



MEMORANDUM

TO: Chair Springer and Members of the
Marijuana Control Board

DATE: June 13, 2018

FROM: Erika McConnell, Director

RE: Director's Report

OPERATIONS

I have received several requests to create prioritize transfer applications over new applications. At this time, staff processes applications in the order in which they are received, mixing new and transfer applications. Does the board wish AMCO to prioritize transfer applications over new applications? Additionally, I request that the board stress to licensees that they may not transfer ownership of their business until the license transfer is approved by the board, unless the new business owner stops operating from the time they take over ownership until the time their license transfer is approved. Otherwise, contracts between the current business owner and the buyer of the business should be effective and contingent on board approval of the license transfer.

TRAVEL/CONFERENCES

Regulators' Roundtable – Denver, CO – May 2018

Harriet Milks and I attended this meeting, along with representatives from 13 other states, four Canadian provinces, and the federal government of Canada.

We heard from Mark Kleiman, professor of public policy at New York University, and Beau Kilmer of the Rand Corporation, who are two of the three authors of a comprehensive book on marijuana legalization. One interesting idea put forth by Mr. Kleiman was a tax based on THC content rather than weight or price. Mr. Kilmer spoke on twelve recommended “design factors” for regulatory structures: production, profit motive, power, promotion, prevention and treatment, policing and enforcement, penalties, potency, purity, public consumption, price, and permanency. The speakers noted the following:

- Cannabis use disorder is trending upwards over the past ± 20 years; individuals reporting heavy use increased from 9% in 1990 to 35% in 2017
- Similar to alcohol, approximately 80% of marijuana sold is consumed by 20% of the consumer population
- Budtenders are the primary source of advice for consumers on use and health consequences, despite potential lack of education and/or training
- More studies of the product and marketplace are needed to produce more reliable data
- There is no “measured dose” of marijuana as a standard unit of consumption, as there is with a “standard drink” of alcohol

In the state-by-state roundup, we learned that most states are wrestling with the hemp/CBD issue and find establishing laboratory standards to be a challenge. Those states that don't regulate supply have concerns, similar to Alaska, that oversupply could be an upcoming problem.

Efforts to create a formal regulator's organization continue; adoption of constitution/bylaws is anticipated within the next year. The next meeting of the group is planned for the fall in Boston.

Bob Troyer, the US Attorney for the District of Colorado, provided information about cooperation between various law enforcement agencies in Colorado and the state's Marijuana Enforcement Division.

CannaWest: Compliance, Testing & Product Safety – Redondo Beach, CA – June 2018

I was invited to be on a panel at this conference, and attended the majority of sessions. A few takeaways:

- There are a variety of groups looking at developing national testing standards, including AOAC International (informally the Association of Analytical Communities), the Institute of Food Technologists, ASTM (previously American Section of the International Association for Testing Materials), and the American Council of Independent Laboratories.
- Some states require their testing facilities to be accredited to ISO 17025, which is the ISO standard for testing and calibration laboratories.

LEGISLATION WRAP-UP

HB 273 extends the termination date of the MCB to June 30, 2024. This bill was transmitted to the governor on June 11.

SB 81 was the final vehicle for the background checks issue. The bill requires background checks for marijuana licenses every five years rather than yearly. This bill is awaiting transmittal to the governor. Until such time as this bill becomes law, we are continuing to require background checks with renewals this year.

SB 6, relating to industrial hemp, was signed into law on April 13, 2018, with an immediate effective date. Ms. Milks provided an overview of this bill at the April meeting.

Legislative requests will be due around the end of summer, so please start thinking about requests the board may wish to send to the legislature. This will be an item on the August agenda for the board to finalize. Staff may have some requests at that time. Attachment 1 to this report is thoughts from a licensee.

REGULATIONS

- **Current Regulations Projects**

Attachment 2 to this report is a regulations projects status spreadsheet.

SPECIFIC ISSUES

- **Testing Working Group and Testing Issues**

The testing working group continues to hold productive meetings—its first recommendations for regulations changes are in Tab 10 of this meeting's agenda.

The Environmental Health Lab (EHL) audit of CannTest and Steep Hill is finished and attached for your review. The testing working group will be reviewing the audit and using it to inform future recommendations. (Attachment 3)

NEXT MEETINGS

The next regularly scheduled MCB meeting is August 15-16 in Denali. Applications must be complete and any other documents for the board must be submitted to our office by July 27, 2018, to be on the June agenda.

