THE STATE of ALASKA
GOVERNOR MICHAEL J. DUNLEAVY

Department of Commerce, Community, and Economic Development

ALCOHOL AND MARIJUANA CONTROL OFFICE
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MEMORANDUM

TO:	Marijuana Control Board	DATE:	November 13, 2019
FROM:	Erika McConnell, Director	RE:	Regulations Project – Testing Oversight

This regulations project contains proposed changes to improve the oversight of testing facilities.

The attached proposed regulations changes strengthen the role of the board's contractor by:

- requiring the contractor to review testing facility applications and provide a report on the application to the board;
- adopting by reference a testing facility compliance manual (attached) drafted by Steve Crupi of DEC's Environmental Health Lab; and
- requiring any changes to a testing facility's standard operating procedures to be approved by the board's contractor (or the board).

In addition, the requirement for a marijuana testing facility to pay all costs of random validation is removed, but the renewal fee for a testing facility license is proposed to be increased.

These changes support the board's "contract" with DEC to fulfill the role of the board's contractor as referenced in 3 AAC 306 Article 6.

The changes to the regulations language in 3 AAC 306.100, 3 AAC 306.620, 3 AAC 306.635, and 3 AAC 306.640 were not specifically reviewed by the Testing Working Group, but the language has now been through three public comment periods so there has been ample opportunity for comment. The Testing Working Group reviewed the proposed compliance manual. In addition, as required by the board, Mr. Crupi specifically sought comments on the compliance manual from all licensed testing facilities in order to make any necessary final changes before sending it out for a third round of comments.

The proposed regulations and compliance document were put out for a third round of public comments for 32 days. Four comments were received which are attached.

Options for the board:

- Vote to adopt as written
- Amend; if amendment is significant, put out for public comment
- Send back to staff for revisions
- Close the project without action

3 AAC 306.100(d) is amended to read:

(d) The annual license or endorsement fee, to be paid with each application for a new marijuana establishment facility license or endorsement and each license or endorsement renewal application is

(1) for a new retail marijuana store license, $5,000, and for a renewed retail marijuana store license, $7,000;

(2) for a new limited marijuana cultivation facility license, $1,000, and for a renewed limited marijuana cultivation facility license, $1,400;

(3) for a new standard marijuana cultivation facility license, $5,000, and for a renewed standard marijuana cultivation facility license, $7,000;

(4) for a new marijuana concentrate manufacturing facility license, $1,000, and for a renewed marijuana concentrate manufacturing facility license, $2,000;

(5) for a new marijuana product manufacturing facility license, $5,000, and for a renewed marijuana product manufacturing facility license, $7,000;

(6) for a new marijuana testing facility license, $1,000, and for a renewed marijuana testing facility license, **$5,000** [$2,000];

(7) for an onsite consumption endorsement to a retail marijuana store license, $2,000. (Eff. 2/21/2016, Register 217; am 7/19/2017, Register 223; am 8/11/2018, Register 227; am 2/21/2019, Register 229; am____/_____/_____, Register____)

Authority: AS 17.38.010 AS 17.38.150 AS 17.38.200
AS 17.38.070 AS 17.38.190 AS 17.38.900
AS 17.38.121

3 AAC 306.620(c) is amended to read:

(c) The board will approve a marijuana testing facility license if, after the board or the board's contractor has examined the qualifications and procedures of the marijuana testing facility license applicant **and documented the conclusions of the examination in a written report**, the board finds them generally in compliance with good laboratory practices **and their application meets the requirements of this section**. Nothing in AS 17.38 or this chapter constitutes a board guarantee that a licensed marijuana testing facility can or will protect the public from all potential hazards of marijuana including microbials, poisons or toxins, residual solvents, pesticides, or other contaminants. (Eff. 2/21/2016, Register 217; am____/_____/ _____, Register____)

Authority: AS 17.38.010 AS 17.38.150 AS 17.38.200
AS 17.38.070 AS 17.38.190 AS 17.38.900
AS 17.38.121

3 AAC 306.635(a) is amended to read:

(a) An applicant for a marijuana testing facility license and a licensed marijuana testing facility shall

(1) use as guidelines or references for testing methodologies

(A) the American Herbal Pharmacopoeia's Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control, Revision 2014, adopted by reference; and

(B) the United Nations Office on Drugs and Crime's Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products: Manual

for Use by National Drug Analysis Laboratories, dated 2009 and adopted by reference; and

(2) notify the board of any alternative scientifically valid testing methodology the marijuana testing facility proposes to use for any laboratory test it conducts; the board may require third-party validation of any monograph, peer-reviewed scientific journal article, or analytical method the marijuana testing facility proposes to follow to ensure the methodology produces comparable and accurate results**; and**

(3) comply with the Marijuana Testing Facility Compliance Document, dated 2019 and adopted by reference; a marijuana testing facility whose license was first issued prior to [effective date] shall comply with this subsection by [effective date + six months].

3 AAC 306.635(c) is amended to read:

(c) The board or the board's contractor may inspect the practices, procedures, and programs adopted, followed, and maintained by the applicant or the licensed marijuana testing facility and may examine all records of the applicant or the licensed marijuana testing facility that are related to the inspection. The board may require an applicant or a licensed marijuana testing facility to have an independent third party inspect and monitor laboratory operations to assess testing competency and the marijuana testing facility's compliance with its quality program. The board may require random validation of a marijuana testing facility's execution of each testing methodology the facility uses. [THE MARIJUANA TESTING FACILITY SHALL PAY ALL COSTS OF VALIDATION.] (Eff. 2/21/2016, Register 217; am __/__/____Register ___)

Authority: AS 17.38.010 AS 17.38.150 AS 17.38.200

AS 17.38.070 AS 17.38.190 AS 17.38.900

AS 17.38.121

3 AAC 306.640(b) is amended to read:

(b) The scientific director of a marijuana testing facility shall approve, sign, and date each standard operating procedure, and each revision to any standard operating procedure. **Each revision to any standard operating procedure shall be provided to the board within 10 days of approval by the scientific director for review by the board or the board's contractor. The revised standard operating procedure shall not be implemented until approved by the board or the board's contractor.** (Eff. 2/21/2016, Register 217; am __/__/____, Register ___)

Authority: AS 17.38.010 AS 17.38.150 AS 17.38.200

AS 17.38.070 AS 17.38.190 AS 17.38.900

AS 17.38.121

CANNABIS TESTING LABORATORY COMPLIANCE DOCUMENT

Prepared for:

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

Revision Date

September 30, 2019

Revision History

This section summarizes revisions made since the last revision of this document.

September 24, 2019 public comment updates:

- Page 3 – Expanded "Purpose and Scope" section, providing background on motivation for creating this document.
- Page 4 – Blank and Duplicate Sample definitions updated. For Duplicate Sample, the 'per batch' requirement is removed, leaving a per sample frequency requirement. (Text under the preparation batch QC section discusses rotating matrices used for the duplicate sample.)
- Page 5 – The Matrix Spike (MS), Method Validation, and Method Verification definitions are updated. Definitions are added for Negative Control and Positive Control. For the MS, the 'per batch' requirement is removed, leaving a per sample frequency requirement. (Text under the preparation batch QC section discusses rotating matrices used for the MS.)
- Page 6 – Secondary Source Material definition is updated.
- Page 11 – Second paragraph added to "Method Blank (MB)" section.
- Page 12 – Third paragraph added to "Surrogate" section. Second paragraph added to "LCS" section. The "MS" (matrix spike) section updated to remove the per batch requirement, leaving a per sample frequency requirement. Also added to the "MS" section is discussion on rotating the matrix used as the parent sample, as possible.
- Page 13 – "Duplicate", "Instrument Blank", and "Second Source Standard" sections are updated. The "Duplicate" section is updated to remove the per batch requirement, leaving a per sample frequency requirement. Also added to the "Duplicate" section is discussion on rotating the matrix used as the parent sample, as possible. For the "Second Source Standard", additional options added.
- Page 14 – Second paragraph added to "Continuing Calibration Verification" section.
- Page 15 - "Duplicate Sample" section updated to remove the per batch requirement. Frequency is 1 per 20 samples, rotating the parent sample choice to capture all matrices received.

August 1, 2019 public comment updates:

- Page 4 – Definitions expanded for Duplicate Sample, Internal Standard, Laboratory Control Sample, and Matrix Spikes.
- Page 5 – Definition expanded for Surrogate.
- Page 10 – Minor grammatical changes.
- Page 11 – The sections Selectivity, Peer Review, and Safety Plan and Training moved here from page 13.
- Page 11 – 13 – Quality control samples segregated into two sections, "Preparation Batch QC" and "Analytical Batch QC".
- Page 14 – Use of negative and positive controls for microbiology QC clarified.
- Page 19 – Clarifications in paragraph 2 where and entire sample cannot be homogenized.

