# ACCREDITATION AND PROFICIENCY TESTING IN CANNABIS TESTING LABORATORIES - TIME FOR A UNIFIED APPROACH?

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AFDOSS 2024 Conference

*In Food & Agriculture, We Set the Standard*

# AGENDA

- Current situation
- Common requirements
- ISO 17025 requirements
- Commonly misunderstood requirements
- Difficulties with ISO requirements
- ALACC

# CURRENT SITUATION

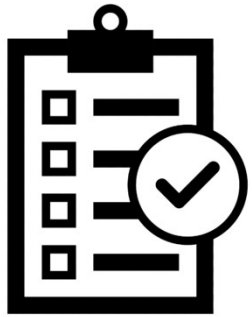

From MJBizDaily.com

- Still illegal federally
- Materials very limited in shipping
- Legalized to some degree in 40 states plus DC
- Recreational in 24 states plus DC
- Each jurisdiction has unique rules
- Includes unique testing rules

# COMMON REQUIREMENTS

- Method validation for all methods
  - *Aside: Cannot validate a method without the matrix but cannot legally receive the matrix until method validated…(more to come on this!)*
- ISO 17025 accreditation for laboratories

- Testing
  - Cannabinoids
  - Terpenes
  - Solvents
  - Pesticides
  - Heavy metals
  - Microorganisms
  - Mycotoxins
  - Moisture/Aw
  - Foreign materials



# ISO 17025 REQUIREMENTS

4. General Requirements
5. Structural Requirements
6. Resource Requirements
7. Process Requirements
8. Management System Requirements

- Commonly misunderstood
  - 6.2 Personnel
  - 7.7 Validity of Results
  - 7.10/8.7 Nonconformances/CA
  - 8.8 Internal Audits
  - 8.9 Management Review

# 6.2 PERSONNEL

- 6.2.2 "...shall document the competence requirements..."
- 6.2.3 "...shall ensure that the personnel have the competence..."
- 6.2.5 Procedure and records:
  - Competence requirements
  - Selection
  - Training
  - Supervision
  - Authorization
  - Monitoring competence

# 7.7 VALIDITY OF RESULTS

- 7.7.1 “shall have a procedure for monitoring the validity of results.”
- “…data shall be recorded in such a way that trends are detectable, and where practicable, statistical techniques shall be applied to review the results.”

# 7.7 VALIDITY OF RESULTS

- **Includes:**
  - Use of RM or QC materials
  - Use of alternative instrumentation
  - Functional checks
  - Use of check or working standards with control charts
  - Intermediate checks on equipment
  - Replicate tests by different methods
  - Retesting of retained items
  - Correlation of results for different characteristics of an item
  - Review of reported results
  - Intralaboratory comparisons
  - Testing blind samples

# 7.7 VALIDITY OF RESULTS

- Proficiency testing
- Other interlaboratory comparisons

# 7.10/8.7 NONCONFORMANCES & CA

- NC Procedure
  - Responsibilities & authorities
  - Actions (halting, holding reports) based on RISK
  - Evaluation of significance
  - Decision on acceptability
  - Customer notification (recall work?)
  - Responsibility for resuming work
- When NC occurs:
  - Take action
  - Evaluate need to eliminate cause
  - Implement actions needed
  - Review effectiveness
  - Update risks/opportunities
  - Make changes to management system if necessary

# 8.8 INTERNAL AUDITS

- Laboratory plans the intervals
- Audits may be small in scope or larger
- Effectively implemented and maintained
- CA without delay

# INTERNAL AUDIT COMMON MISTAKES

Cursory overview – checking “yes” to everything

No depth of records – no comments, records of what was reviewed

Not giving it the time it needs

Remember internal audits should be the more in-depth audit…not external audits

# 8.9 MANAGEMENT REVIEW

- Laboratory plans the intervals (usually annual)
- Laboratory defines the format
- 15 required topics
- As long as you can tell all required pieces were discussed it is acceptable

# MANAGEMENT REVIEW MISTAKES

- No covering all required pieces
- Not recording outcome or action items
- Not taking the appropriate amount of time
- Not going the appropriate depth – glossing over things
- Going to deep in details – caught in the weeds
- Not taking advantage of the unique opportunity this offers

