- **State of MI LARA**
  Presenter: Claire Patterson
  10:00 AM - 10:30 AM EDT

- **ASTM International**
  Presenters: Kathleen May & Bob Morgan
  10:30 AM - 11:00 AM EDT

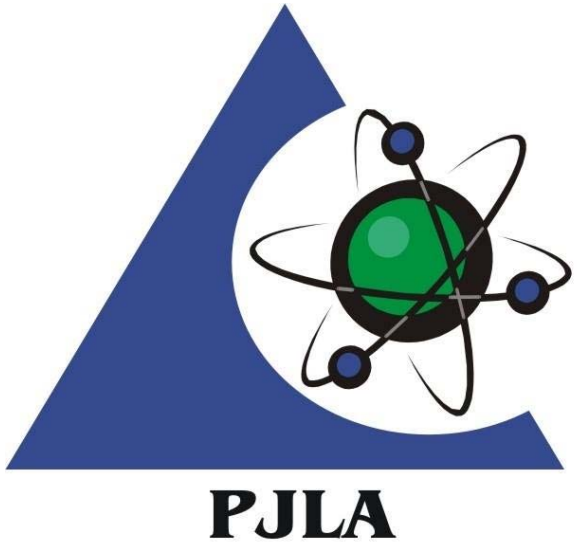
- **Absolute Standards, Inc. & Emerald Scientific**
  Presenters: Stephen J. Arpie & Kirsten Blake
  11:00 AM - 11:30 AM EDT

- **Qualtrax**
  Presenter: Karen Arrivillaga
  11:30 AM - 12:00 PM EDT

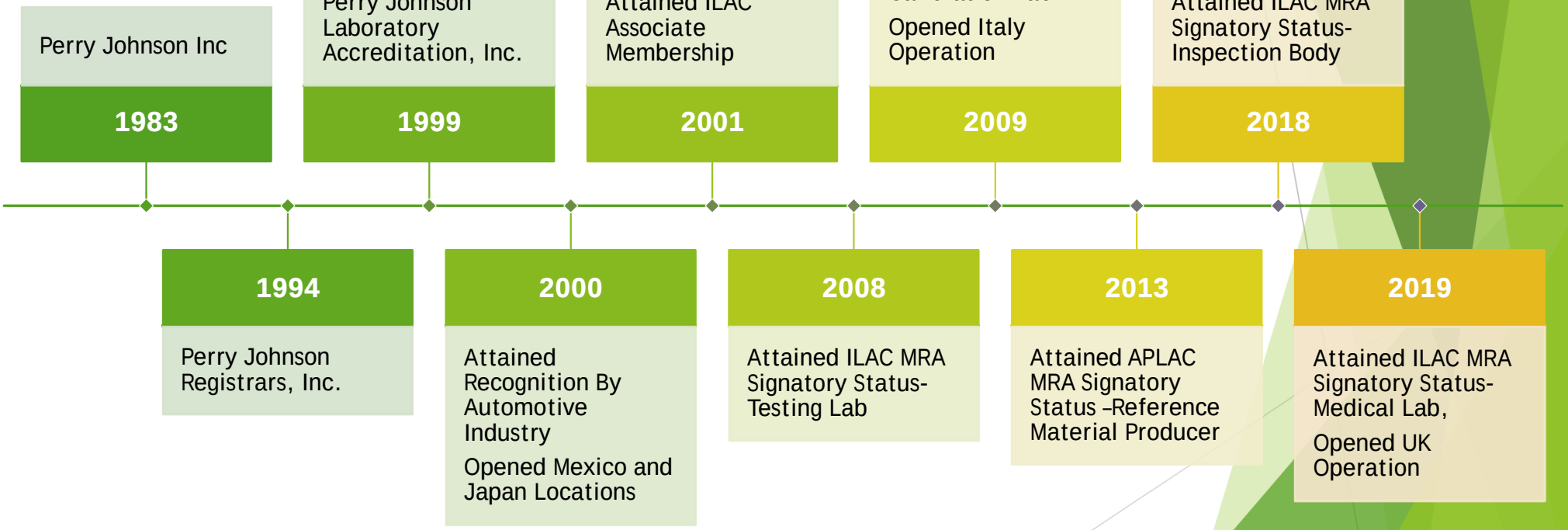
- **Perry Johnson Laboratory Accreditation, Inc.**
  Presenter: Tracy Szerszen
  12:00 PM - 12:30 PM EDT

Perry Johnson Laboratory Accreditation, Inc. (PJLA) & the Cannabis/Hemp Industry

- Accredited first Cannabis Lab in 2012 to ISO/IEC 17025 and expanding
- Attended and Participated in Several Cannabis/Hemp Associations in support of the industry
- Experienced Accreditation Body with over 1500 accredited facilities globally
- Free Training and Client Support Services
  - Virtual Remote Assessments
- Internationally Recognized ILAC Accreditation Body



Perry Johnson Laboratory Accreditation, Inc.



Working Together as Partners in the Industry

Partnerships

Resources for Labs

Common Interests

Opportunity to share information

PJLA

Master of Ceremonies: **Brett McMillen**

With over 10 years of experience in the Quality and Regulatory business with the Perry Johnson Family of Companies, Brett has assisted in the development of their Cannabis and Hemp Accreditation and Certification programs. His contributions to the development of their GMP, GAP, Organic, and other Cannabis and Hemp programs have been instrumental given his range of experience witnessing manufacture of products from a wide range of industry areas.

Presenter: **Claire Patterson**
10:00 AM - 10:30 AM EDT

Claire was hired as the manager of the Scientific & Legal Section of the Marijuana Regulatory Agency (MRA) in March 2020. The agency oversees the Medical Marihuana Facilities Licensing Act, the Michigan Regulation and Taxation of Marihuana the Marihuana Tracking Act, and the Marihuana Tracking Act. MRA's mission is to establish Michigan as the national model for a regulatory program that stimulates business growth while preserving safe consumer access to marijuana. Claire has been providing guidance for quality control oversight and laboratory performance optimization for the cannabis industry since 2013.