Introduction

History and Purpose

In December 2017, responding to accusations of alleged gaps and inconsistencies in the results from two licensed testing facilities, as well as concerns of "results shopping" and unfair trade practices, the Alcohol and Marijuana Control Office (AMCO), collected several plant samples and food products from retail marijuana establishments and submitted the samples to two licensed testing facilities in an attempt to independently verify the labeled results. The two laboratories' results did not compare well, resulting in AMCO requesting a data audit. The data audit revealed quality control (QC) inconsistencies and gaps in the data supporting the laboratories' results. The findings revealed the need for guidance on quality assurance (QA) and quality control (QC) requirements for licensed marijuana testing laboratories. Current regulations do not provide usable guidance evaluating compliance or applying consistent standards. The language is limited, in part, to the requirement that a testing facility simply have standard operating procedures (SOPs) and follow "good laboratory practices" (3AAC306.620(c) and 3AAC3060635(c)). However, regulation does not provide definition for the term "good laboratory practices".

The two testing facilities requested clarification on regulatory language. At the direction of the Marijuana Control Board, a collaborative process that included contributions from board members, licensed cultivators and product manufacturers, AMCO enforcement, and public health and environmental health experts, informed this document, which ultimately achieves a clearer definition for the term "good laboratory practices."

The QA/QC concepts, requirements, and terminology used in this document have supported nationwide laboratory data for decades (e.g. EPA's CERCLA (aka Superfund) and RCRA programs). Together, all the QC samples provide a sound statistical and legally defensible foundation for reported sample results. These requirements must be reflected in a laboratory's SOPs and consistently adhered to as part of legal defensibility.

The purpose of this document is to establish requirements and guidance for laboratories performing cannabis industry-related testing. Matrices may include, but are not limited to cannabis plant material, concentrates, and sugar-based or oil-based consumables. This document shall be applied as reference to regulation set forth in 3 AAC 306 of the Alaska Administrative Code.

Definitions

Accuracy – a combination of random and systematic error that assesses the difference between a result and a "true" value.

Analyte – a chemical compound or organism of interest.

Analyte group – a collection of chemical compounds or organisms consisting of similar characteristics.

Analytical balance – a type of balance capable of measuring sub-milligram quantities, typically 0.1 mg or better.

Analytical staff – employees with demonstrated competency to routinely prepare samples for testing and/or perform the testing.

Aqueous – a solution in which the base solvent is water.

Audit – a systematic and independent examination.

Batch – a group of samples governed by the same quality control measures and subjected to the same protocols at the same time.

Bias – a tendency towards or away from an expected outcome.

Blank – a material or container absent of a material, analyte, or organism of interest.

Calibration (CB) – the base solvent or reagent used to subject a sample to analysis that is free of the analyte of interest.

Method (MB) – a material free of the analyte of interest (e.g. oregano, oil) to demonstrate the cleanliness of the testing and analytical process without contribution or interference from the actual targeted matrix.

Temperature (TB) – a media utilized to determine a representative temperature for the entire space of a temperature controlled unit (e.g. sample shipment cooler, refrigerator, oven).

Calibration –

Initial calibration (ICAL) – reference material prepared at incremental concentrations to assess the range within which an instrument can predictively quantitate an analyte of interest.

Continuing calibration verification (CCV) – reference material prepared at a known concentration to determine if instrument performance is at the same level as assessed at the time of the ICAL.

Calibration Range – the concentration range within which an instrument can predictively quantitate an analyte of interest, defined by the lowest and highest possible concentrations. Ideally, it is the range of linear instrument response vs. target analyte concentration.

Chain of custody (COC) – trail of information that documents the sequence of custody, person or storage control, transfer, and final disposition of sample, hardcopy, or electronic evidence.

Comparability – demonstration of a procedure or set of procedures to generate a similar result upon changing a matrix, quality control materials, or quality control operating parameters.

Completeness – a measure of the extent that sample and quality controls meet data quality objectives (e.g. sensitivity requirements, quality control results within acceptance limits)

Control Material - {compare to reference material}

Correlation coefficient (CC) – a measure of the linear relationship between two or more data points differentiated by each point's concentration.

Corrective action – a change in policy or procedure intended to prevent a nonconformance, anomaly, or unwanted trend from recurring.

Deficiency – lacking something or to describe a situation or material containing less than the desired amount of a particular defining characteristic.

Document – contains or relays information that does not change until there is a change in policy, procedure, or related external reference material or used to record data.

Duplicate Sample – a second portion of a sample, subsampled in the same manner as the original sample and subjected to the same procedures as the original sample and in the same batch as the original sample. For chemistry and microbiology testing, one duplicate is required for every 20 client samples, rotating matrices to include all matrices the laboratory typically encounters. For chemistry testing, if insufficient sample volume is available for a duplicate analysis, this requirement may be substituted by generation of an LCSD (LCS duplicate; see definition of LCS below).

Form – A document created by the lab to record visual observations or data. Each form must minimally

contain the laboratory name, unique form ID, revision date of the form template, a title indicating the activity being documented, and initials and date of staff recording information.
Internal Standard (IS) – a compound chemically similar to an analyte or analyte of interest, used to independently assess the effectiveness of an analytical procedure on an individual sample, control, or reference material and also serve to quantitate an analyte of interest. The IS is added to the sample after all preparation, cleanup, and dilution steps and immediately prior to introducing the sample, control, or reference material into the instrument. Use of an IS is recommended, but not required.
Laboratory Control Sample (LCS) – For chemistry testing, a known amount of analyte of interest or chemically similar analyte in addition to the surrogate, added to a blank matrix (i.e. a matrix that does not contain the analyte of interest but is similar in phase (i.e. aqueous, solid, organic (e.g. oil for concentrates or oregano for plants)) to test the effectiveness of a method to test for the analyte in that phase. One LCS is required for each preparation batch of 20 samples or less, regardless of matrix type of samples being tested.
Matrix – the main material; the non-analyte components of a material
Matrix Spike (MS) – a known amount of analyte of interest or chemically similar analyte in addition to the surrogate, added to an aliquot of a sample to test the effectiveness of a method to test for the analyte in that sample's matrix. For chemistry testing, one MS is required for every 20 client samples, rotating matrices to include all matrices the laboratory typically encounters. The matrix spike assesses a method's extraction efficiency for a given target analyte on a per batch basis as implemented by the lab. The analyte is added after sample reduction, homogenization, and subsampling and just before the start of the sample preparation/extraction phase.
Measurement uncertainty (MU) – an indication of incomplete information of a quantitative value, indicating to what degree the value may be biased on both the low and high end.
Method detection limit (MDL) – the lowest quantity or concentration at which a substance or analyte can be identified with 99% confidence under a given set of conditions.
Method reporting limit (MRL) – the lowest quantity or concentration at which a substance or analyte can be quantitated with 99% confidence under a given set of conditions.
Method validation – demonstrating the effectiveness of implementing a new method, a method new to a lab, or a significant change to an existing method. The SOP for the test must be strictly adhered to for the method validation.
Method verification – demonstrating the effectiveness of an existing method's ability to manage a new variable, e.g. new matrix, new location of testing, change in reagents, change in prep or testing conditions. The SOP for the test must be strictly adhered to for the method verification.
Negative Control – material lacking the target substance or organism, but containing a non-targeted substance or organism, demonstrating the ability of the laboratory to control processes sufficiently enough such that a process does not result in a false positive.
NIST – National Institute of Standards and Technology
Nonconformance – a defect or occurrence that deviates from procedure or falls outside of acceptable limits
PARRCCS – precision, accuracy, representativeness, reproducibility, comparability, completeness, sensitivity
Positive Control – material containing the target substance or organism, demonstrating the ability of a laboratory to identify the substance or organism.
Precision – {Mean % Difference, CV/RPD,} - assess repeatability of a procedure given the same conditions, materials, and steps for each attempt. Common statistical measurements include mean percent difference, relative percent difference (RPD) and coefficient of variation (CV).
Primary source – a vendor that supplies reference material for instrument calibration or as the primary reference for initially identifying and/or quantifying an analyte of interest.
Quality assurance (QA) – the outline of quality policies and expectations that govern overall how and why a business operates.
Quality control (QC) – daily quality procedures or activities that are implementing a QA program.
Quality manual (QM) – the document that outline quality policies and expectations that govern a business.
Raw data – original numbers collected by an instrument or original observations recorded by a technician.
Record – input or output containing data, observations, or actual operating parameters.
Representativeness – demonstration of thoroughness that a particular procedure or set of procedures is

characterizing a sample matrix through identification and quantitation of analytes of interest. Typically an intra-laboratory measure.
Reproducibility – demonstration of a procedure or set of procedures to generate the same result when employed at different labs or if implementation of a procedure change is able to achieve the same result.
Secondary source material – a vendor that supplies reference material from a different lot than the associated primary source that is used to confirm the identity and/or quantitation of an analyte of interest determined by comparison to the primary source. Alternatively, a second source material can be reference material from a vendor other than the vendor considered the primary source provider.
Sensitivity – the lowest quantity of an analyte of interest that can be observed in a sample, evaluated as part of a method validation for the ability to meet the desired data quality standards.
Subcontract – requesting service from an entity operated as a separate business unit.
Surrogate – a compound chemically similar to an analyte or analyte of interest, used to independently assess the effectiveness of the extraction and analytical procedures on an individual sample, control, or reference material basis. The surrogate is added after sample reduction, homogenization, and subsampling and just before the start of the sample preparation/extraction phase. Surrogate addition is required for plant and edible matrices. The surrogate assesses a method's extraction efficiency on a per sample basis as implemented by the lab for each batch.