# DIFFICULT REQUIREMENTS – ISO 17025

- 6.3 Facilities and Environmental Conditions
- 7.2 Selection, Verification, and Validation of Methods
- 7.3 Sampling
- 7.4 Handling of Test Items
- 7.6 Evaluation of Measurement Uncertainty
- 7.7 Ensuring the Validity of Results
- 7.11 Control of Data and Information Management
- 8.5 Actions to Address Risks and Opportunities

# 7.2 SELECTION, VERIFICATION, AND VALIDATION OF METHODS

- Matrix concerns
  - Cannabis
  - Hemp
  - Edibles
  - Etc.
- Homogeneity of the matrix
- Ability to validate prior to accreditation
  - Validation for scope methods required for assessment
  - Some states do not allow matrix onsite until accredited
  - Can't validate without the matrix
  - Alternate matrices?

# MICROBIOLOGY METHOD VALIDATION GUIDELINES HISTORY

- aka OMA, Appendix J
- Current version approved 2011
- Aligned with FDA requirements at the time
- Prior documents published as journal articles
- Current ISO 16140 references it

Appendix J AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces

https://doi.org/10.1093/9780197610145.005.010 Pages AJ-1–AJ-21
**Published:** January 2023

**Collection:** Official Methods of Analysis of AOAC INTERNATIONAL

## Appendix J

### 1 Scope

The purpose of this document is to provide comprehensive AOAC INTERNATIONAL (AOAC) technical guidelines for conducting microbiological validation studies of food and environmental analysis methods submitted for AOAC® *Official Methods of Analysis* SM (OMA) status and/or *Performance Tested Methods* SM (PTM) certification.

# WHY UPDATE?

- Global alignment on matrix categorization, sample sizes, etc.
- Alignment on inclusivity and exclusivity
- Does not address certain topics related to:
  - Identification
  - Confirmation
  - Some quantitative/semi-quantitative approaches
  - No information related to parasite and viruses
  - Updates needed for statistical models

# 7.3 SAMPLING

- Who is responsible?
- Sample size
  - Most methods validated with a 10g sample size
  - Most labs test 1g sample sizes
- Sample homogeneity

# 7.6 EVALUATION OF MEASUREMENT UNCERTAINTY

- Sampling
- Matrix
- Sample size
- Homogeneity
- Method validation

# 7.7 ENSURING THE VALIDITY OF RESULTS

- Some regulations are prescriptive of what tests must be run
- Otherwise, it is left to the lab to decide based on risk
- Control charts
- Handling failures
  - Evaluate situation following NC SOP
  - Consider risks
  - Perform CA as appropriate
  - Determine disposition of results
- Proficiency Testing

# WHAT SETS AOAC PT APART

- In addition to Hemp, AOAC can ship >0.3% (low, med, and high) Δ-9-THC Cannabis
- AOAC samples arrive homogeneous and ready to analyze, no spiking required
- Use of reference labs for statistics (most competitors use consensus)
- Scientific Association with access to many SMEs
- Developed through CASP based on feedback from over 500 stakeholders
- Less expensive than top competitors

# PROBLEM SOLVING

- Labs must spike their own samples
  - Creates opportunity for errors
- Cannabis labs must analyze Hemp
- Pesticide analyses much different for cannabis v hemp
- Microbial contaminants programs needed in actual matrices.
- Program needed that can compare performance between states and internationally

- Ready to analyze, like routine, samples
  - Reduces opportunity for error
- > 0.3% Δ-9-THC Cannabis Programs offered
- Program for Pesticides in Cannabis & Hemp
- Microbial Contaminants Programs offered
- AOAC program can be shipped across state lines and internationally