STATISTICS

Sales

March	\$8,758,954
April	\$8,592,428
May	\$9,643,296

Total sales from program inception to 5/31/18: \$100,465,721

Taxes

February – from 87 taxpayers:	\$897,082
March – from 92 taxpayers:	\$1,089,580
April – from 90 taxpayers:	\$1,063,847

Total taxes from program inception to 4/30/18: \$10,405,794

Attachment 1 to Director's Report June 2018



Alaska Green Resources

4 hrs · 🌐



Statewide licensees, this is your opportunity to request that changes be made regarding problematic marijuana regulations and poor regulatory practices within the AMCO enforcement division. Sen. Peter Micciche and Commissioner of the Dept. of Commerce Mike Navarre are interested in the major regulatory problems we as an industry are facing, and implementing some progressive changes to support the industry. Licensees from the Kenai Pen. had a lengthy meeting with them both on Monday and discussed several issues, one of them being enforcement not following written regulations and "interpreting" what they wish. Another very pressing issue is the inability to grind un-sellable bud into trim and selling as trim. According to AMCO enforcement, the Director, and the DOR, this is currently not allowed and anyone suspected of doing this will be reported to the DOR for tax evasion.

We have compiled a list of the MOST important issues and are asking that any additional concerns be added. Please no petty requests as they will only be focused on the most urgent issues. We would like you to add your comments and provide your area, name, business, and email. This email, signed by as many people as possible, will be sent to Sen. Micciche and Mike Navarre for further action. We are needing a minimum of 40 "signatures" statewide to land on his desk next week.

Thank you all for your participation, we are very powerful with one collective voice.

Kenai- Dollynda Phelps, Peace Frog Botanicals, jeffndol@yahoo.com

Kenai- Jeffery Phelps, Peace Frog Botanicals, jeffndol@yahoo.com

-Bud that cannot be sold to retail for a bud price should be able to be sold as trim to a manufacturer and be taxed at the trim tax of \$240/lb instead of \$800/lb bud tax.

-AMCO enforcement is not following regulations or state law in some cases. ie: Entering new genetics after licensing as allowed in AS 17.38.070(b)(6) is prohibited by enforcement.

-Proposed regulations pertaining to waste reporting are hazardous and not practical. Proposed regulations require that waste is bagged up for 3 days prior to grinding and making unusable. Bagged waste will begin growing mold in 3 days, grinding moldy waste will contaminate the entire facility with mold spores, creating a hazardous environment for those working in a cultivation facility and creating a health hazard for consumers. This must be avoided.

-The \$800/lb for bud or flower tax structure is problematic. As the wholesale price drops, the percentage of tax implied increases. This creates an additional financial burden to cultivators. Propose a 17.5% tax rate on bud or flower.

-Cultivators need enforcement to recognize statute AS 17.38.070(b)(6) allowing a licensed cultivator to receive immature plants or seeds from an individual 21 years of age, and stop prohibiting this at time of licensing.

-AMCO is extremely slow communicating with licensees, both during the review process which is taking up to 6 months on average, and when the Director is contacted by licensees with urgent matters. This is extremely costly to licensees and is unacceptable.

-Onsite consumption is a necessary step to provide a safe place for patrons to consume that is not forcing them to consume in public. This has been discussed well over a year and needs to be supported.

-Edible products are currently subject to very rigorous, pointless, and expensive daily testing requirements. There needs to be common sense standard practices for required testing of edibles.

Please contact me with any questions...Dollynda Phelps 907-252-8026

Dollynda Phelps

907-252-8026

DOL Project Number	Topic	Date Opened by MCB	Board member point person(s)	Current Status/Notes	Date Adopted by MCB	Effective Date
JU2015200669	Omnibus Regulations			Adopted by board; filed with Lt Gov	11/20/15 Pg 23	2/21/16
JU2016200436-1	Conduct of board meetings in alcohol	2/11/16 pg 2		Adopted by board; filed with Lt Gov	7/6/16	12/28/16
JU2016200436-2	[Reserved for anticipated future work]					
JU2015201028	Onsite consumption	2/11/16		Board voted not to continue project 2/2/17	N/A	N/A
JU2016200617	Handler permits	4/27/16; 2/2/17		sent to Lt. Gov 4/20/18	1/25/18	5/23/18
JU2016200611	Testing	6/9/16 pg 22		signed by Lt. Gov. 6/5/17	4/5/17	7/5/17
JU2016200610	Advertising requirements	6/9/16 pg 22	Schulte	vote to put out for comment failed 7/14/17	N/A	N/A
	Space planning and layout					
	Labeling and packaging			Approved 7/14/17; rescinded 11/28(29?)	N/A	N/A
JU2016200612	Video surveillance (Schulte handout)	6/9/16 pg 22	Schulte			
JU2016200609	Participation of outside entities – residency requirements (BE handout)	6/9/16 pg 22	Emmett			
JU2016200605	Waste disposal (Springer motion)	6/9/16 pg 23	Springer	Combined with waste disposal #2	N/A	N/A
JU2016200613	Retail store notices	7/8/16 pg 16		signed by Lt. Gov. 6/22/17	4/5/17	7/22/17
JU2016200837	Requiring fingerprints for new owners	9/7/16		signed by Lt. Gov. 6/19/17	4/5/17	7/19/17
JU2016200838	What happens to existing licenses if local gov opts out by ordinance	9/7/16		signed by Lt. Gov. 6/27/17	4/5/17	7/27/17
JU2016200839	DEC approval before acceptance of license application (food safety permit)	9/7/16		signed by Lt. Gov. 6/27/17	4/5/17	7/27/17
	Advertisement; definition of “advertisement” and “logo”	12/7/16		Board took no action on proposal (2/2/17)	N/A	N/A
JU2017200165	Transportation	2/2/17		signed by Lt. Gov. 9/11/17	7/13/17	10/11/17
JU2017200542	Quality control	2/2/17		sent to Lt Gov 4/24/18	11/29/17	5/25/18
	Notify AMCO of crime on licensed premises	5/15/17	Springer	sent to Lt Gov 4/24/18	11/29/17	5/25/18
JU2018200397	Waste disposal #2	2/2/17		Voted out for public comment 7/14/17; posted 8/17/17; cmts due 9/29/17; on 11/14 agenda; returned for more work 11/29/17; cmts due 6/5/18		
JU2017200548	Onsite Consumption	3/7/17		Voted out for public comment on 7/14/17; posted 8/21/17; cmts due 10/27/17; on 11/14 agenda; referred to cmte and postponed to April 2018 mtg 11/15/17; new draft on 4/4/18 agenda; postponed to June '18		