Program Administration

Sample Receiving/Login/Storage. A Sample Receiving SOP is required, detailing instructions and requirements for documenting the receipt of samples, such as:

- number of samples received
- the matrix or matrices received
- relinquishing and receiving signatures demonstrating custody transfer
- dates and times of sample collection
- courier delivering the samples (e.g. hand carried, commercial courier)
- verification of sample condition
- sufficient volume received for requested tests
- sample properly preserved and packaged for the tests requested
- documentation of client requested tests
- instructions for receiving samples in METRC
- instructions for reconciling weight discrepancies between METRC and throughout the pre-testing, testing, and post-testing phases of the sample.
- instructions that follow METRC requirements for transferring samples from one lab to another lab.

The SOP must explain how the laboratory tracks and manages samples from receipt, to analysis, to reporting, to storage, to disposal. The detail shall include how samples are uniquely numbered, the internal sample labeling procedures, protocols for reviewing for clerical errors, and sample login data entry errors.

Acceptance/rejection criteria are required in the SOP, including (as applicable):

- identification of who can reject samples
- administrative errors that can result in rejection
- rejection based on weight deficiencies or discrepancies
- rejection based on observations at receiving (e.g. leaking container, obvious contamination)
- procedure for handling rejected samples.

An SOP outlining sample storage procedures is also required, discussing requirements for storing samples upon receipt, during the testing process, and long term storage. Details to include are:

- temperature of storage
- dates of storage, removal of storage, return to storage
- comments (e.g. reason for removing sample)
- the security of the samples and related hardcopy and digital records documenting custody
- initials of the recorder

Subcontracting. Receiving lab must have an Alaska cannabis license and be located within the State of Alaska. If incorporating a subcontract lab result into a report of other results, the subcontract lab must be identified on the report for the result(s) it provided. The report must also include sample custody transfer documentation.

By definition, a subcontract lab is another business unit, whether its own discrete company or a separate business unit (different physical location) of the same company. A customer service center location is not a subcontractor.

Training. The laboratory must document responsibilities, training, and competency for all staff via curriculum vitae (CV), resumes, training records, competency assessment (internal and/or external), and professional certifications. The documentation must identify the analyses and procedures each individual is authorized to independently perform and which require supervision. The criteria for which a person must demonstrate competency for the task or method must be documented.

Record keeping. Visual observations of sample testing that either support the final result or affect the final result must be recorded.

Raw data, including manual integrations (chromatograms representing before and after the manual integration must be available, initialed and dated by the person making the change(s)), including original observations and calculations recorded at the time they were made, having been correctly interpreted and performed.

A data reviewer/auditor must be able to recreate the testing environment with which the results were analyzed/determined. Observations that do not directly factor into the final result, but support test results, confirm integrity of sample, standard, and reagent storage conditions, must also be recorded. Examples include but are not restricted to:

- incubation times and temperatures,
- analysis dates and times
- identification of analysts performing the testing and which steps were completed by each person
- instrument IDs, instrument settings and calibrations (see Laboratory Facilities and Equipment section)
- manufacturer and lot numbers of reagents and materials used
- results of control samples (see Quality Control sections below)
- results of quality control checks performed on media and reagents

Laboratory facilities and equipment – environmental controls, separation of office activities from laboratory

The laboratory must outline protocols in an SOP or throughout SOPs (as applicable) regarding general housekeeping, including glassware cleaning, to avoid the impact of poor housekeeping on the quality of results.

Instrument maintenance logs are required for documenting scheduled (e.g. daily, weekly) and unscheduled maintenance and repair events. The logs are an important tool for troubleshooting and ensuring that all maintenance and repair are in agreement with manufacturer specifications. After adjustments, the instrument must be verified fit for use by analyzing controls, calibration material, or blanks, as appropriate.

Temperature charts and logs are required for documenting adherence to requirements for temperature dependent equipment (e.g. refrigerators, freezers, incubators, water baths) and tests. The frequency of measurements is dependent on the intended use of the unit or the characteristic of the subject method. Units intended for sample preparation and analysis must minimally have start and stop temperatures recorded. Incubation periods that are more than a day require starting temperature readings, a temperature reading each day of the incubation period, and an incubation period ending temperature, including the date and time of each reading, and documenting date and time of the start and stop of the full incubation period. The required temperature range must be stated on each log to assist in identifying outliers. Outliers must be acknowledged on the form, to include corrective action (e.g. temperature adjustment and follow-up reading) or reference to a corrective action document.

Quality Systems

General

This section covers QA, QC, method selection, sample handling, and documentation requirements for the laboratory. The laboratory must discuss these elements in their QM and SOPs (as applicable) and implement them in operations.

Quality manual (QM).

- Defines the laboratory's quality system. Policies and procedures guiding the laboratory are documented or referenced in the QM. Annual review and updates required.
- Identify key staff positions and the corresponding responsibilities.
- Describe how and the frequency in which the possibility of conflicts of interest are assessed and prevention measures in place to identify or avoid conflicts.
- State commitment from management regarding ethics, code of conduct, and commitment to quality.
- Describe calibration requirements for support equipment, covering balances, thermometers (reference and working) (liquid, digital, data loggers), weights (reference and working), pipettes, and fume hoods. Certificate documentation must be maintained, whether performed in-house or by an outside vendor. In-house service/calibrations required and the associated SOP, documented annual training of technicians, and demonstration of competency for the calibration and service.
- Procedures for calibration, verification, and maintenance of support equipment.
- Detail procedures for control, maintenance, and retention of records and documents.
- Discuss document procedures: error correction, completing forms digitally or on hardcopy, traceability, and record and evidence retention time requirements for hardcopy (sample, testing, and custody evidence related) (5 years required), and digital data acquisition (5 years required).
- Describe calculation and data reduction procedures for results. It is recommended to adopt EPA rules for rounding.
- Describe review and reporting procedures, indicating individual qualifications required to perform data review and reporting.
- Provide procedures for achieving and maintaining traceability of chemical, biological, and metrological standards, reagents, and reference materials used to support or derive any results or measurements.
- Describe sample receiving, control, storage, and disposal handling procedures.
- Describe corrective action procedures – Required:
    - When deviation or nonconformance from policies and procedures are identified.
    - When QC or PT sample results are outside of acceptance limits
    - Identify:

        - The reason for initiating the corrective action.
        - The individual ultimately responsible for action resolution occurring.
        - The date the problem was identified.
        - Source of the problem identified through root cause analysis.
        - Indicate if customer data is impacted.
        - Apply correction.
        - Have a mechanism to verify implementation of the correction and take additional action if initial corrective action implementation fails.

- Document the corrective action process.

- Discuss situations which may occur where data, which do not meet all quality criteria, are accepted and reported to the client and METRC. Authority for making this decision, i.e. professional judgment, must be discussed in the QM, defining what laboratory positions have authorization for making the decision. Situations of professional judgment must be documented in the report's project narrative to include:
  - the nature of the outlier,
  - the QC limit or other criterion not met,
  - the parameter/analyte(s) impacted,
  - the impact on the data,
  - any conversation with the client and resulting outcome(s), and
  - the reason the data are reported, despite the exceedance.
- Demonstration of Capability (staff competence)
- Method selection, validation, and verification procedures
- Measurement traceability
- Measurement uncertainty procedure and frequency of review.

SOPs. Standard operating procedures (SOPs) provide detailed instructions to perform routine operations and practices implemented at the laboratory. These documents represent the procedural flow and give guidance on how to address reasonably anticipated expected and unexpected scenarios.

SOPs must be approved, signed and dated by the Laboratory Director prior to initial use and upon revision. Annual reviews and corresponding updates (if any) are required. SOP documents can be maintained as hardcopy or electronically. If the former, a controlled and documented distribution of documents must be maintained. Only the current versions can be accessible by staff.

Variances to SOPs must be pre-approved by the Laboratory Director or Quality Manager and documented. Each SOP shall have a revision summary that documents the revisions made to generate the current version.

Written procedures are required for calibration, verification, and maintenance of major analytical instruments. Written procedures are required for incorporating and evaluating quality control samples, including, but not limited to instrument tuning and calibration standards, blanks, LCS samples, matrix fortified samples (matrix spikes) and duplicates. Specify QC sample frequency, acceptance criteria, and corrective action guidance for outliers. Either in one document or in several individual documents, discuss protocols for homogenizing samples prior to obtaining a representative subaliquot for testing, and identify instituted controls for not contaminating the source material in the process.

Quality Control Requirements for Chemistry

General. A QC program that includes QC samples, which assess background contamination (background or blank subtraction is not permitted), sensitivity, level of control, level of bias (results may not be adjusted as a result of QC recovery), reproducibility and selectivity. At least annually, the laboratory shall evaluate its QC program, including implementation of QC samples, applicability of acceptance criteria, trends, and document any updates.

- All new and revised methods must be validated prior to use, characterizing the PARRCCS parameters.
- Establish MDL and MRL for testing that results in the reporting of a numerical result.
- Documentation requirements for reagents, controls, and standards –
  - Reagent/Control/Standard containers must be labeled with identity of material.

- Receipt date or preparation date, as applicable.
- Expiration date.
- Receiver's or preparer's initials.
- If received, open date.
- Storage conditions
- Lot number and manufacturer or lab-assigned standard ID number
- Lot numbers or standard ID numbers must be documented for each preparation and analytical batch.