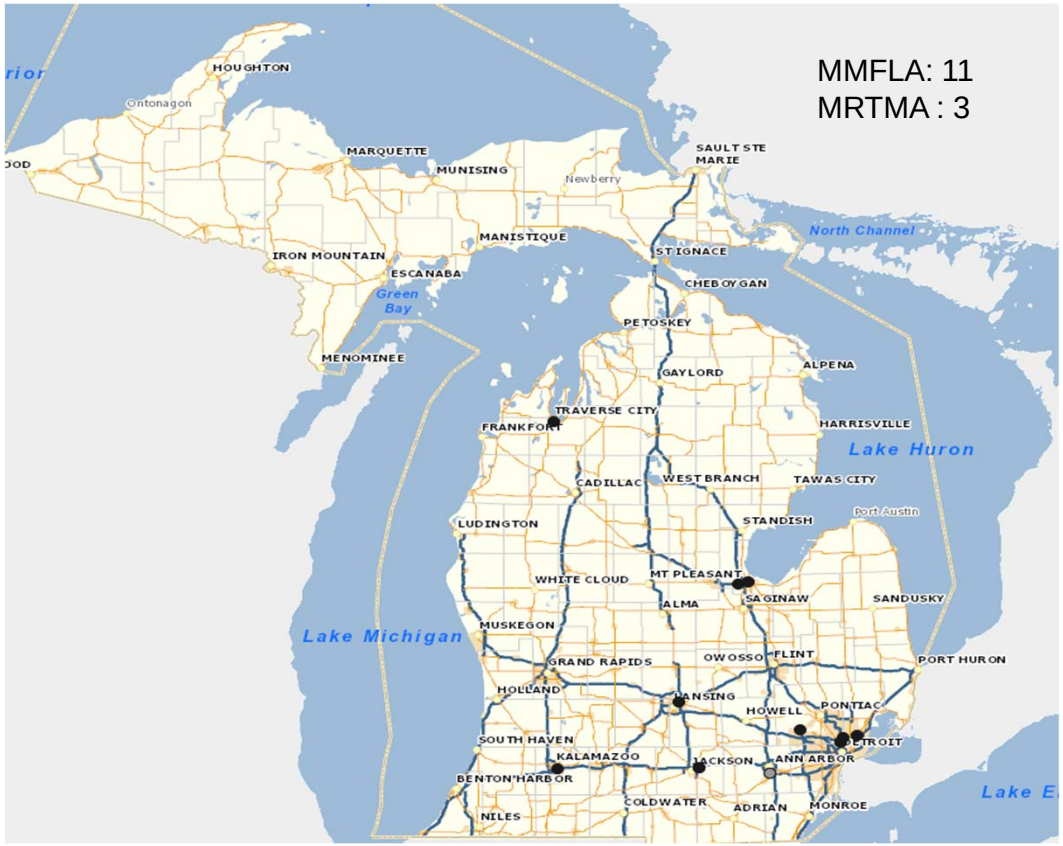
LARA
LICENSING AND REGULATORY AFFAIRS

The MRA's Role in Providing Education and Oversight to Safety Compliance Facilities in Michigan

Claire T. Patterson
Section Manager
Scientific & Legal
Marijuana Regulatory Agency

Safety Compliance Facilities (SCFs)

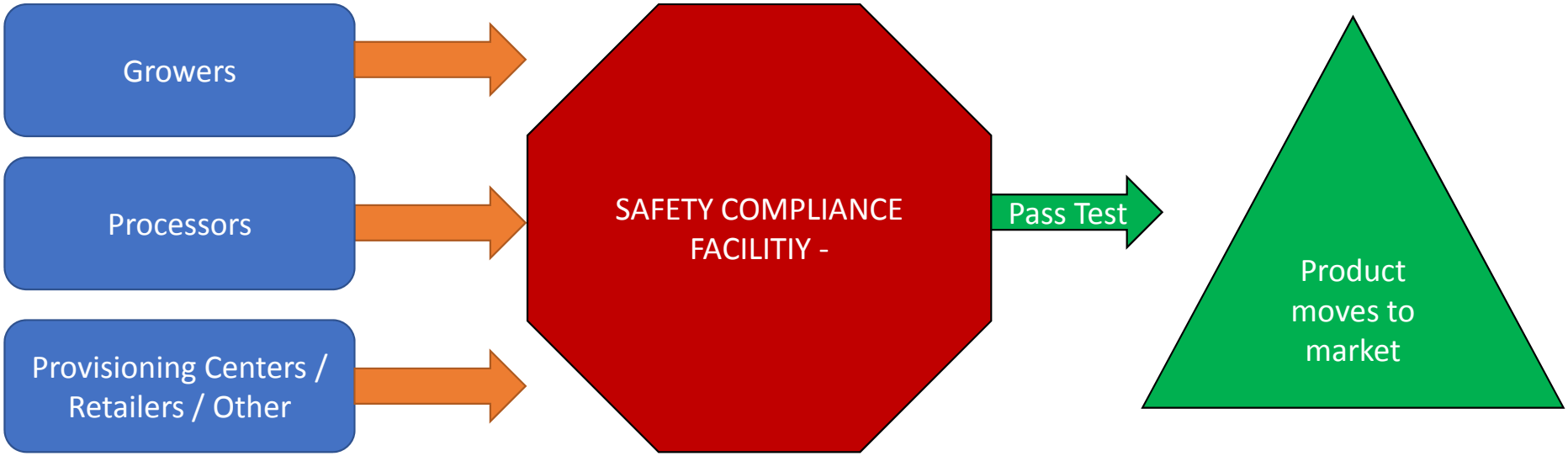
- Test marihuana for all other facility types licensed under MMFLA / MRTMA
- Collect samples pursuant to the rules under which they are licensed
- Test samples in accordance with rules
- Enter data in statewide monitoring system (Metrc)
- **Results from SCFs guide the future path of the product**



Importance of Safety Compliance Facilities

- SCFs act as ‘gate-keeper’ for regulated marijuana supply chain
- SCFs must keep up with emerging science –research, methodology, instrumentation, etc.
- SCFs are critical in ensuring that product from the marijuana industry is reasonably free of contaminants
- **Goal**: provide defensible, consistent, and reliable data to licensees to ensure safe access to consumers

LARA
LICENSING AND REGULATORY AFFAIRS



Role of Safety Compliance Facilities

- ✓ Potency (THC, THCA, CBD, CBDA)
- ✓ Foreign Matter (filth / extraneous matter)
- ✓ Microbial Screening (qualitative & quantitative)
- ✓ Chemical Residue Screening
- ✓ Heavy Metals
- ✓ Residual Solvents
- ✓ Water activity / Moisture content
- ✓ Homogeneity (infused products only)

Action limits and additional information can be found here:
Safety Compliance Facility Sampling and Testing Technical Guidance for Medical Marijuana Products

Safety Compliance Testing Guide

- ✓ Quality Assurance and Quality Control
- ✓ SOP Requirements
- ✓ Validation Requirements
- ✓ Official Methods, Standard Methods, and SMPRs
- ✓ Suggested training / qualifications for some employees
- ✓ Sampling and testing guidance
- ✓ Action limits
- ✓ Methods and tips