DOL Project Number	Topic	Date Opened by MCB	Board member point person(s)	Current Status/Notes	Date Adopted by MCB	Effective Date
JU2018200370	Plant count for new cultivators	4/5/17		Voted out for public comment 7/14/17; posted 8/15/17; cmts due 9/22/17; on 11/14 agenda; returned for more work 11/29/17; new draft on 4/4/18 agenda; amended and voted out for public comment 4/6/18; posted 4/26/18; cmts due 6/1/18		
JU2017200536-1	Require testing licensee to notify director of significant equipment failure	5/15/17	Springer	Voted out for public comment 7/14/17; posted 8/15/17; cmts due 9/22/17; on 11/14 agenda; approved 11/29/17	11/29/17	
	Separation distance	4/5/17	Springer	Draft on 9/14 agenda; no action		
JU2017200477	Timing of public objections	5/15/17	Emmett	Signed by Lt. Gov on 11/28/17	9/15/17	12/28/17
	Local government jurisdiction					
JU2017200533	Revise definition of "direct or indirect financial interest" at 3 AAC 306.015(e)	5/15/17	Springer	Voted out for public comment 7/14/17; posted 8/14/17; cmts due 9/29/17; on 11/14 agenda; failed 11/29/17		
	"Advertisement" and "promotional activities"		Mlynarik; Miller	Voted out for public comment 7/14/17; posted 8/14/17; cmts due 9/29/17; on 11/14 agenda; referred to cmte 11/29/17; amended and voted out for public comment 4/6/18; posted 4/26/18; cmts due 6/1/18		
JU2017200827	Allow licensees to participate in trade shows	5/15/17	Emmett	Voted out for public comment 9/14/17 comment period closed 1/11/18; approved 1/25/18 agenda; missing section approved 5/7/18; sent to DOL 5/17	1/25/18 & 5/7/18	
	Require corporation bylaws	9/14/17	Jones	Draft on 11/14 agenda; voted out for public comment 11/29/17; comment period closed 1/11/18; approved 1/25/18; sent to DOL 5/17	1/25/18	
	Multiple businesses on a lease				1/25/18	
	Removal of affiliates				1/25/18	
	Charging for multiple inspections	9/14/17		Draft on 11/14 agenda; voted out for public comment 11/29/17 comment period closed 1/11/18; approved 1/25/18; sent to DOL 5/17	1/25/18	
	Local gov approval of odor emissions	9/14/17	Springer	Draft on 11/14 agenda; voted out for public comment 11/29/17 comment period closed 1/11/18; approved 1/25/18; sent to DOL 5/17	1/25/18	
JU2018200331	Revise definition of "recreation or youth center"	5/15/17	Miller	Draft on 7/12 agenda; sent back to drawing board; new draft on 4/4/18 agenda; voted out for public comment 4/6/18; posted 4/19; cmts due 6/1		