Batching. A preparation or analysis batch consists of at most 20 samples of a similar matrix. Examples:

- Plant samples – Flower, trim, and kief samples can be in the same batch.
- Concentrates – Concentrates can be in one batch, though the laboratory should consider placing samples with an aqueous based solvent (e.g. water) in one batch and samples with an organic based solvent (e.g. oil, butane, propane) in a separate batch.
- Edibles – Segregating edibles into batches is determined by the base constituent of each matrix. For example, separate samples with a flour base from sugar based samples.

For multi-parameter analyses, data acquisition conditions for each parameter must be the same as for all associated quality control samples or measures. The latter includes internal and surrogate standards.

Selectivity. For non-mass spec methods, have a procedure in place to confirm target analyte identity (e.g. dual column, dual detector, dual wavelength, RT windows)

Peer Review. Data review procedures must be sufficient to assess the accuracy, precision, and other performance measures are attained and the tests performed as required to ensure accurate and reliable results are reported. Timing and number of reviewers should be assessed periodically for effectiveness.

Safety Plan and Training.

- Fume hoods are recommended for any work involving toxic chemicals.
- SDS's should be readily available, either hardcopy or electronically.
- Spill kits must be available.
- Signage is recommended for areas where hazardous chemicals are stored and used.
- Fire extinguishers or other fire suppression system is recommended.
- Hand washing stations are required.
- Eye wash stations and emergency showers are recommended.
- Designated space apart from laboratory operations for desk work, eating and drinking is required.

Preparation Batch QC.

- Method blanks (MB) – One MB is required per sample preparation batch of 20 client samples or less. If sample preparation is not a required step, then one MB is required per analytical batch. An MB consists of a matrix similar to the samples and is known to not contain the parameter of interest. For a batch of plant material, a matrix like oregano is an option. An MB is subjected to all of the same steps as a sample. The MB result must be less than the MRL. Samples associated with a failing MB must be re-prepared and reanalyzed with a new set of preparation QC.

  An MB supports the data by proving there was nothing in the preparation or analysis process or materials contributing to contamination of the client samples.

- Other Blanks – other blanks may be used by the laboratory depending on the type of method and concerns of the laboratory and/or client. For instance, trip blanks are used to check for interferences encountered during sample collection and handling for the analysis of solvents.

- Surrogates – A compound chemically similar to the test parameter, used to determine method efficiency. The surrogate signal ideally must not interfere with that of the target analytes, or as little as possible. Surrogate addition is required for all organic testing (e.g. potency, terpenes). The surrogate is added to all samples, preparation batch QC samples (including, but not limited to MB, LCS, MS, and Duplicates), and analytical batch QC samples (including, but not limited to calibration standards, calibration check standards, QC or second source standards, MSA analyses, and IB). The surrogate is added to the samples at the beginning step of sample preparation and directly into the matrix. This addition occurs after sample reduction, homogenization, and subsampling processes and is required for plant and edible matrices.

  The surrogate is measured in the same way as the target analyte (i.e. same channel or wavelength). The laboratory shall establish performance based QC limits (PBQLs) based on historical data generated at the lab. If sufficient historical data are not available, the laboratory will use 80 – 120% as interim limits until which time sufficient data points are available to generate PBQLs. PBQLs shall represent a 99% confidence interval. Samples and QC samples with surrogate results not meeting the QC limits must be re-prepared and reanalyzed. Preparation batch QC samples with failing surrogate results necessitate the re-preparation of all samples and QC samples.

  Surrogate analysis supports the data by proving that each sample preparation vessel and analysis injection were free of any process conditions which would significantly affect the result of a compound similar to the target analyte.

- LCS – One LCS is required per sample preparation batch of 20 client samples or less. An LCS is subjected to all of the same steps as a sample. The LCS is measured in the same way as the samples (i.e. same channel, wavelength, parent ion, etc.). The laboratory shall establish performance based QC limits (PBQLs) based on historical data generated at the lab. If sufficient historical data are not available, the laboratory will use 80 – 120% as interim limits until which time sufficient data points are available to generate PBQLs. PBQLs shall represent a 99% confidence interval. Samples with target parameter or surrogate results not meeting the QC limits must be re-prepared and reanalyzed. If a recovery failure occurs for a target analyte or surrogate, the entire preparation batch must be re-prepared and reanalyzed. A recommended LCS duplicate (LCSD) can provide on-going method precision information, and decrease the number of batches needed to accumulate performance-based data.

  LCS analysis supports the data by proving that the preparation and analysis processes for the batch efficiently extracts and accurately identifies the target parameter for a matrix similar to the matrix of the client samples (e.g. oregano may be chosen for the plant material matrix, and olive oil chosen for the concentrates matrix).

- MS - One MS is required per 20 client samples. An MS is subjected to all of the same steps as a sample, and it is best practice to use the same parent sample as the Duplicate Sample (see below). The matrix of the duplicate sample is rotated to include all matrices the laboratory typically encounters. The MS is measured in the same way as the samples (i.e. same channel, wavelength, parent ion, etc.). The laboratory shall establish performance based QC limits (PBQLs) based on historical data generated at the lab. If sufficient historical data are not available, the laboratory will use 80 – 120% as interim limits until which time sufficient data points are available to generate PBQLs. PBQLs shall represent a 99% confidence interval. Samples with surrogate results not meeting the QC limits must be re-prepared and reanalyzed. If a recovery failure occurs for a target

analyte or surrogate and the recovery is greater than or equal to 50%, data can be accepted if all target analyte and surrogate results in the associated batch LCS are acceptable. If the MS recovery is less than 50%, the parent sample, MS, and associated duplicate must be re-prepared and reanalyzed.

- Duplicate (sample duplicate or matrix spike duplicate) – One duplicate is required per 20 client sample. The matrix of the duplicate sample is rotated to include all matrices the laboratory typically encounters. Given sufficient sample volume, it is best practice to use the same parent sample for the Duplicate sample as used for the MS sample. A duplicate sample is subjected to all of the same steps as a sample. The Duplicate is measured in the same way as the samples (i.e. same channel, wavelength, parent ion, etc.). The laboratory shall establish performance based QC limits (PBQLs) based on historical data generated at the lab. If sufficient historical data are not available, the laboratory will use an RPD of 20 as an interim limit until which time sufficient data points are available to generate PBQLs. PBQLs shall represent a 99% confidence interval. Samples with surrogate results not meeting the QC limits must be re-prepared and reanalyzed. If an RPD failure occurs for a target analyte and the recovery is less than or equal to 100, data can be accepted if all target analyte and surrogate recovery results in the associated batch LCS are acceptable. If the duplicate sample RPD recovery is greater than 100, the parent sample, duplicate, and associated MS sample must be re-prepared and reanalyzed.

  A Duplicate supports reproducibility of the data for the sample preparation and analysis processes as implemented by the laboratory.

Analytical Batch QC.

- Instrument blanks (IB) – One IB is required at the start of each analytical batch. The IB consists of the same solvent make-up used to introduce samples onto the instrument. The IB result must be less than the MRL. Samples and preparation batch QC associated with a failing IB must be reanalyzed.

  An IB supports the data by proving there was nothing in analysis process or materials contributing to contamination of the client samples.

- QC or second source standard – A second source standard must be analyzed immediately after each multi-point initial calibration and before samples and QC samples can be analyzed. Results of this standard must be between 80 – 120% for target analytes and surrogates before sample and QC sample analysis can proceed. If the second source standard is accompanied by a vendor supplied certificate indicating PBQLs specific for the standard, those limits may be used instead.
  Option 1: Purchase a standard from a manufacturer other than the standard used to calibrate the instrument, or the same manufacturer can be used if the secondary standard is a different lot. Analyze secondary standard immediately after the calibration curve is run.
  Option 2: Purchase the same type of standard as in option 1, but use it to spike the LCS in each batch.
  Option 3: Purchase the second source with enough time to analyze it before the primary lot expires. Analyze the new standard immediately after running the calibration curve with the old standard, and before using the new standard for any other purpose. Once the new standard passes, it may be used as the primary standard.

- Instrument calibration (ICAL) – The ICAL must consist of a minimum of three standards analyzed at varying concentrations with the lowest concentration standard at or greater than the MRL, but greater than zero (0). All standards analyzed to establish the ICAL must be analyzed within a 12-hour period. An acceptable ICAL will have a %RSD greater than or equal to 15%, a linear regression correlation coefficient greater than or equal to 0.995, or a coefficient of determination value greater than or equal to 0.99 for target analytes and surrogates before the second source standard, sample,

and QC sample analyses may proceed. Ideally, the calibration is not forced through zero. An IB may be used as an additional calibration point, but it cannot replace one of the three known concentrations.

- Continuing calibration verification (CCV) – A CCV standard, which is prepared from the same stock standard as the ICAL standards, must be analyzed at the start of the run, after every 10 injections, and at the end of the run. If an ICAL starts the analytical run, the CCV must be analyzed after the second source standard and before samples and QC samples are analyzed. The target analytes and surrogates in the CCV must have recoveries between 85 – 115%. Analyses of the sample and QC samples must be bracketed (before and after analysis) by compliant CCVs. Any samples or QC samples associated with a noncompliant CCV must be reanalyzed. Bracketing CCVs must be no longer than 12 hours apart.

