

# TNI Board of Directors Meeting Summary

## April 12, 2017

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### 1. Roll Call

Directors	Present
Jordan Adelson	X
Aaren Alger	X
Steve Arms	X
Justin Brown	X
Jack Farrell	
Chris Gunning	X
Myron Gunsalus	X
Daniel Lashbrook	X
Judy Morgan	X
Cheryl Nolan	X
Lara Phelps	X
Patsy Root	X
Debbie Rosano	
Scott Siders	
Alfredo Sotomayor	X
Dave Speis	X
Past President	
Sharon Mertens	X
Staff	
Lynn Bradley	X
Carol Batterton	X
Ken Jackson	X
Jerry Parr	X
Ilona Taunton	X
Janice Wlodarski	X

### 2. Approval of March 2017 Minutes

**Motion to Approve Minutes:** Judy Morgan  
**Second:** Daniel Lashbrook  
**Approved:** Unanimous

### 3. 2016 Annual Report

This issue is tabled until May to get feedback from the committee chairs.

### 4. 2017 Budget

The preliminary budget has been approved by the Finance Committee and was provided as a separate document. The Finance Committee also wants to consider moving the fiscal year to a later date so that the budget can be prepared after the annual financial report. The Executive Director will discuss this with the TNI accounting firm after April 15.

Dave Spies discussed the budget (provided as a separate document with restricted distribution) and noted that revenue from training is expected to exceed the amount budgeted, but since this will be the first year of expanded training activities, it seemed best to utilize a conservative estimate.

A question arose about the budgeted amount for the NELAP evaluations being too low for this year. Jerry explained that the overall costs are pro-rated across the three-year evaluation cycle, and the final year costs are much less, so that it balances out. Evaluation costs for the PTPEC and NEFAP programs are similarly spread across more than the single year in which those reviews occur.

**Motion to Approve the 2017 Budget:** Steve Arms

**Second:** Judy Morgan

**Approved:** Unanimous

## 5. Revision of Bylaws

The revisions to the TNI Bylaws were offered at the March 8 meeting, and have now been available for review, for the required 28 days. The draft is included with the March 8th minutes.

**Motion to Approve:** Steve Arms

**Second:** Dave Spies

**Approved:** Unanimous

## 6. Accreditation of Mobile Laboratories (Attachment 1)

The Mobile Lab Subcommittee of NEFAP Executive Committee provided a draft Charter for a Mobile Laboratory Task Force. The draft Charter document also includes some examples of the issues requiring resolution by this Task Force, but those will not be part of the formally-approved Charter document.

Membership of the Task Force was not determined, pending approval of the Charter. The individuals selected will be named in the Task Force's Work Plan, but all agreed that membership should include one or more representatives from the mobile laboratory community as well as representatives of NELAP Accreditation Bodies having different approaches to mobile lab accreditation.

Discussion points included:

- the possible need for a separate standard or new material to be included in Volume 2 addressing mobile labs,
- a strong recommendation that mobile labs continue to be required to meet the same stringency of requirements as NELAP and NEFAP, so that the data from mobile labs will be of the same known and documented quality as that of fixed base labs now, and
- that the Task Force consider developing guidance materials for mobile laboratories, depending on the decisions made and processes implemented.

**Motion to Approve Mobile Laboratory Task Force Charter:** Judy Morgan

**Second:** Myron Gunsalus

**Approved:** Unanimous

*Next Steps:*

Justin Brown and Ilona Taunton will begin recruiting Task Force members, while coordinating with Jerry. A decision should be made soon about whether the Task Force should have a public session at conference in Washington, DC this summer.

## 7. SOPs for Review

Two SOPs were provided for Board consideration and endorsement. No participants requested discussion of, or expressed objection to, these items. Both are thus considered approved by the Board without further action.

- SOP 1-117, Continuing Education Units (CEUs) was developed by the TNI Training Coordinator (Ilona Taunton) in conjunction with the Executive Director. It has been reviewed and approved by the Policy Committee. This SOP describes the process by how TNI awards CEUs for training events, and
- SOP 3-102, Evaluation of ABs, was approved by the Board in June 2016. This new version only has minor changes, correcting typos in the headers in some of the appendices and replacing the Conflict of Interest form in Appendix A with a "Participation Form."

## 8. Board of Directors Work Plan

An updated work plan was provided. No discussion was needed or requested. Rather, this is a tool that will be used to keep track of the Board's activities and will be provided as part of the Executive Director's routine communications with the Board.