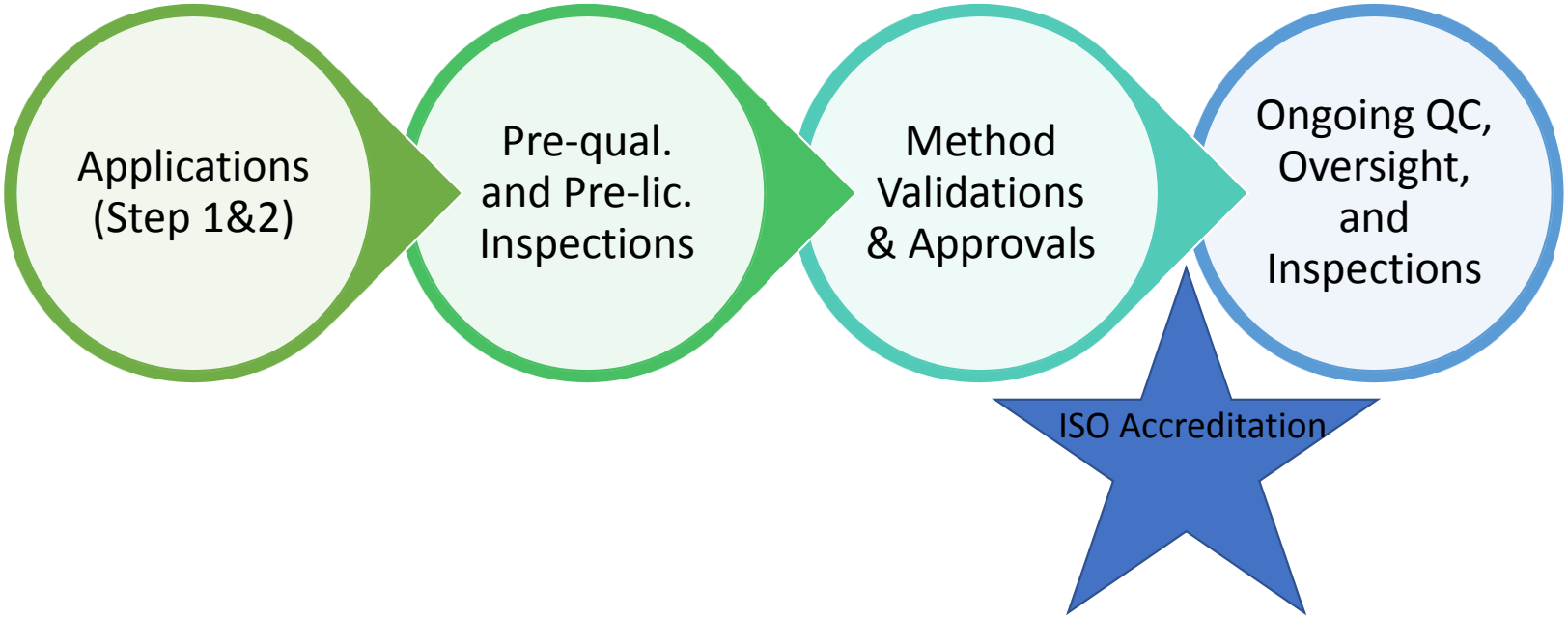
Laboratory Scientist Specialist (LSS)

Laboratory Scientist Specialists have a unique role in the MRA and an important relationship with SCFs

- **Guide**: through the pre-licensure process, inspections, regular check-ins to assess readiness
- **Review**: method validation, method approvals, quality control (where appropriate)
- **Oversee**: data review, scheduled audits, proficiency testing
- **Educate**: Quarterly educational sessions for SCFs
- LSS serves as a point of contact for SCFs for all questions related to compliance and testing

Assist all license types with scientific questions and SCF related issues

From Applicant to Licensee



Pre-licensure Questionnaire

1. Instruments on site? (Not Required)

2. Does the SCF currently employ at least one person that holds an advanced degree in a medical or laboratory science? Full name and CV (Required to pass)

3. Does the SCF have methods validated on cannabis for any of the analyses required by the MRA? (Not Required)

4. Is the facility currently operational and in what capacity? (Not Required)

5. Has the SCF received ISO 170205:2017 (or newer) accreditation if so, for which methods? (Not Required)

On-site vs. Off-site Inspection

- Based only on facility readiness – does not indicate deficiency

- If the facility has instruments installed and operational, on-site inspection is warranted

  Assigned LSS will schedule an inspection

- If the facility does not have instruments, an off-site inspection may be performed

  The applicant may request consultation via phone or assistance via email by reaching out to: MRA-scf@Michigan.gov

Credentialing in Metrc

- After licensure, SCF should be credentialed in the statewide monitoring system (Metrc)
- When access is granted, order RFID tags
- Designate validation inventory if necessary
- All steps outlined in the onboarding documents provided to the licensee by their LSS

Important steps as a licensee

1 year from licensing date, the licensee should complete the following:

- ✓ Outline strategy- All methods? Matrix?
- ✓ Write validation plan using resources
- ✓ Begin validations and quality control
- ✓ Submit validations and methods to LSS for MRA approval
- ✓ Submit methods and quality control to ISO for accreditation*

***R 333.247 Testing; safety compliance facility. (b)**

Become fully accredited to the International Organization for Standardization (ISO), ISO/IEC 17025:2005 or 17025:2017 by an International Laboratory Accreditation Cooperation (ILAC) recognized accreditation body or by an entity approved by the department within 1 year after the date the license is issued…

Method Review Process

What is required for a method to get approved?

1. Complete method and associated SOPs
2. Validation report and resulting data
3. Acceptable, externally graded PT
4. Follow all guidelines from the Safety Compliance Facility Sampling and Testing Guide

- May submit methods in any order for any/all matrices or complete package
- LSS reviews methods, provides formal feedback
- Cooperative relationship to help the SCF work toward compliance and successful operation

First sampling event

- Once approved, the SCF schedules their first sampling event
- May request that LSS is present during the event to ensure compliance and provide oversight
- If the SCF requests the LSS to attend, submit field sampling guide and associated SOPs for real-time audit and feedback
- On-site the LSS may offer suggestions and tips to the SCF and the licensee about best practices, working in Metrc, etc.

Quality Control and Oversight

An SCF licensed with the MRA is subject to ongoing Quality Control and Oversight:

- ✓ Daily & weekly - review of all data in Metrc and statistics
- ✓ Monthly – Scientific Advisory Workgroup
- ✓ Quarterly - interlaboratory comparisons
- ✓ Quarterly - training events held by MRA
- ✓ Quarterly - selection for Random Audit
- ✓ Annual - PT submission for all approved methods
- ✓ Investigation - complaints and anomalies as warranted

On-going Oversight

- Assess SCF progress and adherence to rules & regulations
- Address common concerns and questions about compliance
- On-site audit of methods as part of inspection or investigation
- Provide recommendations to improve operations

Tips for Success

- ✓ When questions arise, contact the MRA for assistance – Available to assist with questions in the lab or in the field
- ✓ Use the MRA as a resource for information
- ✓ Research and updates? SCFs can them submit to the MRA for consideration and discussion at the Scientific Advisory Workgroup
- ✓ All licensees are welcome to submit comments, questions, concerns related to testing to MRA-scf@Michigan.gov

LARA
LICENSING AND REGULATORY AFFAIRS

PROTECT PEOPLE &
PROMOTE BUSINESS

MRA
MICHIGAN MARIJUANA REGULATORY AGENCY

For additional information and to sign up for updates please visit
Department of Licensing and Regulatory Affairs - MRA:

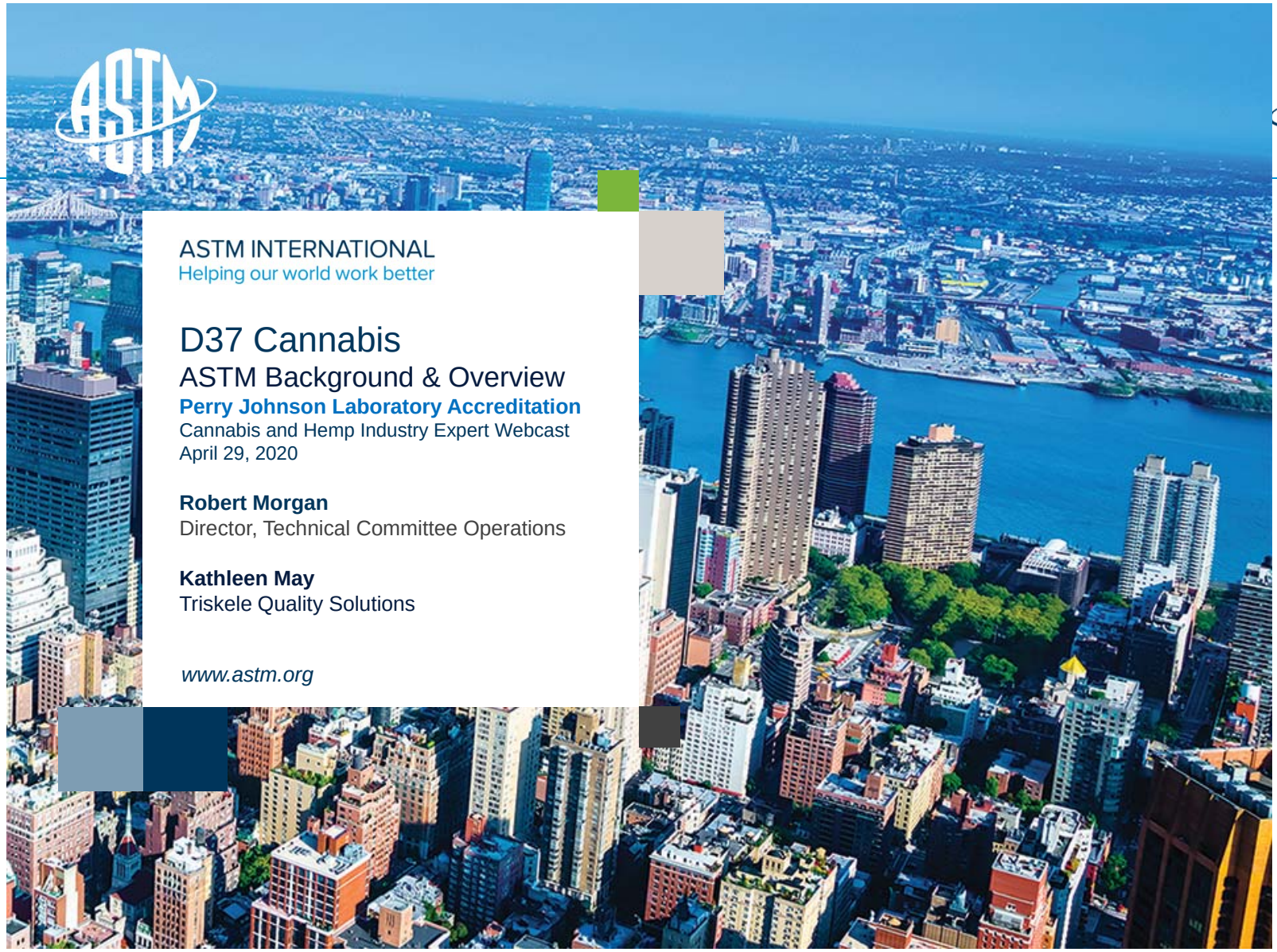
QUESTIONS?

ASTM INTERNATIONAL

Presenters: Kathleen May & Robert Morgan
10:30 AM - 11:00 AM EDT

Kathleen May, Founder and Owner of Triskele Quality Solutions, has more than 20 years' experience as a Quality professional in the pharmaceutical, medical device and cannabis industries. She has worked in every aspect of quality management systems and is a sought-after consultant in regulatory and scientific standards. Kathleen earned a B.A. in Biology with a minor in Chemistry from Carthage College in Kenosha, WI. She has held multiple management roles and earned a certification as a Certified Quality Auditor (CQA) from the American Society for Quality. Kathleen is an executive member of the ASTM International Cannabis Standards Committee, D37. D37 is focused on creating quality and safety standards and guidance materials for cannabis products and processes.

Bob Morgan has a Bachelor's Degree in Geoenvironmental Science from Shippensburg University and has spent over 35 years working for ASTM International. Bob provides the standards development resources for the development of standard guides, practices, test methods and specifications in an open and transparent process, ensuring that all points of view are considered. In his current position as Director of Technical Committee Operations, Bob is responsible for the operations that support 40 Technical Committees in developing voluntary consensus standards. Bob is also directly involved with ASTM's Committee D37 on Cannabis which consists of 700 members representing 26 countries.



ASTM INTERNATIONAL
Helping our world work better

D37 Cannabis

ASTM Background & Overview

Perry Johnson Laboratory Accreditation
Cannabis and Hemp Industry Expert Webcast
April 29, 2020

Robert Morgan
Director, Technical Committee Operations

Kathleen May
Triskele Quality Solutions

www.astm.org

What is ASTM?

A Proven and Practical System

- Established in 1898
- 148 Committees & 12,500+ Standards
- 32,000 members
  - 8,000+ International Members from 135 countries
  - 5,100 ASTM standards used in 75 countries
- Accreditation: American National Standards Institute (ANSI) & Standards Council of Canada (SCC)
- Process complies with WTO principles: Annex 4 of WTO/TBT Agreement

- Development and delivery of information made uncomplicated
- A common sense approach: industry driven
- Market relevant globally
- No project costs

Important. Every Day.

The Role of ASTM Standards

- **Ensures safety, quality and reliability**
- **Emerging Industry Support**: Standards are a foundation to build upon
- **Responsive:** innovations, new challenges, new technology and new markets
- **Industry Lead:** Effective and relevant across diverse markets
- **Built on Consensus**: 90% approval; balanced and equal
- **Helping Everyone**: all stakeholders involved directly impacts content
- **Voluntary until Referenced**: contracts, regulations, codes, and laws around the world.

Over a Century of Openness

How We Work

- **Provide Infrastructure and Tools**
  - Templates, Online balloting, Online collaboration areas, meetings support, managers, administrative support, editors, promotional support
- **Industry comes Together:**
  - Exchange expertise and knowledge
  - Participating in a transparent process – open to anyone, anywhere
- Staff does not write standards, remain neutral

How Are ASTM Standards Used?

Developed voluntarily and used voluntarily
Cited in a contract

Government agency reference them in codes, certification, regulations, and laws, supports P.L. 104-113

Used by tens of thousands of individuals, companies, and agencies globally

D37 on Cannabis

Overview

Formed in 2017; 800 Members from 26 countries

Title: Cannabis

Scope: The development & maintenance of standards and guidance materials for cannabis and its products and processes.

D37.01 Indoor and Outdoor Horticulture and Agriculture
D37.02 Quality Management Systems
D37.03 Laboratory
D37.04 Processing and Handling
D37.05 Security and Transportation
D37.06 Personnel Training, Assessment, Credentialing
D37.07 Industrial Hemp
D37.08 Devices and Appliances
D37.90 Executive
D37.91 Terminology

Represented by

- Associations
- Academia
- Laboratories
- Supplier
- Cultivation Centers
- Government
- Transportation Services
- Software Providers
- Accreditation bodies

Collaborating to Develop Robust Solutions Toolbox

Global Partnerships

International Cannabis and Cannabinoid Institute (ICCI) – 3rd European Workshop to be held in Prague – October 22-23, 2020

European Industrial Hemp Association (EIHA) – Assisting with UE stakeholder engagement

Canadian Hemp Trade Alliance (CHTA) – Providing technical content for Industrial Hemp standards

National Research Council of Canada (NRC) – Dr. Ralph Paroli, Director of R&D and Chair of Committee D37, Dr. Jeremy Melanson, Chair of D37.03 on Laboratory

American Trade Association for Cannabis and Hemp (ATACH) – Coordinating activities with states AG's

American Herbal Products Association (AHPA) – Sharing technical content and assisting with state engagement