  CCV analysis supports the data by proving that the analysis process for the batch did not significantly affect the target compound results. The CCV also proves the correct operation of the instrument throughout the analysis day, being run at the beginning, every 10 samples, and at the end. Trends of the CCV analyses throughout the day can protect against errors caused by instrument drift.

- Internal standards (IS) – ISs can be added to samples and preparation and analysis QC samples for quantitative and retention time (RT) shift monitoring purposes. If ISs are used, they must be added to all samples, blanks, and preparation and analysis QC samples. IS addition occurs after all preparation, cleanup, and dilution steps are completed and immediately prior to introduction into the instrument. Use of an IS is recommended, but not required.

  The IS area and RT data are compared to the area(s) and RT(s) of the mid-level standard in the ICAL. The quality control limits for the area are from 50% to 200% percent of the IS area in the mid-level ICAL standard. The quality control limits for the RT are ± 0.50 minutes of the IS RT in the mid-level ICAL standard. If the IS area or RT does not fall within the QC limits, the sample or QC sample must be reanalyzed.

Quality Control Requirements for Microbiology.

Documentation requirements for reagents, controls, and standards –

- Reagent/Control/Standard containers must be labeled with identity of material.
- Receipt date or preparation date, as applicable.
- Expiration date.
- Receiver's and/or preparer's initials.
- Open date.
- Storage conditions
- Lot number or lab-assigned standard ID number
- Lot numbers or standard ID numbers must be documented for each preparation and analytical batch.

- Negative control –Negative controls will differ depending on the technology used. For media methods, the negative control contains another organism to demonstrate method selectivity. The organism may be similar in nature to the target organism and does not produce the same reaction as the target organism. For media based methods, one negative control must be analyzed on each lot of media before use. If a negative control fails and samples were analyzed concurrently, samples with a negative result may be reported with comment. All other samples must be invalidated. For qPCR, a negative control is a blank sample made with a reagent that does not contain an organism (e.g. sterile water). For qPCR, a negative control is required for every batch, or more often if required by the

manufacturer's validated method (reference method). If a negative control fails, associated samples with a negative result may be reported with comment. All other samples must be invalidated.

- Positive control – Positive controls will differ depending on the technology used. For media methods, the positive control contains the target analyte/strain of interest. For media based methods, one positive control must be analyzed on each lot of media before use. If a positive control fails and samples were analyzed concurrently, presence/absence samples with a positive result may be reported with comment. All other samples must be invalidated. For qPCR, a positive control contains either the target analyte/strain of interest or a commercial positive control, based on manufacturer's instructions. For qPCR, a positive control is required for each analyte/strain of interest for every batch, or more often if required by the reference method. If a positive control fails, associated presence/absence samples with a positive result may be reported with comment. All other samples must be invalidated.

- Duplicate sample - One duplicate is required per twenty (20) client samples or less. A duplicate sample is subjected to all of the same steps as the original sample. For qualitative analyses, if the duplicate sample does not equal the sample result, the sample and its duplicate must be reanalyzed. Consideration should also be given to possibility of re-preparing and reanalyzing all associated samples. For quantitative analyses, if the RPD of the sample and duplicate is greater than 100, the parent sample and duplicate sample must be reanalyzed. Consideration should also be given to possibility of re-preparing and reanalyzing all associated samples. When data are accepted, the result for the sample portion designated as the "original sample" is reported.

- Temperature monitoring (see "Laboratory facilities and equipment")

- Sample preparation documentation is required for pre-enrichment and sample preparation steps and shall include the unique ID of the negative and positive controls, the client samples associated with the controls, the weight of the subsample used, the unique ID of all media and reagents used in pre-enrichment and to prepare the samples, dates/times and temperature samples are placed into and remove from the incubator, the preparer's initials, and the date and time of preparation.

- Sample analysis documentation is required. Time and date samples are placed in the incubator, removed from incubator, and analyzed or examined must be recorded, along with observations or instrument raw data.

- Any verification steps required by the method must also meet the same documentation requirements as preparation and analysis.

- Documentation of macroscopic and microscopic examinations shall include pictures and written observations.

Reporting

The laboratory report is required to contain the following elements.

- Testing laboratory's name and physical address. If a subcontract laboratory is used for part or all of the testing, the report must identify the name of the subcontract laboratory and identify the specific testing it performed.
- The report date.
- A unique sample number or alpha-numeric number assigned by the laboratory's receiving and accessioning processes.
- The name of the person submitting the sample for testing and the identifier assigned by the submitter for each sample.
- The date and time the laboratory received the sample.
- Sample matrix.
- The chain of custody record documenting the transfer of the sample from the submitter to the laboratory. If the laboratory submits a sample to a subcontract laboratory, documentation of that custody transfer must also be included in the report.
- A name for each test method and identity of each individual parameter determined by the method.
- The published method or laboratory SOP unique ID for each test method.
- The numerical or text result for each method or individual parameters of a method. If the parameter is not detected, the laboratory can provide the result as "Not Detected", "ND", "Not found", etc.
- The units for each result, as applicable. If the parameter is not detected, the units are still required for the report.
- The MRL for each numerical result, as applicable. If the parameter is not detected, the MRL is still required for the report.
- A report project narrative discussing anomalies or quality control outliers and related corrective action steps encountered during sample receiving, sample preparation, or analytical testing.
- Report results to the MRL, as applicable, unless otherwise specified on a 'per client' or per project basis.
- Amended reports must indicate in the report project narrative what changed from the original report, the reason for the change, and the date of the revised report.
- Chemistry results for plant material must be reported on a dry weight basis (DWB). The percent (%) moisture of the plant sample 'as received' must be reported separately. The % moisture value is used to calculate the dry weight chemistry result. Chemistry results for all other sample matrices are reported on an 'as received' basis.

$$\text{Result (DWB)} = \text{ wet wt. sample result} \times \frac{100}{100 - \%\ \text{moisture}}$$

- Each required test, whether failing or passing, must be reported in METRC within 24 hours (i.e. one (1) calendar day) of the test completing as per 3AAC306.670. "Test completing" is defined by this document as the sample and related preparation batch and analytical batch QC have been successfully analyzed.

Proficiency Testing

To obtain and maintain a license to perform testing, the laboratory must participate in Proficiency Testing (PT) for each test. This testing ensures accurate results are being produced by licensed laboratories, regardless of methodology. For multi-parameter tests (e.g. potency and terpenes testing), the laboratory must successfully identify and quantitate 80% of the target analytes. Any false positive or false negative results are considered unsatisfactory.

Required analyses – applies to regulated constituents (*Aspergillus niger, flavus, fumigatus, E.coli, Salmonella,* THC, THCA, CBD, CBDA, CBN for each matrix being tested. Sample matrices are cannabis plant material, any edible matrix, or a concentrate. PTs are required for a new analyst, a method validation, and ongoing on an annual basis per lab (vs. per analyst).

Treatment of PT samples – PT samples are treated the same as commercial samples, undergoing the same size reduction, subsampling, pre-treatment, extraction, number of analyses, and analysis procedures. If any special handling is necessary (e.g. sample prep, unit conversion), this treatment is documented with the statement. PT samples may not be reanalyzed to confirm results, may not be analyzed in duplicate, or analyzed with additional QC beyond what is performed for client samples.

Laboratories may report multiple results for a given sample that represent multiple prep and/or analytical protocols/combinations, multiple matrices, or multiple analytical staff. Laboratories may not send a PT sample to another lab and report that lab's result(s). Conversely, a laboratory may not knowingly analyze a PT sample received from another laboratory. Laboratories may not compare results with another laboratory.

The Laboratory Director must sign an attestation statement when submitting results that indicates the PT samples were integrated into the routine sample workflow and did not receive special treatment.

Reporting - PT reports are submitted to the entity producing and issuing the samples for scoring. Score reports are sent to the laboratory and AMCO simultaneously. The scored results may be used in part or in whole for decisions regarding licensing/certification status. Reports of PT results may be amended when errors attributed to the PT sample provider are identified or when a clerical error unique to the reporting of PT samples is discovered. The reason for an amended report must be discussed in the PT report project narrative and is subject to rejection or request for additional information issued by the PT provider or AMCO.

Acceptance limits and grading – established by the PT provider and determined by provider's in-house testing, factoring in participating lab performance. Acceptance limits are associated with all quality control testing processes and analytes.

Corrective action – see corrective action in QM section.

Audits

Internal. One internal audit for each sample preparation and test method the laboratory performs must be conducted within six months from the date of implementation. A report must be generated for each internal audit, containing:

- Audit date(s)
- Auditor name
- Date of the report
- Title of the report indicating the method(s) audited
- Name(s) of staff interviewed for the audit
- Questions/topics explored during the audit
- Findings
- Due date for corrective action response

Internal audit reports and the associated corrective action response must be minimally available for inspection within five years of the end of the audit.

Internal audits may be horizontal or vertical in nature. A horizontal audit reviews one particular aspect that is implemented across a laboratory, e.g. document control. A vertical audit reviews one aspect of an operation that is not performed throughout an organization, e.g. extraction for potency testing. These audits are intended, in part, to assess adherence to SOPs and good laboratory practice and to perform a gap analysis of a procedure or quality system(s).