## 9. Program Reports (Attachment 2)

Additional information provided by Ken Jackson, about the Expert Committees for which he is Program Administrator, has been added to that attachment in italicized font, since Ken was unable to provide a program report for the month.

## 10. Cannabis Issues (Attachment 3)

This topic was delayed until the end of the meeting to allow our Federal Directors to recuse themselves.

At the March meeting, the Board requested the Executive Director assemble a small group of individuals to look at this issue and develop a "Feasibility study on a potential business opportunity." The Executive Director, after additional research, concluded this effort was not needed. Attachment 3 reflects the current status of what the NGABs, AOAC and FDA are already doing in this arena.

At best, TNI's FSMO standard might be used for accrediting sampling. We are, therefore, back to two issues:

1. Do we allow the use of our symbols?
2. Should we revise our FSMO standard to make it more generic? (The word "environmental" appears in the standard 6 times and if removed, it would be a great generic FSMO standard.)

Discussion points follow:

- The NEFAP standard could be used for sampling, but the problem in the industry is that growers are reluctant to provide adequate sample sizes, to represent the various products. The main reason for this is revenue loss, from product that cannot be sold.
- Labs testing cannabis samples cannot be prohibited from stating in their report that the lab itself is accredited to the NELAP standard, so long as they do not claim accreditation for a specific method not included in the lab's scope.

- At least one NELAP AB (Oregon, and possibly Minnesota) is required by regulation to accredit cannabis testing labs. In this case, it would be difficult to prohibit use of the NELAP logo.
- TNI cannot prohibit use of its standards for the purpose of certifying cannabis testing labs.
- Cannabis plant material should be considered part of “biological tissue” in the AB’s fields of accreditation.
- Some governmental units (for instance, California) may require testing of cannabis metabolites (specifically the delta-8 isomer) in wastewater.
- Proficiency testing and reference materials are not yet considered to be of adequate quality and traceability.
- TNI’s policy on the use of its logos does not address the legality of the analyte for which accreditation is granted.

The Board endorsed formation of another small group of individuals to focus solely on the use of TNI and NELAP’s logos for cannabis testing labs. Jerry will schedule the initial meeting of this group, which will include Alfredo Sotomayor, Dave Spies, Daniel Lashbrook, Sharon Mertens, Chris Gunning, Justin Brown and someone from one of the Oregon cannabis testing labs (several are TNI members).

## Attachment 1

### Proposed Charter for a Field Activities Accreditation Task Force

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#### Mission

Develop an organizational approach to field activities accreditation throughout all TNI programs including NELAP, TNI Environmental Laboratory Standard Recognition and NEFAP.

Under the direction of the TNI Board of Directors, the Field Activities Task Force will:

1. Develop and recommend consistent policies for the accreditation of field activities; including the standardization of the approach to listing scopes of accreditation.
2. Develop an organizational approach to field activities including mobile laboratories under multiple TNI programs and identify or clarify when each program is appropriate for accreditation.
3. Recommend standard definition of mobile laboratories and field activities (e.g.; sampling, testing).

#### Composition of the Committee

1. The Task Force will be chaired by a volunteer serving on the task force.
2. The Task Force will be composed of 6-8 members.
3. At a minimum, the committee will include at least one member of the following stakeholder categories; NELAP AB, NEFAP AB, TNI Environmental Laboratory Standard Recognition AB, and Mobile Laboratory.
4. It is preferable that NELAP AB representative include those with differing requirements/approaches to field activities or mobile labs accreditation within the state regulation/legislation.
5. There is no requirement for balance of membership.

#### Objectives

1. Develop consistent process for accreditation of field activities (e.g.; field testing, mobile laboratories) in NELAP
  - **Success Measure:**
    - The State ABs in NELAP and TNI Environmental Laboratory Standard Recognized ABs in TNI harmonize approach to field activities (e.g.; field testing, sample and mobile laboratory) accreditation so the process is consistent throughout program.
2. Develop organizational approach to field activities accreditation within TNI to clarify which program is appropriate for field activities seeking accreditation.
  - **Success Measures:**
    - Develop consensus on approach to accrediting field activities between NELAP, TNI Environmental Laboratory Standard Recognition, and NEFAP.
    - Develop guidance, flow chart, etc. to clarify which program/recognition is appropriate in different circumstances for field activities to understand their options and select the appropriate accreditation.
3. Standardize definition of field activities and mobile laboratories (or testing/sampling not performed at permanent facility).
  - **Success Measure:**
    - Develop a TNI organization endorsed definition of field activities (including field sampling/testing, mobile labs) for use in all TNI Standards and throughout the organization.
4. Review and recommend language in Standard revision(s) relating to field activities, if necessary.
  - **Success Measure:**
    - All TNI Standards have clear language addressing field activities that do not conflict with other Standards.

