Steep Hill Pennsylvania

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

From: Dr. Daniel Niesen, Steep Hill Pennsylvania Laboratory Director

Date: April 5, 2021

Subject: Regulation #10-219-Medical Marijuana;
Pa.B. Doc. No. 21-327. Filed for public inspection March 5, 2021, 9:00 a.m

Dear Director Collins,

Thank you for providing the opportunity to submit public comments. On behalf of Green Analytics North LLC, a Pennsylvania limited liability company doing business as Steep Hill Pennsylvania, I would like to submit the following comments regarding the proposed regulations.

Dr. Daniel Niesen
Laboratory Director
Steep Hill Pennsylvania
6360 Flank Drive Suite 700 Harrisburg, PA 17112

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§ 1171A.29. TESTING REQUIREMENTS

Subsection (c)

"(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."

"Subsection (c). The current subsection (c) specifies that an approved laboratory must minimally test two samples at harvest and at process stages. This proposed subsection (c) amends the current subsection (c) by providing that one approved laboratory must conduct testing on the harvest sample and a different approved laboratory must conduct testing on the processed sample. This revision creates checks and balances in the testing process."

Comment 1: Unnecessary and Unwanted Disruption

There is no evidence of a need for additional "*checks and balances*" in the existing testing process and, thus, the proposed revisions to §1171a.29(c) are wholly unnecessary. Rather, as demonstrated in this Comment and the following Comments, there is substantial evidence that approved laboratories are entirely safe and reliable, and that requiring two approved laboratories in the testing process is both *unnecessary and unwanted*. The existing testing process provides structure, compliance, and safety to the program. It meets the needs of growers and processors, and has proved to be functional. The current testing process should not be bifurcated as proposed in the revisions.

The proposed changes to §1171a.29(c)(2) will impose immediate disruption and uncertainty to the existing marketplace's obligation of contracts. At many of the grower-processor facilities, process testing is timed to take place *immediately* after harvest data delivery. A synchronous, organized schedule managed between the grower-processor and a single approved laboratory has, in many instances, become the standard across the state to meet the demands of the patient population. The proposed changes would require grower-processors to manage schedules with two approved laboratories, creating challenges to maintain their current contractual demands where those challenges do not presently exist. The disruption to existing and established operations across the state will result in increased costs and undue administrative burden, which will affect supply. Increased costs will inevitably be passed along to program's patients who are already facing high costs, and challenges with availability.

There is no mechanism described for the *"checks and balances"*, or anything to ensure that they will be effective. The existing process has allowed and will continue to allow the market to grow and thrive safely. There is no evidence that a required addition of a second approved laboratory will improve the existing testing process.

Comment 2: Approved Laboratories Already Enforce Checks and Balances

The proposed changes to §1171a.29(c)(2) make it onerous to reconcile any differences observed between harvest and process testing. With the establishment of a quality system per *ISO 17025*, as well as in accordance with §1171a.32, the approved laboratories implement, and enforce, *checks and balances* upon themselves using internal procedures, such as data integrity, confidentiality, intra-laboratory established quality controls, and risk and deviation mitigations.

The laboratory's accreditation from an ILAC recognized Accreditation Body is a *continuous* checks and balances process. The accredited laboratories are required to confirm compliance with the entirety of the *ISO/IEC 17025* standard. The list below includes only some of the areas that are part of the required checks and balances system:

ISO/IEC 17025:2017 4.1 and 8.5: These sections require a laboratory to identify and mitigate risks.

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.

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.

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

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.

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

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.

ISO/IEC 17025:2017 7.7: This requires a laboratory to monitor their results to ensure that they are valid.

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

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.

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

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

In addition to routine assessments, the approved laboratories also evaluate ongoing performance through proficiency testing review, off-cycle annual reviews, and any scope expansion requests. Inter-laboratory comparison proficiency testing (ILC/PT) studies are conducted by *ISO 17043* accredited providers such as NSI or Absolute Standards. These trusted providers conduct ILC/PT studies for a span of industries outside of cannabis. The laboratories submit results confidentially to the test providers, as well as to the laboratories' accreditation body who then can oversee the laboratory's corrective actions on any "not acceptable" analyte scores. A redacted report of all submitted laboratory data is also provided to the laboratory participants, allowing for inter-laboratory comparison.

Recent ILC/PT studies included upward of 40 participating laboratories nationwide for the Fall 2020 cannabinoid potency and pesticide residues series. The results promote accurate testing and display any outlying numbers, or bias, among the laboratories. The laboratories of PA are participating and passing the ILC/PT as part of their continuous *ISO 17025:2017* accreditation.

Comment 3: Compromise the Laboratory's Accreditation Standard

The proposed changes to §1171a.29(c)(2) are inconsistent with other industry safety and efficacy testing, especially when the state has previously given authority to independent third-party accreditation. The state's stance on independent third-party accreditation is enforced by the §1141a.21 definitions of *"accreditation body", "approved laboratory", "certificate of accreditation"*, and the requirements for laboratory approval held within §1171a.23 and §1171a.30 which include a recurring accreditation to the *ISO 17025* standard. By implementing the proposed changes to §1171a.29(c)(2) for undefined *"checks and balances"*, the state pushes the laboratories into a position that could compromise their quality systems, and established accreditation which may be against the states intent.

Within the accreditation standard, laboratories must adhere to confidentiality and impartiality clauses which limit the sharing of customer data. Any laboratory interactions, including a cooperative investigation, could be a risk to laboratory independence, data integrity, data impartiality, and client confidentiality, potentially compromising sections of the accreditation standard including *ISO 17025:2017 4.1.3, 4.2.1,* and *4.2.2*.

Comment 4: Decreases the Effectiveness of the Laboratory's Quality System

The proposed changes to §1171a.29(c)(2) will directly decrease the approved laboratory's abilities to identify and minimize deviations between the harvest to final product data on behalf of their customers. The disconnection of data generation is a direct loss to data integrity. Two laboratories may not be performing analysis using the same technology. The proposed change would impede laboratory's requirements to identify risks, opportunities, and improvements without violating impartiality and confidentiality, therefore *decreasing the effectiveness* of the laboratory's quality management system by impeding *ISO 17025:2017 4.1.5, 7.1.7, 8.5.1, 8.5.2, 8.5.3, 8.6.1, and 8.6.2.*

§ 1171A.35. LABORATORY REPORTING

Subsection (b):

"(b)(1) Regarding tests results not entered into the electronic tracking system, <u>the approved laboratory shall immediately provide to the Department an electronic copy of the certificate of analysis.</u>"

<u>Comment 5: Additional Testing Reporting</u>

While the state has provided clarity on testing beyond the harvest and process lots (§1171a.29, §1171a.31, §1171a.35), they continue by stating that the results are required to be turned in to the department immediately. There is no system of how the laboratories would comply with this request, which will be voluminous in some cases. This is an unnecessary and burdensome intervention.

§1151A.25 ACCESS TO GROWER/PROCESSOR FACILITIES

Subsection (e):

"(e) A grower/processor shall do the following when admitting an individual to a site or facility:

(5) Ensure that the individual does not touch any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products located in a limited access area.

Comment 6: Sampling Access

Laboratory agents must touch "seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products" in order to collect samples in compliance with sampling outlined §1171a.29.