Auditor qualifications for internal audits

The concept of someone being trained or qualified as an auditor is defined by a person's skill set and experience. The following aspects are traits and skills to evaluate when identifying a person to be an internal auditor. All of the items below are not required to have a 'yes' answer.

- Overall technical knowledge and experience relative to the audit subject.
- Objective thinking ability.
- Capability to investigate independent of a checklist and has the initiative to pursue unplanned routes of inquiry.
- Professionalism demonstrated with sound judgment and strength in interpersonal skills.
- Fair and respectful of confidentiality when needed.
- Understanding of the lab's quality policies and procedures.
- Ability to stay focused on an audit scope.
- Ability to write a detailed and coherent narrative.

External. External audits may be requested and/or conducted by AMCO or other entity that is an unrelated business concern to the laboratory. The laboratory must allow access to the laboratory and all documentation for purposes of the onsite audit, in order to maintain laboratory certification with AMCO. The resulting audit reports and the corrective action response(s) must be submitted to the auditor and AMCO within one week of completion of the corrective action plan, even if not all of the corrective actions have been implemented or verified to be effective. All corrective actions must be approved by the auditing entity before the audit is considered to be closed.

Corrective action – see corrective action in QM section.

Homogenization and Subsampling Considerations

Homogenization can be thought of as two parts: breaking the sample down into smaller pieces, and mixing those pieces uniformly. While breaking down a sample into smaller pieces may need only occur initially, mixing should take place each time a subsample is taken. All samples are expected to exhibit some degree of non-uniform distribution of target analytes. Therefore, the entire sample should, ideally, be homogenized before taking subsamples or aliquots for testing.

If not practical to homogenize the entire sample, multiple portions must be taken from all parts of the sample, combined, and homogenized before a single subsample is taken for testing. Considerations must be taken to prevent contamination or cross contamination between samples. Using clean (sterile if microbiology testing) scissors/scalpel and tweezers to randomly and representatively collect multiple portions. Visually assess the sample for varying features, taking portions from each feature. If the sample is in a container that makes difficult accessing all areas of the sample, considering emptying the sample out onto a clean (sterile if microbiology testing) surface.

The QA Manual or SOP(s) must describe, in detail, homogenization and subsampling procedures, including:

- How are subsamples taken?
- How are sample materials homogenized?
- What are the required sample sizes for different types of samples and tests?
- Sample homogenization and subsampling for each of the following types of samples:
    - Flower and other plant parts may be homogenized in a mill, blender, food processor, laboratory homogenizer or other mechanical method.
    - Concentrates: Liquid concentrates may be homogenized by agitation (vortexing, blending, or shaking) before subsamples are aliquoted. Foam generated during agitation can result in a non-homogeneous distribution of target parameters. Use mechanical means (e.g. sterile wood applicator), freezing, or chemical means (e.g. mixing in salt) to force the foam back into solution. If multiple subsamples are taken, agitation should take place frequently during subsampling (no more than about two minutes should elapse between agitation and aliquoting). Thicker (oil like) concentrates may be mixed using sterile spoons or other utensils (clean utensils free of the analytes of interest may be used if not sampling for microorganisms.)
    - Edibles: Consideration for each of the following types of edibles must also be described in detail:
        - Flour Based: may be homogenized using a mill, blender, food processor, laboratory homogenizer, or other chemical method.
        - Sugar Based: may require different techniques depending on the matrix. Hard candies or chocolates may be pulverized in a mill or food processor (avoid elevated temperatures), while gummies and other soft/chewy candies may be cut into small pieces using sterile utensils. (Note: FDA recommends mixing hard candies/caramels with equal masses of water and heat to boiling, except if testing for microbial or volatile constituents.)
        - Drinks: may be homogenized by agitation (vortexing, blending, or shaking) before subsamples are aliquoted. If multiple subsamples are taken, agitation should take place frequently during subsampling (no more than 2 minutes

should elapse between agitation and aliquoting).

- Crystalline: may be broken down into finer particles and homogenized by blenders, food processors, mills, or a laboratory homogenizer before taking subsamples.

AmericansFor SafeAccess
Advancing Legal Medical Marijuana Therapeutics and Research

October 24, 2019

Marijuana Control Board - Comments to Proposed Changes

The Marijuana Control Board proposes to adopt regulation changes in 3 AAC 306 of the Alaska Administrative Code, dealing with marijuana testing oversight, including the following:

- 3 AAC 306.100 is proposed to increase the license fee for marijuana testing facilities.
- 3 AAC 306.620 is proposed to require the board's contractor to examine a marijuana testing facility prior to being issued a license.
- 3 AAC 306.635 is proposed to require compliance with the Marijuana Testing Facility Compliance Document.
- 3 AAC 306.640 is proposed to require changes to standard operating procedures be submitted and approved by the board's contract.

Americans for Safe Access (ASA) is an independent nonprofit organization that does not have a financial stake in any laboratory in Alaska. ASA is aware of the risks of unregulated and untested products in the marketplace and supports mandatory third-party testing of cannabis and cannabis-containing products prior to sale. We respectfully submit the following comments with regards to the proposed changes.

3 AAC 306.100 - Proposed increase in the license fee for marijuana testing facilities.

The current initial laboratory testing fee is $1000 and the renewal fee is $2000, which is consistent with the structure of other initial and renewal fees given that the renewal fees listed in 3 AAC 306.100(d) are 40-100 percent higher than the initial fees. The proposed change is a renewal fee of $5000, which is not consistent with other fee schedules, none of which have a renewal fee five times that of the initial fee.

Cannabis testing laboratories must acquire specialized laboratory equipment that can cost over a million dollars. They also employ technicians who require specialized training and education in specific areas of testing, which leads to higher overall operating costs. Also, it can take months to validate instruments and testing methodologies, all of which must be done prior to testing any samples. Thus, a lab may be forced to pay a license renewal fee prior to receiving samples, and a high fee could force small operations to close before they have a chance to provide their services to the industry and gain a loyal client base.

Americans for Safe Access would propose that the renewal fee be left unchanged.

ASA

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Received by AMCO 10.30.19

AmericansFor SafeAccess
Advancing Legal Medical Marijuana Therapeutics and Research

3 AAC 306.620 - Proposed to require the board's contractor to examine a marijuana testing facility prior to being issued a license.

Americans for Safe Access supports the proposed changes to 3 AAC 306.620. In 2014, ASA and the American Herbal Products Association partnered to create standards for the cannabis industry and ASA launched the Patient Focused Certification program to provide the industry with an independent, third-party compliance mechanism.

An initial site inspection is only one step in ensuring continued compliance with industry standards and local laws and regulations. Facilities should be inspected annually or biannually, and independent auditing contractors that carry out such inspections while also verifying standard operating procedures and protocols, record keeping, and legal and regulatory compliance are an efficient and cost-effective way to ensure that the highest standards are met without placing undue burden on MCB's resources. We would request that the Marijuana Control Board solicit a Request for Qualifications to identify a pool of contractors that could meet the board's requirements.

3 AAC 306.635 - Proposed to require compliance with the Marijuana Testing Facility Compliance Document.

The Marijuana Testing Facility Compliance Document outlines standards to which laboratories must adhere. These standards include provisions for record keeping, staff training, and sample homogenization. In order to ensure that laboratories meet the standards of the Compliance Document, Americans for Safe Access would propose that laboratories be permitted to seek an independent certification or accreditation that has been verified by the MCB and awarded by an approved contractor. The cost for certifications and assessments would be borne by the laboratory, meaning that comprehensive oversight of laboratory operations could be provided without straining the Marijuana Control Board's employees or financial resources..

Americans for Safe Access would also propose to add provisions to the Compliance Document and the rules and regulations to require that authorized representatives of independent testing laboratories collect representative samples of the plant material or product(s) to be tested. When businesses are allowed to submit their own samples to laboratories for testing, there is no guarantee that they are submitting the correct volume of sample (based on representative sampling guidelines) or that they have not adulterated the sample in order to pass testing.

3 AAC 306.640 - Proposed to require changes to standard operating procedures be submitted and approved by the board's contract.

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ASA is the largest national nonprofit organization of patients, medical cannabis providers, medical professionals, scientists, and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research, with over 100,000 advocates in all 50 states.

Received by AMCO 10.30.19

AmericansFor SafeAccess
Advancing Legal Medical Marijuana Therapeutics and Research

Americans for Safe Access is opposed to requiring laboratories to submit changes to standard operating procedures (SOPs) for approval. The Marijuana Testing Facility Compliance Document outlines the standards to which laboratories must adhere, which includes the implementation of a Quality Management System (QMS). The QMS should have procedures for making changes to SOPs and other policies and procedures and should define how the documentation changes are tracked, reviewed, and approved. Most QMS systems require a specific Quality Manager or other authority figure, such as the Laboratory Director, to be responsible for maintaining and implementing changes to SOPs, policies, and procedures.

SOPs may be added or updated for minor reasons, such as spelling errors or an insignificant change in procedure, or for major ones, such as implementing a new test method. Senior laboratory staff (e.g., Quality Managers, Laboratory Directors) are tasked with maintaining significant numbers of these procedures, all of which undergo a review annually, at a minimum. Requiring that any change be submitted for approval prior to implementation could impede a laboratory's workflow, delay the implementation of any necessary changes to procedures, and create a bottleneck at the Marijuana Control Board if the pace at which changes are submitted exceeds the pace at which they can be reviewed.