# AOAC CHEM CONSTITUENTS & CONTAMINANTS PT

| PT Round | Analytes | Matrices | Shipping Date |
|---|---|---|---|
| **Chemical Constituents & Contaminants**   | • Cannabinoids (18)<br>• Terpenes (33)<br>• Water Activity<br>• Moisture<br>• Heavy Metals (12)<br>• Pesticide Residues (104)*<br>• Mycotoxins (5)* | **Dried Flower/Biomass**<br><0.3% THC Hemp<br>&<br>>0.3% THC Cannabis | Live Round<br>9/23/2024 |
| **Chemical Constituents & Contaminants**<br><br>**In Process for Accreditation** | • Cannabinoids (18)<br>• Terpenes (33)<br>• Water Activity<br>• Heavy Metals (12)<br>• Pesticide Residues (104)<br>• Mycotoxins (5)<br>• Residual Solvents | **Oil**<br><0.3% THC<br>&<br>>0.3% THC | Live Round Q4 |
| **Chemical Constituents & Contaminants**<br><br>**In Development** | • Cannabinoids (18)<br>• Terpenes (33)<br>• Moisture<br>• Water Activity<br>• Heavy Metals (12)<br>• Pesticide Residues (104)<br>• Mycotoxins (5)<br>• Residual Solvents | **Edibles/Gummies**<br><0.3% THC<br>&<br>>0.3% THC | Pilot Q4 |

# AOAC MICROBIAL CONTAMINANTS PT

| PT Round | Analytes | Matrices | Shipping Date |
|---|---|---|---|
| **Microbial Contaminants**<br><br>**In Process for Accreditation** | **QUALITATIVE**<br>• **Aspergillus**<br>• **E. coli (STEC)**<br>• **Salmonella**<br>• **S. aureus**<br><br>**QUANTITATIVE**<br>• APC/TAC<br>• Coliforms<br>• E. coli (generic)<br>• BTGN<br>• Y&M | Dried Flower/Biomass<br><0.3% THC Hemp | Pilot Q4 |

- **AOAC is the only Accredited PT provider able to ship > 03% THC Cannabis across state lines**
- **Quality Assurance & Educational Samples (QAES) Now Available (Dries Flower/Biomass & Oils)**
- **NOW OFFERS ENTIRE SUITE OF PRODUCTS – ONE STOP SHOP**

# 7.11 CONTROL OF DATA AND INFORMATION MANAGEMENT

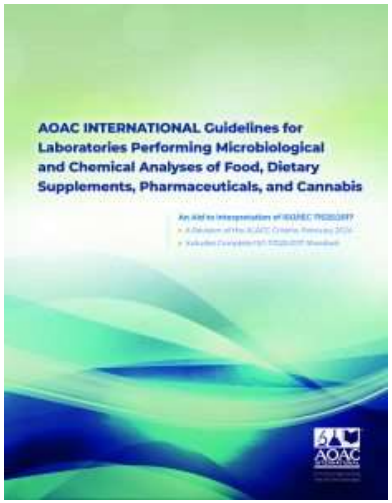
- State reporting
- Confidentiality of data
- Record retention

# 8.5 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

- ISO standard is centered around risk mitigation
- Cannabis requirements tend to remove risk evaluation need
- Requirements
  - Policy
  - Procedure
  - Records

# ALACC

- AOAC INTERNATIONAL
  - Technical Division for Laboratory Management (TDLM)
    - Analytical Laboratory Accreditation Criteria Committee (ALACC)
      - *AOAC INTERNATIONAL Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, Pharmaceuticals, and Cannabis* -2024
- **Purpose: take generic standard and make it better apply to areas defined in scope**
- **First edition with cannabis**



# ALACC APPENDICES

- Allows for very specific detail for subject area
  - Appendix A: Equipment
  - Appendix B: Microbiology (food)
  - Appendix C: Chemistry (food)
  - Appendix D: Pharmaceutical Analysis
  - Appendix E: Dietary Supplement Laboratories
  - Appendix F: Cannabis

# APPENDIX F

- During revision, cannabis subcommittee had suggestions we changed for all
- Some were not appropriate for all – those are in Appendix F
- Appendix F is by far the longest appendix
  - Many requirements are specific regulations
  - Little room for risk evaluation of lab-specific interpretation

# APPENDIX F REQUIREMENTS

- Employees
  - Federally prohibited substance
  - Impartiality
- Facilities
  - Monitoring procedure
  - Security, video surveillance
- Quality Assurance Manual
- Handling of CRMs