DOL Project Number	Topic	Date Opened by MCB	Board member point person(s)	Current Status/Notes	Date Adopted by MCB	Effective Date
	Extend video storage retention time	11/14/17	Springer	Draft on 4/3/18 agenda; voted out for public comment 4/6/18; posted 4/19; cmts due 6/1		
	Date of issuance of handler permits	1/25/18	Jones	Draft on 4/3/18 agenda; amended and voted out for public comment 4/6/18; posted 4/19; cmts due 6/1		
JU2017200829	Definition of resident	9/14/17		Draft on 11/14 agenda; voted out for public comment 11/29/17 comment period closed 1/3/18; approved 1/25/18; rescinded 5/7/18		
	Financial background investigations	9/14/17	Jones	Draft on 11/14 agenda; voted out for public comment 11/29/17 comment period closed 1/3/18; sent to cmte 1/25/18		
	Random sampling	2/2/17		Draft on 11/14 agenda; referred to testing cmte 11/29/17		
	Require trim that is sold separately to be tested separately; kief	5/15/17	Emmett; Miller	Voted out for public comment 7/14/17; posted 8/15/17; cmts due 9/22/17; on 11/14 agenda; referred to testing cmte 11/29/17		
	Streamline edibles testing	7/14/17	Emmett	Draft on 11/14 agenda; referred to testing cmte 11/29/17		
	Allow out-of-state investment in testing labs	1/25/18	Springer	Draft on 6/13/18 agenda		
	Overlapping premises	1/25/18	Jones			
	Change from limited to standard cultivation license	1/25/18	Jones			
	Ownership change when licensees don't change	1/25/18	Jones			
	Sample jars					

**Department of Environmental Conservation
Division of Environmental Health**



State of Alaska Environmental Health Laboratory
5251 Dr. Martin Luther King Jr. Avenue
Anchorage, AK 99507

DATA VALIDATION REPORT

Laboratory Result Comparison

Prepared for:

Alcohol Marijuana Control Office (AMCO)
550 W. 7th Ave., Suite 1600
Anchorage, AK 99501

Prepared by:

Alaska State Environmental Health Laboratory
5251 Dr. Martin Luther King Jr. Avenue
Anchorage, AK 99507

June 4, 2018

Approved for Release:

Steven R. Crupi
Quality Systems Manager
State of Alaska -
Environmental Health Laboratory



Project Narrative

Summary

This report summarizes the results of the data validation performed on samples collected and submitted by AMCO to two testing laboratories, CannTest and Steep Hill, both located in Anchorage, AK.

On December 1, 2017, the Alaska Marijuana Control Office (AMCO) submitted CannaBanana muffin samples to both laboratories. Each of two muffins in three different retail packages were cut in half and submitted as separate samples. One half of each muffin went to CannTest and the other half of each muffin went to Steep Hill for testing and reporting.

On December 22, 2017, AMCO submitted additional samples of three matrices: cookie crumbs, capsules, and flowers. CannTest and Steep Hill each received approximately half of each sample.

Sample name	Potency (THC)				RPD
	CannTest		Steep Hill		
	mg/serving (unless otherwise noted)	mg/g	mg/serving (unless otherwise noted)	mg/g	
01-0992	5.26	0.34	11.9	0.58	52
02-0992	6.02	0.36	8.33	0.57	44
01-5332	5.66	0.29	8.00	0.41	34
02-5332	4.96	0.26	7.26	0.41	45
01-5922	6.28	0.28	8.86	0.45	47
02-5922	4.47	0.28	7.31	0.38	30
Cookie crumbs	13.8	NR	19.8	1.31	36
Capsules	4.40	NR	8.18	12.8	60
Dried Flower	24.70%	NR	16.2%	184	42
Dried Flower	12.8%	NR	12.1%	137	5.6

RPD = relative percent difference

NR = not reported

This report documents the review of the potency and microbial data. The samples were analyzed by CannTest and Steep Hill utilizing different extraction protocols for potency, but similar analytical techniques. The two labs used different microbial test methods.



TEST METHODS

Test	Method
Cannabinoid Potency Extraction	Agitation/QuEChERS Salt (CannTest)
	Sonication/Agitation(Steep Hill)
Cannabinoid Potency Analysis	HPLC – UV
Microbial	Plating (Steep Hill)
	qPCR (CannTest)

A summary of the results is provided below.

Laboratory Result Comparison

Sample name	Microbial					
	CannTest			Steep Hill		
	<i>Salmonella</i>	<i>E.coli</i>	<i>Aspergillus niger</i>	<i>Salmonella</i>	<i>E.coli</i>	<i>Aspergillus niger</i>
01-0992	ND	ND	ND	ND	ND	Detected
01-5332	ND	ND	ND	ND	ND	Detected
01-5922	ND	ND	ND	ND	ND	Detected
Cookie crumbs	ND	ND	ND	ND	ND	ND
Capsules	ND	ND	ND	ND	ND	ND
Dried flower	ND	ND	ND	ND	ND	ND
Dried flower	ND	ND	Detected	ND	ND	Detected
Dried flower	ND	ND	ND	ND	ND	ND

ND = Not detected

AMCO requested the Environmental Health Laboratory (EHL) perform data validation to investigate the differences in the results.

Briefly, the data review, with assumptions made, reproduced the reported results; however, several pieces of documentation needed to support the data were missing and there is a general lack of accuracy assessment occurring at the labs. The recommendation is for, 1) a complete assessment of lab operations as a follow-up to that of A2LA. Essential items to cover in this assessment are verifying implementation of critical parameters (e.g. incubation temperatures and times, calibrations of support equipment), procedures (e.g. laboratory homogenization and sub-sampling protocols), and general adherence to the laboratory SOPs) 2) accuracy controls (including all applicable positive controls for microbial testing and frequency) must be incorporated into lab activities, and 3) a regulation update that incorporates framework for regular oversight of the laboratories. Details of observations are provided in the following report.