In our comments above regarding 3 ACC 306.635, we propose that laboratories be required to adhere to industry standards and that they be permitted to seek independent certification or accreditation of their adherence thereto. Were this proposal to be implemented, certifying or accrediting bodies that the Marijuana Control Board approves after a competitive process would review changes to laboratories' standard operating procedures on an annual and/or biannual basis. This would transfer some of the oversight burden from the Marijuana Control Board to an independent, board-approved contractor while ensuring rigorous compliance with laws, regulations, and standards designed to promote product quality and protect patient and consumer safety.

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ASA is the largest national nonprofit organization of patients, medical cannabis providers, medical professionals, scientists, and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research, with over 100,000 advocates in all 50 states.

Received by AMCO 10.30.19

October 29, 2019
Via email

Subject: Public Comment on 3 AAC 306.100, 306.620, 306.635, 306.640, dealing with marijuana testing oversight

Dear Honorable Marijuana Control Board Members:

The proposed regulation **should not be adopted**. We ask the MCB to table this project.

As far as we can tell, the testing working group has essentially been disbanded and now consists of only one individual. While we appreciate his time on this project, no one person is qualified to create and review scientific testing lab standards on their own.

The AMIA feels strongly that the testing working group should be re-established and maintained. The group should include qualified industry stakeholders, representatives from all licensed marijuana testing facilities, and scientists with the appropriate experience and credentials.

We suggest a microbial biologist and analytical chemist experienced with potency and residual solvents to be included in the working group. These scientists should also be experts in gas chromatography and high-performance liquid chromatography.

We would like Brandon Emmett to be reappointed to the testing working group as he is capable of communicating effectively with lab operators, scientists, and industry members.

Representatives from Fairbanks Analytical Testing and Peak Analytical in Ketchikan are interested in volunteering their time to ensure sound testing lab standards.

Thank you for the opportunity to comment on the proposed regulations.

Respectfully,

Alaska Marijuana Industry Association
Board of Directors

www.alaskamarijuanaindustry.org

Received by AMCO 10.30.19

From: Tina
To: CED AMCO REGS (CED sponsored)
Subject: Proposed Regulations change comments
Date: Wednesday, October 30, 2019 2:25:04 PM

Here are the public comments for the Proposed Regulation changes from Midnight Greenery CEO and Director of AKCannaED Tina Smith.

OWNERSHIP OF MARIJUANA TESTING FACILITIES (3 AAC 306.015)
I am NOT in support of ANY outside marijuana related business types at this time.

APPLICATION AND RENEWAL DATES (3 AAC.306.025, 3 AAC 306.035)
I am in general support of these regulation changes.

INFANTS ON PREMISES (3 AAC 306.710)
I am in complete favor of these regulation changes

OVERLAPPING PREMISES (3 AAC 306.405, 3 AAC 306.705 3 AAC 306.710, 3 AAC 306.990)
I am in general favor of these regulation changes

TESTING OVERSIGHT (3AAC 306.100, 3 AAC 306.620, 3 AAC 306.635, 3 AAC 306.640)
I am in general favor of these proposed regulation changes

UMBRELLA CATEGORIES (3 AAC 306.520, 3 AAC 306.525, 3 AAC 306.990)
EXCEPT for specifically 306.525 (e)(1) I am in general favor of these proposed regulations .
306.525(e)(1) can be problematic for individual business book keeping and product labeling inside business records as well as waiting for the board to give them those numbers before being able to produce and distribute product to the retail establishments. I would suggest allowing the businesses themselves to assign the product numbers they choose, while being required to share those numbers along with the rest of their plan for each product being created..

Thank you for your time and consideration regarding smart business practices and regulations for our ever growing industry.
Sent from my iPad

From:	kara jurczak
To:	CED AMCO REGS (CED sponsored)
Subject:	Proposed Regs-Testing Compliance Doc and Increased License Fee
Date:	Saturday, November 02, 2019 2:57:15 PM
Attachments:	191102 Comments to Revision 3.docx 191030 AMCO response Comments to Revision 3.docx Testing Compliance Doc Rev 3 QC Costs.pdf Shipping Costs.pdf

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Dear AMCO,

Thank you for the opportunity to comment. See attached comments and supporting documentation. I would be happy to provide backup calculations for Exhibit A.

Sincerely,

Kara Jurczak, P.E.
Peak Analytical

To: AMCO

From: Kara Jurczak P.E. and Julie Martellini PhD, Peak Analytical

Date: 10/30/19

Re: Response to Mr. Crupi's comments

As stated in the History and Purpose section of the Laboratory Compliance Document (the document) the problem is inconsistent results between laboratories. I agree that this is a problem, unfortunately the only way to solve the problem is to publish and require the use of Standard Test Procedures (STPs) to be used by each laboratory. Even then there is still going to be variability within each plant or batch of sample, each analyst will have slightly different techniques and each instrument has differences in performance based on manufacturer, quality and age of consumable parts used and maintenance practices. Until STPs are issued this is all just wasted motion; please don't confuse PROGRESS with motion as they are very different things. The board and this working group are all intelligent people and thus I ask that you take a step back and take another look at the proposed document and ask yourself what parts of it are going to result in actual forward progress and which parts are just motion.

In my opinion, the parts of the document which will result in real progress are as follows with recommended frequencies:

1. Duplicate Sample, 1/20
    a. Duplicates are a great way to confirm the use of good laboratory practices
2. Lab Control Sample, 7 required during method validation then 1 confirmatory test per year and 1 with any modification to a test procedure (preparation only)
    a. As stated in the document, an LCS is used to test the effectiveness of a method to test for the analyte in that phase; once a method has proven its ability to test for an analyte in a phase (which is done during method validation) that should be the end of it until the method is modified. What is gained by confirming this over and over with every batch of samples? Running an LCS with every batch is wasted motion without forward progress.
3. Matrix Spike, 7 required during method validation then 1 confirmatory test per year and 1 with any modification to a test procedure (preparation only)
    a. As stated in the document, an MS is used to test the effectiveness of a method to test for the analyte in that samples matrix; once a method has proven its ability to test for an analyte in a matrix (which is done during method validation) that should be the end of it until the method is modified. What is gained by confirming this over and over with every twenty samples? Running an MS with every batch is wasted motion without forward progress.
4. Method Blank, 1/20
    a. MBs are a great way to confirm the use of good laboratory practices

Commented [CS1]: AOAC and other professional organizations are engaged in this process already. Until methods are finalized, next best option is gaining a level of consistency through the topics this document addresses.

Commented [CS2]: It is for this reason that some of the controls have a frequency of per batch or in the case of surrogates, per sample, to monitor for these variabilities

Commented [kj3R2]: So what happens after you identify that two analysts have different techniques? What is the real world positive outcome from this? Until we have robots performing these tests you cannot take the human factor out of the test results; not possible and a waste of time, energy and money trying to do so.

Commented [CS4]: See comment above addressing matrix and technique variability

Commented [kj5R4]: There is no matrix variability, just harvest to harvest variability, which this does nothing to address. Again, you cannot eliminate the human factor with QC samples

Commented [CS6]: See comment above addressing matrix and technique variability

Commented [kj7R6]: So what happens after you identify that two analysts have different techniques? What is the real world positive outcome from this? Until we have robots performing these tests you cannot take the human factor out of the test results; not possible and a waste of time, energy and money trying to do so.

Commented [CS8]: The current version of the compliance document relaxed the frequency from every batch to every 20 samples of similar matrix (e.g. plant vs. edible vs. concentrate).

Commented [kj9R8]: What is gained by confirming this repeatedly?

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5. Surrogate Standard, 7 required during method validation then 1 confirmatory test per year and 1 with any modification to a test procedure (preparation only)
    a. As stated in the document, a surrogate is used to assess the extraction efficiency of a method. Additionally, surrogate recoveries tell if a method has bias (high or low) toward a group of analytes; once a method's extraction efficiency and bias has been evaluated (which is done during method validation) that should be the end of it until the method is modified. What is gained by evaluating this over and over with every sample? Using a surrogate standard with every batch is wasted motion without forward progress.
6. Secondary Source Standard, 0 required
    a. I would like to know the purpose of this? I can only assume it is either to validate the primary standards or is an attempt to see when the standards have decayed too much?
        i. Certified Reference Standards (CRMs) are accompanied by a Certificate of Analysis and are created by laboratories that are ISO accredited.
        ii. It is obvious when CRMs have begun to decay by observing peak shapes, intensity and most of all the calibration's linear regression correlation coefficient decreases and eventually falls below .995.
        iii. A secondary source standard is not necessary to see when new CRMs are required, see item 7 below.
        iv. Cannabis CRMs are VERY expensive with $108 minimum shipping cost and have a very short life once opened; don't add to the pain of these already expensive and fickle CRMS.
        v. Each CRM you order from a different manufacturer costs $100+ in shipping. There is not one manufacturer that makes all the required CRMs.
        vi. You cannot order two different lots at one time because of the short shelf life. The manufacturers don't stock lot overlap and there is not an option on any website to request different lots.
7. Continuing Calibration Verification, 1 per batch recorded on a CCV & Starting Conditions Log.
    a. We track our starting conditions and CCV performance on a log sheet. This includes CCV pass/fail (+/- 10%), THC retention time and pressure at starting conditions. This practice adds great benefit to the 1 CCV per batch and has aided in identifying system drift, CRM life/decay, system variability and maintenance needs. This simple, cost effective practice results in progress not motion.
8. Proficiency Testing, 1/new analyst, 1/method validation, 1/lab/year (same as the document)
    a. Single handed, a Proficiency Testing program will separate the real labs from the hacks, will force labs to "shape up" so to speak and will evoke ***real progress***.
    b. I used to test potable water and wastewater in a DEC Certified Potable Water Laboratory and DEC hangs their hat on the required PT tests and bare minimum QA/QC samples for millions of people's drinking water and millions of gallons of wastewater discharge to the environment.