# APPENDIX F REQUIREMENTS (CON'T)

- **Sample receipt**
  - COC
  - Acceptance criteria
  - Outsourcing
- **Field sampling**
- **Method development & method validation**
  - Validation on 1 matrix does not mean valid on another
  - Required components for validation
  - Matrix effects
  - Minimum threshold for microbiology methods

# APPENDIX F REQUIREMENTS (CON'T)

- Quality Control
  - QC run through entire analytical process
  - Spiking at initial stage of sample preparation
  - Batch includes matrix blank
  - CCV ever 10 samples
  - LCS in every batch
  - Microbiology specific requirements for spikes
- Procedure required for measurement uncertainty
- QC required on final reports

# APPENDIX F REQUIREMENTS (CON'T)

- **Internal Audits**
  - Must be performed annually
  - All scope methods must be audited every two years
- **Management Review**
  - Must be performed annually

# TIME FOR A UNIFIED APPROACH?


- So many states…
  - Certainly, some common ground
  - Some state-to-state variability
  - Mitigated by illegality at a federal level
  - Will cause confusion if/when legal federally
- ALACC written as a way to even the playing field for all
  - Sort of Greatest Hits of all the states

# Scientific Initiatives - Programs

- ❑ **Stakeholder Program on Infant Formula and Adult Nutritionals**
- ❑ **Stakeholder Program on Agent Detection Assays**
- ❑ **Gluten & Food Allergens**
- ❑ **Analytical International Methods & Standards Program**
- ❑ **Botanical Ingredients & Dietary Supplements Integrity**
- ❑ **Cannabis Analytical Science Program**
- ❑ **Novel Foods from Alternative Protein Sources**

# Scientific Initiatives - Programs Focus

- **Milk fat globule membrane (MFGM) proteins**
- **Metagenomics**
- **G&FA validation guidelines and end-user guidance**
- **Cyclospora, Legionella, validation guidance revision & updates**
- **Botanical identity verification, mushroom authenticity**
- **Cannabis micro validation guidelines, pesticide methods**
- **Novel Foods: Total amino acid analysis**

# Scientific Initiatives - Projects


- ❑ **PFAS in food**
- ❑ **Trace elemental contaminants**
- ❑ **Pesticides in natural color additives**
- ❑ **Residual solvents in natural color additives**


- ❑ **Ethylene oxide residues**
- ❑ **PFAS in food packaging and other FCMs**
- ❑ **Additional trace elements**
- ❑ **Whey protein hydrolysates**

**Collaboration with AOAC Sections**

- ❑ **Pesticides in herbs & spices (AOAC Southeast Asia Section)**
- ❑ **Cyanide in cassava (AOAC Southeast Asia Section)**
- ❑ **Bioassays in food testing (AOAC Europe Section)**
- ❑ **Non-targeted analysis (AOAC Europe Section)**

# Scientific Initiatives

| | Nutrients | Contaminants | Microbiology | Allergens/Gluten | Authenticity |
|---|---|---|---|---|---|
| In progress | SPIFAN | ▪ PFAS in foods<br>▪ PAs<br>▪ ETO<br>▪ Trace elements<br>BIDSI<br>casp<br>▪ Pesticides | AIMS<br>▪ Cyclospora<br>▪ Legionella<br>casp<br>▪ Listeria in edibles | G&FA<br>▪ Validation guidelines for gluten and food allergens | BIDSI<br>▪ Botanical identity verification |
| Launching | ▪ Novel Foods: Amino acids<br>▪ Whey protein hydrolysates | ▪ PFAS in packaging and other food contact materials | SPADA<br>▪ Metagenomics | G&FA<br>▪ End-user guidance (method verification, data interpretation etc.) | |
| Developing Or Ideas | ▪ Vitamins in food and dietary supplements<br>▪ Dietary carbohydrates | ▪ Pesticides in herbs & spices<br>▪ Mineral oil<br>▪ Bisphenol A<br>▪ Plasticizers<br>▪ Bioassays | ▪ Micro method validation guidelines<br>▪ Biostimulants<br>▪ Probiotics (contaminants) | G&FA<br>▪ Food allergens validation guidance (beyond ELISA) | ▪ Mushroom authenticity<br>▪ Illicit drugs in tablets/powders<br>▪ Organic produce authenticity |

# Thank you!

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