increased costs and undue administrative burden, which will affect supply. Increased costs will inevitably be passed along to Medical Marijuana patients who are already facing high costs and challenges with availability.
4. Presumption of cheating or bad-acting by the laboratories reflects poorly on the Commonwealth as a business-friendly state. This casts unwarranted dispersion on the program as a whole. This impacts the ability of the Commonwealth to attract other businesses and revenue to the Commonwealth.
5. <u>The economic and fiscal impact to testing labs will be substantial, resulting in immediate loss of up to 50% of a lab's existing revenue and earning potential. Testing laboratories have acted in good faith, compliantly practicing our trade. Labs have invested millions of dollars in state-of-the-art instruments and methods, created scores of Pennsylvania jobs; all of which are now threatened by the loss of a free market system. After 3 years of program safety and success for Pennsylvania's patients, the state inexplicably and perhaps unintentionally, is proposing to disrupt the free market with no apparent justification and rationale. The proposed regulation sets a troubling precedent of regulatory overreach with a high likelihood of failure to achieve its goal of "checks and balances".</u>

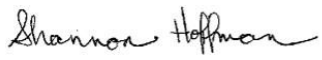
The proposed change does not meet the criteria contained in the regulatory review act because it is not **reasonable of the regulation** for the following reasons:

1. There is no mechanism in place to ensure that the "checks and balances" will be effective. Rather, it seems to rely on some self-correcting nature of the industry. In reality, conflicting results between laboratories will create uncertainty and confusion for patients and business disruption for Growers, Processors and Dispensaries.

2. The lack of standardization in Marijuana testing means that laboratories test by proprietary methods. Not all labs provide the same service, turnaround time, and expertise. Growers and Processors should be free to choose the lab that provides the best service, accuracy, and turnaround time. The regulations propose a slippery slope of overreach into the free market.

We appreciate your consideration in this important matter. Please contact us if you require anything further.

Best Regards,



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