During my career as a professional engineer in charge of administering construction projects I listened to the constant complaining of contractors about their costs to do business. On most occasions I would

Commented [CS10]: See comment above addressing matrix and technique variability.

Commented [kj11R10]: So what happens after you identify that two analysts have different techniques? What is the real world positive outcome from this? Until we have robots performing these tests you cannot take the human factor out of the test results; not possible and a waste of time, energy and money trying to do so.

Commented [CS12]: To verify the accuracy of the calibration curve. A calibration curve can be linear, but not be accurate. A visual assessment of the accuracy is possible by plotting the curve and determining the y-intercept. Experimentally involves a second source standard, which is a standard from a different vendor, or the same vendor, but a different lot.

Commented [kj13R12]: Is there a reason to not trust the accuracy of the calibration curve? Using Certified Reference Materials with certs of analysis from ISO accredited labs…we need to verify these? See attached costs of standards and their shipping.

Commented [CS14]: Not a measure of decay, but an initial assessment of the calibration curve for accuracy.

Commented [CS15]: Do you have a proposal for a sort of rotation for verification?

Commented [kj16R15]: Not at this time

Commented [CS17]: A call to the vendor will accomplish this need.

Commented [kj18R17]: We order standards through an intermediate distributor (emerald scientific) who buys them whole sale from the manufacturer and sells them for less than you can buy them from the manufacturer at a one-at-a-time price. The logistics of trying to keep in stock two different lots of CRMs which are now expiring at different times resulting in more frequent orders with $100 shipping each is just plain crazy

Commented [CS19]: The purpose is to ensure at the run start that the calibration curve is still valid. The purpose of running a CCV every 10 samples and at the end of a run is to verify the curve was valid/system was stable throughout the run. This frequency is reflective of section 7.7.4 of the Manual for the Certification of Laboratories Analyzing Drinking Water (5th ed.). It is also supported in Method 8000, section 11.8.2 of EPA's SW846 Methods Manual, which stems from the federal RCRA program.

Commented [kj20R19]: As stated in my other comments document dated 11/2/19, potable drinking water and hazardous waste should have stringent QC requirements as human life is at risk. Cannabinoid/terpene content should not require the same stringent testing as hazardous waste as they do not threaten human health and life

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automatically think that the extreme costs they spoke of were phony; until I penciled it out. After listing each little item it takes to complete the task I would come to the same number they did in the end. So I thought it would be a good exercise to pencil out the actual costs of the requirements listed in the document rather than just generally complaining about costs. Before I started I guessed it was on the order of $1500/month but the numbers came in higher at $2,280/month, see Exhibit A for details. For the analysis I assumed 60 client samples of flower or concentrate per month which is just below the number I need to break even each month; so the analysis is on a bare minimum number of samples and would go up in cost from there. Please ask yourself how your household/family would fair if your local government suddenly raised your property tax by $2,200 per month; $27,000 per year! It is the same for a business, there is no magic source of revenue I can call upon to get the extra $2,200 per month. This is real money, not monopoly money and every sentence in the document has a cost to each lab. Furthermore, when a business gets stressed for money they have to cut costs in other places which would likely result in a net negative on quality of laboratory results.

Please re-consider the document and assess what is wasted motion versus what will evoke real change and progress.

To: AMCO

From: Kara Jurczak P.E. and Julie Martellini PhD, Peak Analytical

Date: 11/2/19

Re: Comments to proposed regulations – Testing Oversight and the Laboratory Compliance Document

You state that the QA/QC requirements discussed in the Laboratory Compliance Document (the document) are based on EPA's CERCLA and RCRA programs. Super fund law (CERCLA) is for cleaning up sites contaminated with hazardous wastes for the protection of human life and the environment. Similarly, RCRA is EPA's law governing disposal of hazardous waste for the protection of human life and the environment. By ratifying the document you are stating that cannabinoids and terpenes should be treated the same as hazardous waste, are a threat to human life and the environment and should be tested to the same stringent standards as hazardous wastes. That is a non-sensical correlation between hazardous waste and cannabinoids/terpenes. However, residual solvents and microbial contamination could harm humans so it would make sense to require more stringent QA/QC for those tests. Furthermore, I could not find a CERLA or RCRA document that specified the type and frequency of QA/QC samples. Numerous documents that I found required a Quality Assurance Manual/Program that is tailored to each laboratory's needs. Please provide the documents you refer to.

As stated in the History and Purpose section of the Laboratory Compliance Document (the document) the problem you are trying to solve is inconsistent results between laboratories. I don't understand why this is a problem; please elaborate on why this is a problem and how it is unique from other types of laboratories, environmental, water, etc., where some variability between laboratories is unavoidable and expected. In my career as a professional engineer I regularly sent environmental samples out for testing to different labs and the results always varied. There will always be variability due to variables within each plant or batch of sample, each analyst will have slightly different techniques and each instrument has differences in performance based on quality and age of consumable parts used and maintenance practices. As such, the only way to solve the perceived problem is to publish and require the use of Standard Test Procedures (STPs) to be used by each laboratory. Until STPs are issued this is all just wasted motion; please don't confuse PROGRESS with motion as they are very different things. The board and this working group are all intelligent people and thus I ask that you take a step back and take another look at the proposed document and ask yourself what parts of it are going to result in actual forward progress and which parts are just motion.

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To date my laboratory has been operating at a loss and has not been worth the headache of dealing with all the regulations and exorbitant amount of paperwork and reporting already required. This document would make this business even less desirable. If you want the State to be "open for business" for cannabis laboratories, this document and raising the annual license fee by 250% is NOT the way to encourage new labs nor bolster good science from existing labs.

Exhibit A

Lab Compliance Document Rev 3 9/28/2019
Summary of Actual Costs of QC Requirements
Peak Analytical, Ketchikan

Additional QA/QC Requirement	Frequency		Monthly		Annual
Duplicate Sample	1/20	$	85	$	1,020
Lab Control Sample	1/batch	$	672	$	8,064
Matrix Spike	1/20	$	154	$	1,848
Method Blank	1/batch	$	623	$	7,476
Surrogate Standard	every QC & every sample	$	193	$	2,316
Secondary Source Standard	1/ICAL	$	58	$	696
CCV (middle & end of runs)	2 additional/batch	$	49	$	588
Proficiency Testing	1/year (micro & chemistry)	$	156	$	1,872
	Subtotal	*$*	*1,990*	*$*	*23,880*
Additional Documentation Required by the Lab Compliance Document plus additional QC sample documentation	estimated 20 mins/day	$	290	$	3,480
	Total Costs To Laboratory	**$**	**2,280**	**$**	**27,360**

Assumptions:

60 flower or concentrate client samples per month

Consumables for potency test cost $15/test

Consumables consist of vials, tubes, syringes, filters, pipette tips, solvents, acids, cleanup chemicals, mobile phase chemicals. This does not take into account instrument consumeables and wear and tear on analytical columns and instruments nor regular maintenance activities

The monthly costs listed above do not include any allowances for business overhead costs

Exhibit B

EMERALD SCIENTIFIC

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Your Cart (1 Item)

You left some items from a previous cart. We have added those items to your current cart.

Item	Price	Quantity	Total
 Emerald Scientific Warehouse Kimtech KimWipes Delicate Task Wipes (1 bx, 280 wipes/bx)	$3.95	1	$3.95

Subtotal: $3.95

Shipping: *Cancel*

Country: United States

State/province: Alaska

Suburb/city: Suburb/city

Zip/postcode: 99901

ESTIMATE SHIPPING

FedEx (Ground)	$40.45
UPS (UPS® Ground)	$42.46
FedEx (Priority Overnight)	$64.95
UPS (UPS Next Day Air®)	$72.00

UPDATE SHIPPING COST

Shipping Details

Kara Jurczak, Peak Analytical LLC , 2208 Tongass Avenue,...

Shipping Method

Shipping (Ground + 2-Day + Overnight) for $107.41

Order Confirmation

Please review the contents of your order below and then choose how you'd like to pay for your order.

Cart Items	Qty	Item Price	Item Total
Kimtech KimWipes Delicate Task Wipes (1 bx, 280 wipes/bx)	1	$3.95	*$3.95*
Delta-9-Tetrahydrocannabinolic Acid A (THCA-A) Standard (1pk)	1	$240.00	*$240.00*
		Gift Certificate or Coupon Code:	APPLY
		Subtotal	***$243.95***
		Shipping (Shipping (Ground + 2-Day + Overnight))	***$107.41***
		Grand Total	***$351.36***