I. DELIVERABLES/DOCUMENTATION

The laboratories provided data and documentation necessary to reproduce the reported results. However, sufficient documentation was not provided to demonstrate complete adherence to laboratory standard operating procedures (SOPs). Additionally, review of the SOPs found select procedural descriptions missing.

II. TECHNICAL ASSESSMENT

Reviewers

The data were reviewed utilizing laboratory SOPs as a point of reference and also experience auditing and reviewing data from municipal and commercial laboratories for SOP conformance, QA/QC activities and conformance to State of Alaska (SOA), EPA, and industry published methods. The Alaska State Environmental Health Lab (EHL) performed the reviews. The reviewers currently serve as Laboratory Certification officers for the SOA Drinking Water Program and Laboratory Evaluation Officers for the SOA Dairy Program.

Potency

Methodology. Both laboratories utilize high performance liquid chromatography-ultraviolet detection (HPLC-UV) analysis for potency testing. Each laboratory monitors a different wavelength (CannTest 230 nm; Steep Hill 272 nm) to determine presence/absence of and to quantitate the THC and CBD constituents of interest. The data review and an online literature search did not reveal one wavelength as better than the other from quantitative and qualitative perspectives.

Instrument Calibration. Both laboratories submitted instrument calibration raw data, for which the EHL was able to reproduce the linear regression analyses the laboratories generated for determining calibration acceptance. The linear regression analyses were both compliant to a correlation coefficient criterion of 0.995. CannTest used calibration data acquired over a year prior to the analysis of the samples, and Steep Hill used calibration data acquired about two months prior to sample analysis. The difference in lifespan of a calibration curve is statistically acceptable given performance of accuracy assessments and calibration checks within SOP prescribed intervals and QC criteria. Both labs performed calibration checks, but neither lab performed accuracy assessments.

Analytical chemistry techniques in a regulatory environment require consistency in instrument conditions across all calibration, quality control, and sample analyses. Select variations may adversely affect the representativeness of instrument data and are only allowed on a case-by-case basis, typically for a specific matrix that impedes instrument response. Any adjustments made for a parameter must be consistent in the calibration, quality control and sample analyses. Steep Hill's calibration and sample analysis procedures involve gathering data for a quality control parameter from a UV wavelength different from the UV wavelength used for potency parameters (e.g. THC, CBD) data. One way to assess the impact of this deviation is to recalculate Steep Hill's result using a calibration model similar to that of CannTest. This alternate calculation demonstrated differences in results ranging from 8-10% of their reported results.

Calibration Checks. Robust regulatory programs and methods, such as EPA-published or approved methodologies, require a verification of the accuracy of a calibration curve to a specified criteria prior to



sample analysis. Typically, this assessment is performed by analyzing a reference standard from a different vendor than that used for the instrument calibration standards. If a second vendor is not available, it is also permissible to use material from a different production lot from the same vendor that is different from the lot of the calibration standards. A recovery is calculated from the analysis of this standard and compared to acceptance criteria. The laboratories do not perform this calibration accuracy verification as part of their instrument calibration regimen.

The same methods require a stability assessment of the instrument calibration, determined through the use of a calibration verification standard, called a “continuing calibration verification” or CCV. CannTest’s SOP instructs to analyze a CCV at the beginning and ending of the analysis sequence. CCV acceptance criteria are specified in the lab’s SOP. For the CannaBanana sample analysis, the original beginning and ending analysis sequence CCVs had insufficient volume in the autosampler tube, so their chromatograms are simply baselines (i.e. no usable data obtained). A single remedial CCV was analyzed 12 hours after the analysis sequence was completed. The remedial CCV values did not pass the QC criterion for all constituents. For this situation and others where the CCV criteria for potency parameters were not met, no evidence was provided that corrective action was performed, that a reanalysis occurred, or that the data were flagged or a discussion of the outlier was included as part of the report.

The CCV criteria CannTest employs is more stringent than similar analytical organic chemistry methods in EPA-published methods; perhaps more conservative than needed as evidenced by results that are outliers to the criteria. Consideration for the widening of the criteria is warranted.

For each analysis sequence, Steep Hill submitted CCV results analyzed just before the samples, which met the QC criteria requirement in their SOP, criteria that are similar to like EPA-published methods. However, a CCV was not analyzed at the end of any of the analysis sequences, bringing into question the stability of the calibration curve during the entire sample analysis sequence or batch. The SOP should be amended to include a closing CCV at end of the run.

For both labs, a CCV minimally every 20 injections and at the end of each analytical run or batch is recommended, adding instrument calibration accuracy assessments, and re-examining acceptance criteria for achievability without being too generous.

