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DH, MMRegulations

From: Kelly Greenland <dr.kelly@keystonestatetesting.com>
Sent: Monday, April 5, 2021 1:21 PM
To: DH, MMRegulations
Subject: [External] Response to Proposed Rule Change
Attachments: Proposed Rulemaking Response 210405.pdf

Please see attached.

Thank you,
Kelly Greenland, PhD

To: John J Collins, Director
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Response to proposed rulemaking:

1171a.29 An approved laboratory other than the one that tested – This should not be passed as is. Until the Department requires specific methodologies *and enforces them*, forcing any manufacturer to utilize multiple testing facilities with varying methodologies will result in patients getting hurt.

The Department requires laboratories to maintain ISO17025 accreditation, but this does not ensure accredited laboratories are accurately performing testing, only that they adhere to a quality management system prescribed by ISO17025. Proficiency tests are required with accreditation, but as marijuana is a controlled substance, ISO17025 accepts tests that are not in matrix but instead are just the compounds of interest in solution. As a result, proficiency tests are performed without any sample preparation steps or dilutions, which is where a large portion of error and uncertainty come into play.

However, the Department *should* modify the requirements for laboratories to annually pass proficiency tests in matrix. Currently multiple vendors provide cannabinoid potency in hemp flower and hemp oil. Hemp falls under the cannabis family as having a THC concentration below 0.3%, as required by the Federal Farm Bill. Marijuana falls under the cannabis family as having THC concentration above 0.3%. Therefore, proficiency tests utilizing hemp flower and hemp oil are representative of the sample preparation methodologies and analysis techniques the laboratories need to utilize to provide accurate data to the Department.

Likewise, microbial contamination, heavy metals, moisture content, mycotoxin and aflatoxins, pesticides, residual solvents and terpene proficiency tests are commercially available using hemp (or hemp oil) as a matrix to more accurately simulate the testing process used by laboratories for marijuana. Furthermore, by requiring laboratories to complete proficiency tests using matrix samples, it significantly reduces any issue arising between utilizing different technologies. In the Guidance for Quality Testing and Sampling by Approved Laboratories Updated August 10, 2018, the Department outlined suggested testing methodologies for the analyses where proficiency tests should be completed, and none of the testing methodologies varies widely enough that a different result would be obtained from a proficiency test. Microbiological testing states “appropriate methods for performing including plating and culture”. As the results need to be in cfu/g (colony forming units per gram) units, any qPCR system laboratories are currently using must have a conversion factor to convert laboratory qPCR results to cfu/g units, which is the reportable data for proficiency tests in matrix.

Proficiency tests in matrix alone are not sufficient to ensure accredited laboratories can correctly do testing, particularly within similar ranges of uncertainty. Acceptance ranges for proficiency tests can be as wide as 30%, which would imply one laboratory could provide a systematically low value, and a second a systematically high value, and the change in result could be as high as 60%, with both laboratories passing proficiency tests. And everyone knows when a proficiency test is being completed. Even within my laboratory, we have as many technicians prepare proficiency test samples as matrix allows, to obtain a data point on technician uncertainty. There is a bias when proficiency samples are prepared, similar to if the boss was looking over their shoulder. Therefore, the Department which has the authority, as explicitly stated in 1171a.34(a) to provide samples to an approved laboratory for proficiency testing, should provide duplicate samples to multiple laboratories to ensure laboratory results are in agreement within acceptable deviation. While the laboratory would have the bias of being a test for the Department, if the laboratory had previously tested the sample, the Department would be able to determine if the laboratory had previously provided accurate results. With sufficient data points the Department would be able to protect patient safety by identifying laboratories that are consistently providing inaccurate results.

Additionally, by requiring grower/processors to work with multiple laboratories, the Department is nearly encouraging “lab shopping” by having the grower/processor pick and choose which laboratory provides which results. If a laboratory consistently provides inaccurate microbial contamination results benefitting the grower/processor, or if a laboratory artificially inflates cannabinoid potency, the business manager in a grower/processor would be fired if he/she did not choose the lab to proceed with, despite potentially providing inaccurately labeled product to medical patients in Pennsylvania.

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