Foundation for Cannabis Unified Standards (FOCUS)- Sharing technical content

PROGRESS REPORT

D37 Standards thus far…

D8196-18 Standard Practice for Determination of Water Activity (aw) in Cannabis Flower

D8197-18 Standard Specification for Maintaining Acceptable Water Activity (aw) Range (0.55 to 0.65) for Dry Cannabis Flower

D8219–19 Standard Practice for the Cleaning and Disinfection at a Cannabis Cultivation Center

D8233–19 Standard Guide for packaging and labeling of Cannabis resin-derived products for sale to adult consumers, authorized medical cannabis users and caregivers, in a business to consumer retail environment

D8245-19 Standard Guide for Disposal of Cannabis Raw Materials and Downstream Products Containing Resin

D8250-19 Standard Practice for Implementing and Managing Hazard Analyses Critical Control Points (HACCP) Systems for extracted and infused products within the Cannabis Industry

And More Progress

D8229-19 Standard Guide for Corrective Action and Preventive Action (CAPA) for the Cannabis Industry

D8282-19 Standard Practice for Laboratory Test Method Validation and Method Development

D8220-20 Standard Guide for Developing Recall/Removal Procedures for Products in the Cannabis Industry

D8308-20 Standard Practice for Cannabis Operation Compliance Audits

D8308-20 Standard Practice for Cannabis/Hemp Operation Compliance Audits

D8205-20 Standard Guide for Video Surveillance System

D8217-20 Standard Guide for Access Control System

D8218-20 Standard Guide for Intrusion Detection System (IDS)

D8270-20 Standard Terminology Relating to Cannabis

WORK ITEMS SOON TO BE STANDARDS

Standard Practice for the Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses

Standard Practice for Certification Requirements for Analytical Laboratory Professional Vocations Within the Cannabis Industry

Standard Practice for Stability Testing of Cannabis and Cannabis-Based Products

Standard Test Method for Analyses of Terpenoids in Cannabis Plant Materials using Head Space Gas Chromatography-Mass Spectrometry (HS-GC-MS)

Standard Practice for Application of Two Way Humidistatic Control to Meet ASTM Specification D8197 for Cannabis Flower Water Activity (Aw)

Standard Guide for Implementing Cybersecurity in a Cannabis Operation

Standard Specification for Food Safety and Quality of Industrial Hemp Seed

Standard Classification for Personal Cannabis Flower Growing Appliances

Work items….

Subcommittee D37.03 on Laboratory

WK60319 Standard Guide for Laboratory Test Method Validation and Method Development

WK60479 Standard Practice for Quality Assurance and Quality Control for Cannabis Analytical Methods and Laboratories

WK63913 Standard Practice for Analytical Laboratory Operations Supporting the Cannabis Industry

WK63913 * Analytical Laboratory Operations Supporting the Cannabis Industry;

WK64333 * Multiresidue Analysis of Pesticides in Cannabis Leaves and Oils using Gas Chromatography-Mass Spectroscopy (GC-MS) 1

WK64334 Multiresidue Analysis of Pesticides in Cannabis Leaves using Gas Chromatography-Tandem Mass Spectroscopy (GC-MS/MS)

WK64335 Multiresidue Analysis of Pesticides in Cannabis Leaves, Flowers, and Oil using HPLC-tandem mass spectroscopy (HPLC-MS/MS

WK64336 The Sampling of Cannabis Products for Subsequent Laboratory Analyses of Harvest Lots of Usable Marijuana in Support of Regulatory and Quality Control Elements

WK64646 The Sampling of Cannabis Products for Subsequent Laboratory Analyses of Marijuana Process lots including, extracts, concentrates, and products in Support of Laboratory Analyses for Regulatory and Quality Control Elements

WK65013 Determination of Cannabinoid Concentration in Cannabis Using High Performance Liquid Chromatography

Training and Certification

Programs in Development

Training program on the Importance of Water Activity in Cannabis

Training program for Corrective Action Preventative Action (CAPA)

Certification Program for Cannabis Products – Packaging and Labeling

Contact Information

Technical Committee Operations
Robert Morgan
Director, Technical Committee Operations
T: +1-610-832-9732
E:rmorgan@astm.org

www.astm.org

Global Offices:

Canada
Belgium
Peru
China

QUESTIONS?

Presenters: Kirsten Blake & Stephen Arpie

11:00 AM - 11:30 AM EDT

Kirsten Blake is Vice President of Emerald Scientific, a distributor of scientific supplies including reference materials, chemicals, reagents, laboratory and chromatography equipment exclusively for the cannabis scientific community. Kirsten holds a Master's Degree in Industrial and Technical Studies from Cal Poly, San Luis Obispo which drives her to look for improved production and work flow technologies. With over 30 years of sales and customer service experience, she builds lasting relationships with both customers and suppliers by providing exceptional personalized service while working with industry experts to create solutions to the cannabis industry's challenges. While managing the day-to-day operations of a growing company, Kirsten keeps up with the pulse of the cannabis industry's needs and advancements. In an effort to continue to support scientific growth and advancement, she nurtures strategic partnerships to deliver superior scientific solutions

Director General Absolute Standards - 27 years
M.S. Analytical Chemistry

The Evolution of Proficiency Testing in the Cannabis Analytical Industry

PRESENTED BY

STEPHEN ARPIE, MS DIRECTOR GENERAL. ABSOLUTE STANDARDS

KIRSTEN BLAKE, VICE PRESIDENT, EMERALD SCIENTIFIC

What is a Proficiency Test?

Any activity undertaken by a laboratory to provide evidence that they are “proficient” to perform measurements.

ISO/IEC 17043:2010, proficiency testing (PT) is the evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons.

Why Are PT's Important?

- To verify that laboratory's analytical procedures are effective and accurate
- Confirm Methods
- Identify Areas For Improvement
- Evaluate Trends
- Grade Individual Analysts Capacities

Cannabis Analytics-

The Early Landscape- Pre 2013

- Minimal industry regulations
- No PT's required at state or federal level
- Few labs seeking ISO 17025 accreditation

Absolute Standards provided

CRM's in solutions of ACN for potency compounds & PT's to a small group of labs in MA, CA, and a few others that were interested in ISO 17025

The Early Landscape- continued

Industry Challenges-

- Prejudice
- Bad Actors
- Lack of scientific support and community
- Estimated < 25 testing labs

Emerald Scientific Founded- 2013

by Ken Snoke, Wes Burk and Cliff Beneventi

Goal: Support the growth and legitimization of new and struggling scientific industry.