Blanks. An instrument blank (IB) is a portion of the same solvent used to introduce a sample onto the instrument. Analysis of an IB demonstrates that the instrument system itself is not contributing to the concentrations of the target constituents. A method blank (MB) is a portion of “clean” material (e.g. lab water, “clean” solid matrix similar to the sample matrix and shown to be “clean”) that accompanies a batch of samples, undergoing the same sample preparation and analysis steps as the samples. The MB demonstrates the cleanliness of reagents, materials, and handling protocols used during the sample preparation and analysis steps.

CannTest and Steep Hill prepared IBs, which are not extracted, to demonstrate the instrument was not a source of contamination. Both laboratories demonstrated that their analysis processes were not sources of influence on sample result concentrations. Both laboratories also prepared MBs that were extracted and analyzed with the samples, successfully demonstrating that the sample preparation was not a source of contamination. The exact matrix material used for the MBs is unknown.



Accuracy. Data review for potency testing was unable to assess the accuracy (i.e. degree to which results represent the THC/CBD content of the matrix) of the potency methods. The laboratories did not provide quality control (QC) data of spiked control or spiked sample matrices to assess the effectiveness of the combined extraction and analysis procedures implemented at each laboratory. Consequently, the testing accuracy for the full sequence of events of each laboratory is unknown.

The CannTest SOPs cite the use of a laboratory control sample (LCS), described as a sample previously analyzed by CannTest. An LCS is intended as an overall accuracy assessment of the sample preparation and analytical methods on a per test batch basis. Even though stipulated in the SOP, CannTest did not prepare and analyze an LCS in conjunction with the prep and analysis of the samples.

Steep Hill's SOPs describe the use of a surrogate (δ -tocopherol), a compound chemically similar to the constituents of interest. Steep Hill only qualitatively evaluates the surrogate for dilution verification because the instrument calibration does not include δ -tocopherol and therefore a means for quantitating is not available. The surrogate is identified on the chromatogram and Steep Hill solely uses it to assess stability in the elution order of constituents and as an indicator if instrument performance drift may be occurring. Addition of the surrogate to Steep Hill's instrument calibration protocol would allow for an assessment of the sample extraction performance information needed to evaluate overall method accuracy.

Analysis of two of the samples analyzed by CannTest yielded results that exceeded the calibration curve for total THC. The sample extract should have been diluted and reanalyzed to bring the instrument measurement within the calibration range in order to obtain an accurate measurement. Data representing a dilution analysis was not available, when requested. Conversely, Steep Hill analyzed samples at set dilutions as high as 1:20 for the initial analysis of each sample, possibly missing detections (i.e. false negatives) of minor cannabinoids that were detected by CannTest.

Each laboratory participated in a proficiency test (PT) event offered by Emerald for potency, a vendor specialized towards providing reference and PT materials for cannabis testing services. The PT sample consists of an acetonitrile matrix that was fortified with known amounts of THC and CBD constituents. This matrix does not require employing sample homogenization or preparation/extraction techniques required for a plant or edible matrix. Consequently, results generated for the PT study only assess the accuracy of the instrumental technique, not the full sequence of events employed at the laboratory for a plant or edibles matrix. Consequently, the overall analysis performance was not assessed by this study.

For the Fall 2017 Emerald PT event, both laboratories passed all five analytes offered in the potency study. Each analyte had an acceptable variability, as determined by the study's statistical analysis. All reported acceptance values were within $\pm 20\%$ of the true value. (According to Emerald, 41 laboratories participated in the Fall 2017 study and 36 passed all analytes.)

Precision. The entire sample is not used up in the analysis, so the design of subsampling and homogenization procedures are critical towards obtaining representative results. Documentation of the subsampling and homogenization procedures beyond the SOP discussions was not provided for either laboratory, so could not be verified as occurring and to what extent, if any, these procedures may contribute to variability in results between the two labs. Both laboratories indicated they followed their sample preparation SOPs, as written. However, the SOPs submitted by Steep Hill and CannTest for review by the EHL were dated "December 2017" and "1/26/2018", respectively, which is after the prep/analysis dates of the CannaBanana samples. For CannTest, the SOP is dated after the analysis of the edible and plant.



CannTest generated two duplicate samples by subsampling a second portion of two samples from another client (other than the AMCO samples). The processing of these duplicate samples yielded relative percent differences (RPDs) of 1.7% and 2.3%. However, it is unknown if the sample matrix of the CannTest duplicates is similar to that of the CannaBanana, edible, or plant samples, bringing into question the applicability of the these duplicate measurements.

Steep Hill generated duplicate samples of one AMCO sample in each submission, which yielded RPDs of 0.4% and 0.7% for THC.

EPA-published methods for similar instrument techniques allows for a maximum sample duplicate RPD of 20%.