- Scientific Supply Distribution
- ILC-PT Program
- Scientific Conference

Genesis of The Emerald Test™

- Beer
- Program idea developed
- Research potential suppliers
- Relationship with Absolute Standards initiated

The Emerald Test™ The Hurdles

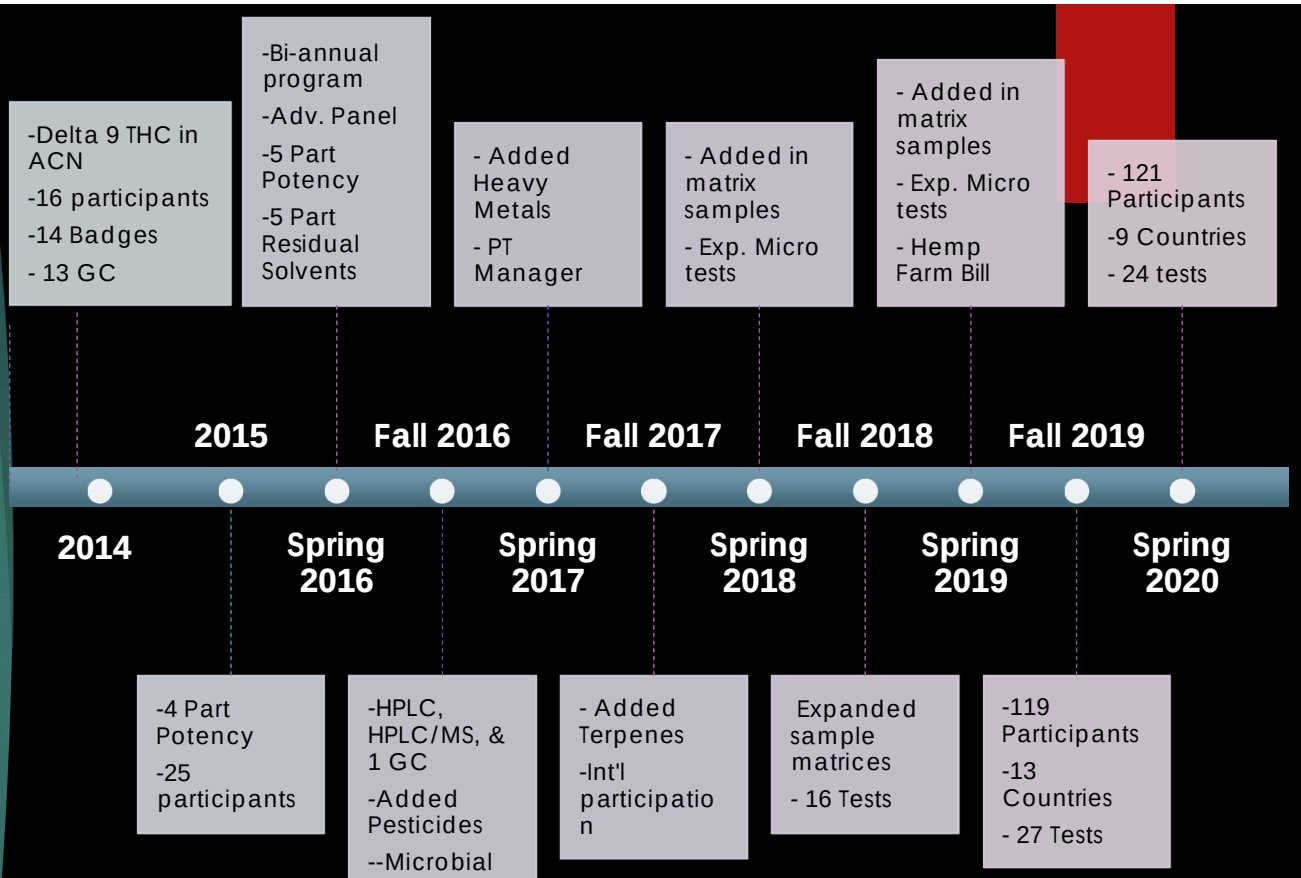
Legal Challenges-

- DEA licensed manufacturing
  - Absolute Standards, 30 years CRM and PT producer with ISO, DEA credentials and ability to expand.
- Nationwide distribution
  - DEA exempt solutions <1000ppm

Sales Challenges-

- Only a few labs interested
- Telemarketing
- Marketing
  - The Emerald Badge™

Broad Historical Overview



Why Is it Important for the Cannabis Industry?

CONSUMER SAFETY!!

MINIMIZE PRODUCT LIABILITY

PT'S ARE STANDARD PRACTICE IN FOOD, PHARMACEUTICALS, PETROCHEMICAL, ETC.

BUILD CONSUMER CONFIDENCE IN LABS AND THEIR WORK PRODUCT

PROVIDE DATA FOR BETTER REGULATION

IMPROVE LAB PERFORMANCE

Who Should Participate?

Any Lab seeking ISO 17025 accreditation

Labs required by state specific regulations

In-House quality control labs

R & D labs

Equipment providers

How the Data is Used

- Overall data benefits the industry
- Analyzed for individual performance
- Evaluated by accreditation and compliance officers
- Used to identify industry trends
- Make correlations about methods and materials
- Aid in the development of methods
- Leverage results to improve public perceptions

Trends

- Cannabis PT programs are gaining broader recognition
- Overall increased enrollment
- Increase participation from research and production QC labs as well as equipment manufacturers
- Improved performance each round
- Increased difficulty of tests
- Increased use of practice PT's in day-to-day operations
- Developing new relevant tests for the industry
- Expanding international markets
- Federal enforcement yielding to culture and state authorities

Challenges

- Cannabinoid tests must meet qualifications for DEA exempt material
- Inability to ship samples above solid matrix samples above .3% THC across state lines
- Variability across state regulations
- Lack of historical data to determine passing criteria

References

- International Standard, ISO/IEC 17025- 3rd Edition 2017-11
- ASTM E691, Standard Practice for Conducting an Interlibrary Study to Determine the Precision of a Test Method
- NIST/SEMATEK (2008), *Handbook of Statistical Methods*
- NELAC-institute.org

ABSOLUTE STANDARDS

EMERALD SCIENTIFIC

QUESTIONS?

Qualtrax®
COMPLIANCE SOFTWARE

Presenter: Karen Arrivillaga
11:30 AM - 12:00 PM EDT

Karen has been with Qualtrax since 2015 with a focus in the laboratory space and is passionate about finding the best ways to use software to manage accreditation, simplify compliance, and inspire a culture of quality. She's a proud member of the Qualtrax internal audit team, and helped transition to ISO/IEC 9001:2015. Over the last 3 years, her focused has shifted to the Cannabis and Hemp industry where she continues to learn and share how Qualtrax can help manage ISO/IEC 17025 and GMP initiatives.

PJLA

Presenter: **Tracy Szerszen**
12:00 PM - 12:30 PM EDT

Tracy Szerszen has been the President and Operations Manager of PJLA, a private, third- party accreditation body located in Troy, Michigan, for 12 years. She is the managing director for PJLA HQ in the US, as well as the branch offices located in Japan, Mexico, Italy and the United Kingdom. Prior to this appointment, she served as the Audit Logistics Manager for PJLA's related body Perry Johnson Registrars. In support of her vast knowledge of quality management system and accreditation regulations, she serves on several international association's committees and boards, such as ILAC, APAC, The NELAC Institute, AOAC, and the American Council of Independent Laboratories (ACIL). Tracy has over 18 years of experience in quality management system and accreditation criteria. She holds a General Science and Business Administration degree as well as several ISO 9000 and ISO 17025 series training certifications.