Sample Preparation. The sample extractions the two laboratories described in their SOPs are similar in principle, but with differences. Both laboratories describe breaking up the entire sample to homogenize it prior to taking a representative sample of about 2 g, depending on the matrix. The differences are in the extraction solvents and the physical extraction techniques employed by each laboratory. Since neither laboratory generates quality control samples assessing the accuracy of the entire process, it is not possible to assess the existence, direction or bias for either technique or make a comparison of the techniques.

Microbial

Methodology. CannTest analyzes for *Aspergillus species* by quantitative polymerase chain reaction (qPCR) assay using a Medicinal Genomics qPCR system. Steep Hill analyzes for *Aspergillus species* using cultural techniques from the US FDA's Bacteriological Analytical Manual (BAM) and Larone, D.H., 1995, "Medically Important Fungi: A Guide to Identification", 3rd ed. ASM Press, Washington D.C. CannTest also uses the qPCR method to analyze for *Salmonella* and *E.coli*, while Steep Hill uses cultural and antibody methods to analyze for *Salmonella* and *E.coli*.

Records necessary to fully evaluate adherence to each laboratory's Standard Operating Procedure (SOP) were not available upon request for both laboratories; however, the records provided did not indicate either laboratory varied from their SOP for the analysis of *Salmonella* or *E.coli*. Both laboratories have SOPs containing modifications to either an equipment manufacturer's procedure or the BAM methods. CannTest did not make available method validation studies demonstrating the effects, if any, of these changes. Steep Hill submitted validation studies with their license application documenting the changes employed for their methods.

Specificity – The qPCR assay utilized by CannTest identifies a species of bacteria or fungi based on a DNA (or RNA) sequence, which is specific to a species.

The cultural procedure employed by Steep Hill, for *Aspergillus* species, incubates the sample on Dichloran Rose Bengal Chloramphenicol (DRBC) plates, a selective media. A selective media is designed to encourage the growth of a targeted species and/or inhibits the growth of competing species. DRBC encourages the growth of more than one genus and species. This scenario allows for the possibility of non-target species to grow on plates, which if the morphology is similar, leaves open the possibility of misidentification. If growth occurs the analyst will look at macroscopic and microscopic morphology to identify the species.



Cultural techniques vary greatly in specificity; for example, Steep Hill uses a chromogenic agar medium, called HardyCHROM Salmonella, which produces colonies of a defined color in the presence of a specific enzyme. This type of media is far more specific than the type of media they use for *Aspergillus* testing, though still not as specific as molecular testing (e.g. qPCR).

Listed below, are some considerations for deciding if one type of method should be used over another for microbial testing.

- Specificity: There are many issues to consider when considering how target-specific the method should be. Is it better to have a test that will only confirm for selected organisms, or should it be able to detect similar organisms as well?
 - o Similar organisms may or may not have similar physiological effects.
 - o Does misidentification of a non-target species lead to higher pesticide/herbicide use?
- Sensitivity: A comparison study by Medicinal Genomics, which manufactures PCR testing kits, indicates PCR analysis identified contaminants more often than plating methods for Total Yeast Mold counts, when running the same sample.
- Living vs. dead organisms: Another consideration is if regulations are only concerned with living organisms. Cultural methods will only identify viable organisms, i.e. only those living organisms healthy enough to grow and reproduce. qPCR will identify DNA so organisms that are not viable or not living will still produce positive results. This consideration takes into account whether the concern is the organism itself, or possible toxins the organism produces. If the organism itself is the main concern, it is reasonable to only test for viable organisms. If toxins are the concern, testing for dead organisms may be more appropriate

Microbial Analysis. Documentation - Neither laboratory provided sufficient documentation of sample preparation protocols upon request, so review of the data assumes the laboratories followed SOP. Use of reagents, incubation temperature, or incubation time different than stipulated in the SOPs could have an adverse effect on microbial testing results. Upon request, the laboratories provided documentation of critical parameters; however, some of the documentation (e.g. incubation times and temperatures) was insufficient for demonstrating adherence to SOPs throughout the testing process.

Positive Control. Positive controls are used to show the method will result in positive identification if a target organism is present. CannTest runs a positive control with each batch. The data CannTest provided demonstrated passing positive controls, indicating the testing was in control and the reported negative results were not a result of a faulty testing method.

Steep Hill runs positive controls. Data provided for what the lab described as the most recent positive controls for *Aspergillus* were run June 27, 2017 and demonstrated acceptable results. The analysis time separation of the controls relative to the sample analysis submitted by AMCO is lengthy in comparison to other industry laboratories (e.g. drinking water) operating under a regulatory environment. Additionally, Steep Hill is using *Aspergillus brasiliensis* as its positive control in the analysis for *Aspergillus niger*.

Review of the positive control data provided by each laboratory did not suggest any deviations to the SOPs.



Extraction Control. An extraction control is used with qPCR (CannTest) to show the sample extraction was done properly. Extraction controls are not usually run with cultural methods (Steep Hill).