ISO/IEC 17025

The Benefits of Accreditation

Presenter: Tracy Szerszen, President

PJLA

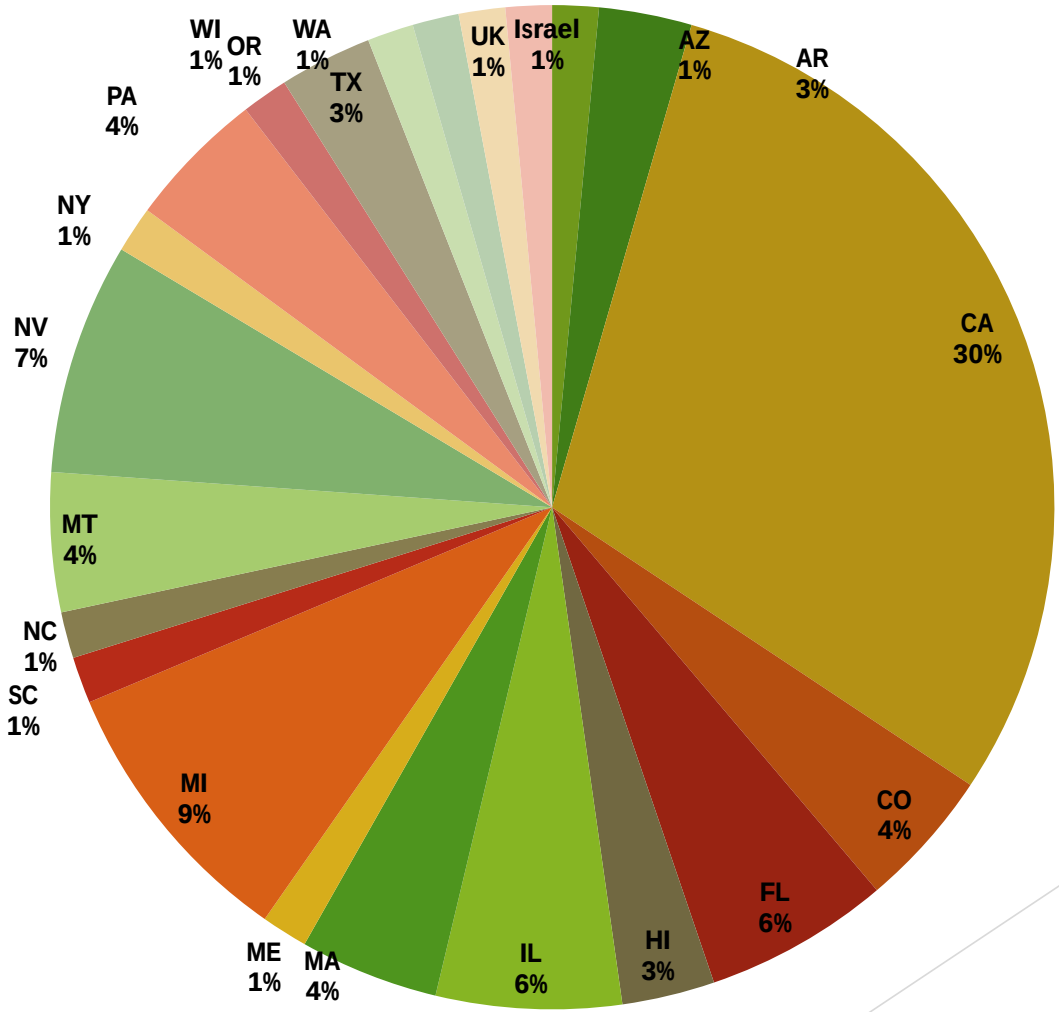
Presentation Overview

- About Accreditation
- The Expectations of Labs
- Benefits of Labs and Users of Labs
- Questions/Answers

PJLA-A Global Accreditation Body

- Headquartered in the United States
- Offers Accreditation Services Globally
  - Mexico
  - Japan
  - Italy
  - United Kingdom
  - Middle East
- ILAC MRA Signatory-Testing, Calibration, Inspection, Reference Material, Medical
- 1500 Accredited Facilities

80 Accredited Hemp/Cannabis Labs



Top States
-CA (20)
-MI (6)
-NV (5)
-FL (4)
-IL (4)
-CO, MT ,MA,PA (3)

PJLA

ilac-MRA

PJLA Credentials and Recognitions

- PJLA, along with over 100 other accreditation bodies across the world holds international recognition through ILAC.
- ILAC-The International Laboratory Accreditation Cooperation
  - Recognizes Accreditation Bodies for multiple ISO standards: ISO/IEC 17025-Testing/Calibration, ISO/IEC 17020:2012-Inspection Bodies, ISO/IEC 15189:2012-Medical Labs, ISO/IEC 17043:2010-Proficency Testing Provider
  - ILAC along with their regional bodies (i.e. APAC, EA, IAAC evaluates accreditation bodies to ISO/IEC 17011: 2017 - *Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies*

Definitions

Accreditation –third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

Conformity Assessment Body-body that performs conformity assessment activities and that can be the object of accreditation (**labs, inspection bodies, proficiency testing providers, reference material provider**)

Accreditation Body-authoritative body that performs accreditation **(i.e. PJLA)**

ISO/IEC 17025-General requirements for the competence of testing and calibration laboratories

ISO/IEC 17025 Overview

PJLA

- 17025 Comprises of 5 Sections that laboratories are required to fulfill
  - Section 4- Impartiality, Confidentiality
  - Section 5-Structural Requirements
  - Section 6-Resource Requirements
  - Section 7-Process Requirements
  - Section 8-Quality Management System Requirements

Section 4- Impartiality

MUST BE STRUCTURED TO MANAGE AND SAFEGUARD IMPARTIALITY AND AVOID COMMERCIAL, FINANCIAL OR OTHER PRESSURES TO INFLUENCE THEIR DECISIONS AND COMPROMISE IMPARTIALITY

RELATIONSHIPS-OWNERSHIP, FAMILY BUSINESSES, FINANCIAL INTERESTS

INTERNAL LABS-PRESSURE FROM MANUFACTURING SIDE

FINANCIAL, COMMERCIAL PRESSURES-COMMISSIONS, PAY OFFS, DRY LABBING

KNOW YOUR LABORATORY, LOOK FOR UNETHICAL SIGNS OR PRACTICES

Section 4- Confidentiality

Requires laboratories to protect customer information

-Agreements with the customer

-Communication with the customer

-Internal Requirements-Employees, third party accreditation bodies, contractors, competitors

Look for this information in service agreements, ask how they protect your information

Section 5- Structural Requirements

Requires laboratories to be a legally responsible entity

-Responsible for the results, service to customer by agreement

Requires the laboratory to have a defined structure

-Management System

-Performance and Approver of test results

-Define Responsibilities, Organizational Relationships (Top Management-Down, Relationships with other organizations (i.e. larger groups, networks)

Ask for Federal Tax ID, General Info about organization, Know who will be working on your tests

Section 6- Resource Requirements

Requires laboratories to have the resources to perform adequate testing

Personnel	Equipment	Environmental Conditions	Reference Material and Standards	Traceability	Appropriate External Providers

Ask for a tour of the lab, review the equipment, example test reports, data storage, understand general process

Section 7- Process Requirements

- **Requires laboratories to ensure that they evaluate requests before performing them, have appropriate tests methods, quality control checks (.i.e. Proficiency testing), methods for determining uncertainty, handling of test equipment, storage, sampling and reporting results, data control and how they handle dissatisfied customers-complaints, nonconforming work.**
  - **7.1 Review of requests, tenders and contracts**
  - **7.2 Selection, verification and validation of methods**
  - **7.3 Sampling**
  - **7.4 Handling of test or calibration items**
  - **7.5 Technical records**
  - **7.6 Evaluation of measurement uncertainty**
  - **7.7 Ensuring the validity of results**
  - **7.8 Reporting of results**
  - **7.9 Complaints**
  - **7.10 Nonconforming work**
  - **7.11 Control of data and information management**

Ensure you clearly communicate with your lab the expectations, understand what they are providing you, if you don't get what you need let them know, know where your information is going

Section 7- Reporting

Requires that accredited labs report the following:

- a) a title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”);
- b) the name and address of the laboratory;
- c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities;
- d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
- e) the name and contact information of the customer;
- f) identification of the method used;
- g) a description, unambiguous identification, and, when necessary, the condition of the item;
- h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;
- i) the date(s) of performance of the laboratory activity;
- j) the date of issue of the report;
- k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;
- l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;
- m) the results with, where appropriate, the units of measurement;
- n) additions to, deviations, or exclusions from the method;
- o) identification of the person(s) authorizing the report;
- p) clear identification when results are from external providers.

Section 7- Reporting

- Specific requirements for test reports

a) information on specific test conditions, such as environmental conditions;

b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:

— it is relevant to the validity or application of the test results;

— a customer's instruction so requires, or

— the measurement uncertainty affects conformity to a specification limit;

d) where appropriate, opinions and interpretations

e) additional information additional information that may be required by specific methods, authorities, customers or groups of customers.

Look for these items. Labs should have these on tests reports unless there is a valid reason for not doing so! Users of labs need to be educated and also be responsible for this evaluation. It can’t all be on the lab.

Section 8- Quality Management System

- Requires laboratories to have a quality management system in place.
- 8.2 Management system documentation
- 8.3 Control of management system documents
- 8.4 Control of records

(ensure that documents are available to demonstrate compliance with 17025, all personnel is trained on related requirements of the standard, records of compliance are available and legible, documents are controlled, names, revisions, dates etc.)

- 8.5 Actions to address risks and opportunities (evaluates risks as required in the standard)
- 8.6 Improvement (identifies items that are not yet nonconforming and put preventives in place to improve efficiency
- 8.7 Corrective actions (has a process to take corrective action for certain issues identified in the lab, response timelines, effectiveness reviews
- 8.8 Internal audits-performs internal audits, takes corrective action
- 8.9 Management reviews-review entire organization, objectives, goals, risks, documents, NCR trends, complaints, overall needs and document outputs (i.e. action items, to do's etc.

Ensure you are receiving corrective actions, ask for it if you have a complaint, contact the accreditation body if you need assistance with a lab, we have to investigate!)

Steps to Accreditation

APPLY FOR ACCREDITATION

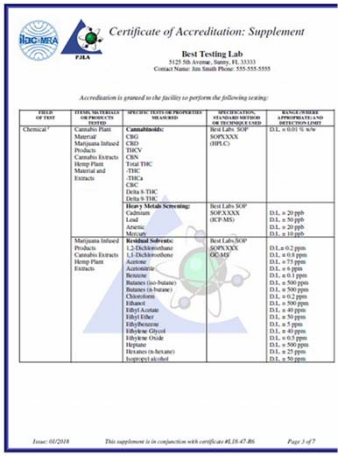
PRE-DOCUMENTATION REVIEW

ON-SITE ASSESSMENT

A FINAL REPORT AND CORRECTIVE ACTION PERIOD

INDEPENDENT FINAL DECISION PROCESS

2 YEAR CERTIFICATE IS GRANTED



Certificate of Accreditation: Supplement

Best Testing Lab
5125 5th Avenue, Sunny, FL 33333
Contact Name: Jim Smith Phone: 555-555-5555

Accreditation is granted to the facility to perform the following testing:

FIELD OF TEST	ITEM/MATERIAL OR PRODUCT TO BE TESTED	SPECIFIC TEST OR PROPERTY MEASURED	SPECIFICATION, STANDARD METHOD AND/OR TECHNIQUE USED	RANGE UNDER ACCREDITATION AND/OR DETECTION LIMIT
Chemical *	Cannabis Plant Material Marijuana Infused Products Cannabis Extracts Hemp Plant Material and Extracts	**Cannabinoids:** CBG CBD THCV CBN Total THC -THC -THCa CBC Delta 8-THC Delta 9-THC	Best Labs SOP SOPXXX (HPLC)	D.L. = 0.01 % W/W
		Heavy Metals Screening: Cadmium Lead Arsenic Mercury	Best Labs SOP SOPXXXX (ICP-MS)	D.L. = 20 ppb D.L. = 50 ppb D.L. = 20 ppb D.L. = 10 ppb
	Marijuana Infused Products Cannabis Extracts Hemp Plant Extracts	**Residual Solvents:** 1,2-Dichloroethane 1,1-Dichloroethene Acetone Acetonitrile Benzene Butanes (iso-butane) Butanes (n-butane) Chloroform Ethanol Ethyl Acetate Ethyl Ether Ethylbenzene Ethylene Glycol Ethylene Oxide Heptane Hexanes (n-hexane) Isopropyl alcohol	Best Labs SOP SOPXXX GC-MS	D.L. = 0.2 ppm D.L. = 0.8 ppm D.L. = 75 ppm D.L. = 6 ppm D.L. = 0.1 ppm D.L. = 500 ppm D.L. = 500 ppm D.L. = 0.2 ppm D.L. = 500 ppm D.L. = 40 ppm D.L. = 50 ppm D.L. = 5 ppm D.L. = 40 ppm D.L. = 0.5 ppm D.L. = 500 ppm D.L. = 25 ppm D.L. = 50 ppm

Issue: 01/2018 *This supplement is in conjunction with certificate #L18-47-B6* *Page 3 of 7*

PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:

Best Testing Lab
5125 5th Avenue, Sunny, FL 33333

(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:

ISO/IEC 17025:2017

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO/ILAC/IAF Communiqué dated April 2017):

Chemical, Microbiological and Non-Destructive Testing
(As detailed in the supplement)

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

	Initial Accreditation Date:	Issue Date:	Expiration Date:
Tracy Szerszen President/Operations Manager	January 25, 2018	January 25, 2018	May 31, 2020
Perry Johnson Laboratory Accreditation, Inc. (PJLA) 755 W. Big Beaver, Suite 1325 Troy, Michigan 48084	Revision Date:	Accreditation No.:	Certificate No.:
	March 23, 2020	72045	L18-00

The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: www.pjlabs.com

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Example Scope of Accreditation

- Look for the standard ISO/IEC 17025:2017
- Look for the Issue and Expiration Date
- Is the accreditation body ILAC approved
- Review the supplement behind the main certificate (tests and capabilities)
- Check the ABs website to verify

Benefit for Labs

- A Recognition of Testing Competence
- A Benchmark for Performance
- A Marketing Advantage
- International Recognition for Your Laboratory
- Reduce Risk and Cost

Benefits for the Industry (Users of Labs)

- Minimize Risk
- Avoid Expensive Re-testing
- Enhance Your Customers' Confidence
- Reduce Costs and Improve Acceptance of Goods Overseas
- Government Assurance and Confidence of Safe Products

Summary

- 17025 Enforces
  - Company structure
  - Policies
  - Employee training
  - Customer Service
  - Good Laboratory Practices
- By becoming accredited it reduces costs to labs and their customers and provides the industry assurance that products are safe!

Contact Information

Perry Johnson Laboratory Accreditation, Inc.

755 West Big Beaver Road, Suite 1325

Troy, MI 48084

Tel: (248)-519-2603

Website: www.pjlabs.com

PJLA

QUESTIONS?