CannTest runs an extraction control with each sample set, using actual plant material vs. the isolated Single Copy Cannabis Gene (SCCG) recommended by the qPCR manufacturer (Medicinal Genomics). Positive results were achieved for related extraction controls, indicating the samples were properly extracted. This difference is believed to not have an adverse effect on the extraction control results; however, a validation study incorporating the change was not made available by CannTest.

Negative Control. Negative controls are run to demonstrate the analysis was free from contamination, which may cause false positives. Both laboratories ran negative controls with every batch for *Aspergillus*.

CannTest's negative controls were negative. Steep Hill's negative controls were also negative, indicating the so-identified *Aspergillus niger* growth identified for some samples was not a result of contamination introduced during the testing process. Negative controls for all microbial analyses were not submitted, but since both laboratories reported negative results for *Salmonella* and *E.coli*, there is no impact on the evaluation of the data.

III. CONCLUSIONS

Potency Analysis. This review was able to reproduce the qualitative and quantitative aspects of the reported results. Demonstration of intra-laboratory precision was evident for both laboratories, indicating each laboratory's data is reproducible. One goal of this review was determining the reason for the variability or precision values for the inter-laboratory comparison of results. This determination could not be made based on data because of a lack of accuracy checks throughout the entire preparation and analytical processes at both laboratories. Differently stated, this review could not determine which set of lab results best represents the true potency content of the matrices submitted by AMCO because the level of accuracy assessment is insufficient at both laboratories.

Microbial Analysis. The instrument results provided by CannTest demonstrate the absence of *Aspergillus niger* for all samples.

There was insufficient macroscopic and microscopic data (pictures and analyst observational notes) provided by Steep Hill to confirm the reported results. Macroscopic and microscopic pictures were provided by Steep Hill; however, the microscopic pictures were date stamped three weeks past the report date, which does not reflect observations at time of analysis. Other species of *Aspergillus*, like *Aspergillus brasiliensis*, have been noted to have a similar appearance to *Aspergillus niger* upon microscopic examination and may also grow on the selective media used by Steep Hill. In the absence of photographs or written observations from Steep Hill's examination, it cannot be determined if misidentification occurred due to mischaracterization or presence of another species with highly similar morphology to *Aspergillus niger*.

Given the lack of documentation on sample preparation and reagent information from either laboratory, adherence to SOPs could not be confirmed and sample preparation cannot be ruled out as a cause for the varying *Aspergillus niger* results. Some false negatives have been demonstrated for Total Yeast Mold analysis by qPCR if the wrong reagents are used in preparing the sample. Although the reagents actually used by



CannTest could not be confirmed beyond the SOP narrative, their controls demonstrated an appropriate response. For either methodology, spore clumping may lead to target organisms not being taken up in the analyzed aliquot, resulting in a false negative. While this cannot be ruled out or confirmed in this case, the available information indicates the samples contained an organism other than *Aspergillus niger*, rather than clumping leading to false negatives in three separate samples. Neither lab provided results of blind PTs for *Aspergillus*, so the ability of either lab to differentiate between *Aspergillus niger* and another organism has not been fully demonstrated.

Based on the available data, a factor in the difference of *Aspergillus niger* results between the two laboratories may arise from the varying specificity between the two methods.

Edibles and Flower Samples

Select elements used to evaluate the reported results for the edible and flower samples are missing. The results from both laboratories coincidentally agree.

IV. RECOMMENDATIONS

The initial audit by A2LA for both laboratories occurred before obtaining their operational licenses. A follow-up audit is recommended for verifying implementation of their SOPs, corrections implement in response to the A2LA audit report, institution of accuracy controls, and in the case of Steep Hill, incorporation of an *Aspergillus niger* positive control into the testing process. Additionally, several questions arose during the data review (e.g. nature of the materials used to create lab blanks), for which documentation was not made available by the labs upon request. The missing information hinders any assessment for completely determining adherence to SOPs.

Oversight of laboratories in Alaska State Regulations is limited to mention of AMCO specifying an entity to audit a laboratory as a condition to receiving a business license. Revising the regulations to include the option for AMCO to request follow-up audits once a lab is operational is recommended, both on a periodic (e.g. annually and for special purpose). The audits should establish and verify on an ongoing basis through audit activities, a list of methods that the auditing entity deems a laboratory has a demonstrated capability to report scientifically valid and defensible data.

Medicinal Genomics has published a new protocol (for 1g sample size) called the “California Protocol”. If CannTest does not have a validation study for the current protocol, it is recommend they switch to the “California Protocol”.

Alaska regulations should require laboratories develop quality assurance activities to characterize the accuracy, precision, and representativeness of all reported data. It is acknowledged the availability of reference material for cannabis constituents is limited. However, alternative methods of demonstrating quality parameters include, but are not limited to, the following:

- Use of compounds similar to the constituents of interest,
- Self-characterizing matrix material to use as a reference source, and
- Utilizing reference materials from more than a single vendor.