**Decision Making (*specify default option from Decision Making SOP 1-102*)**

- Decision on review of any TNI procedure, policy or guide changes made by Majority Vote and in the presence of, or by electronic voting of, a committee quorum; voting options are: Yeah, Nay or Abstain.

**Available Resources:**

- Volunteer task force members
- Teleconference and A/V services
- Program Administrator support
- On-line storage, maintenance and archiving of applicable documents
- Stakeholder groups within TNI (i.e. NELAP AC, NEFAP EC, TNI Environmental Laboratory Standard Recognition, LASEC, CSDEC, etc.)

**Anticipated Meeting Schedule:**

- Teleconferences: regular schedule of monthly calls to be published on the TNI website.
- Additional teleconference calls as needed.
- Face-to-face meetings as needed at TNI conferences.

Examples of current overlap resulting in differences in application.

- A. The TNI EL standard includes the definition of mobile labs. The TNI FSMO standard states the management system work is carried out in or away from the permanent facilities or is associated in temporary or mobile facilities. The major difference is the FSMO standard allows for umbrella accreditation and not a facility-by-facility or mobile lab-by-mobile lab accreditation.
- B. The FSMO standard addresses the requirement for measurement and sampling using discrete, continuously or intermittent techniques using unattended equipment. The laboratory sector was not written specifically for environmental sampling.
- C. The FSMO does not prescribe a specific frequency for proficiency testing and allows the AB to define the frequency. Only limited PTs are available for field measurements and no proficiency tests are available for sampling at this time. All ABs have a policy to address when a PT is not available; the FSMO sector must define how it plans to meet the requirements of 5.9 of ISO/IEC 17025. PTs are mandated and available for most laboratory testing so the need for addressing the requirements of 5.9 are not needed in the environmental laboratory standard.
- D. The mobile lab definition is not consistent through the industry. The question of what is a mobile lab depends on state, federal or local jurisdiction. Most jurisdictions only address measurements and not sampling. Tracking mobile labs by VIN number is not helpful if the mobile lab is not part of an enclosure at a specified address.
- E. A mobile lab is:
  - A person/body performing...
  - Sample Collection (no physical structure yet in the field),
  - Sample Collection in a van or enclosure (e.g. non-permanent building or shed),
  - Sample Testing (no physical structure yet in the field),
  - Robot/Person/Body performing sample testing in a trailer or other mobile enclosure,
  - Person/Body performing sample collection and sample testing (no physical structure yet in the field),
  - Person/Body performing sample collection, sample preparation and sample testing in a van or enclosure (e.g. non-permanent building or shed), or
  - Robot/Person/Body performing sample collection, sample preparation and sample testing in a trailer or other mobile enclosure.
- F. There is a need for secondary accreditation for the TNI Environmental Laboratory program since these sampling and testing operations are mobile and sometimes set-up at a given site for a day or a week and then move to another location outside the primary state.

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## Attachment 2 PROGRAM REPORTS

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### CONSENSUS STANDARDS DEVELOPMENT

- *A second notice from the Laboratory Accreditation Body Expert Committee (LAB) requesting input or request for involvement in the revision of Modules 1 and 3 of Volume 2 of the Environmental Laboratory Sector Standard expired on March 31. No responses were received, but a webinar is recommended to explain the proposed changes being considered by the committee.*
- *The initial notice of revising a standard was posted on March 10 for Module 4 of Volume 1, for the Chemistry Expert Committee.*
- *The Chemistry Committee is making final tweaks to the technical edits to the already approved 2016 version of V1M4. With these last-minute clarifications, the "2016 Standard" will be complete.*
- *TNI internal discussions have determined that the formal revision of V1M4 (see second bullet, above) will be incorporated into an upgrade of the "2016 standard" rather than becoming the 2017 version.*
- The Quality Systems Committee is continuing work on the Small Laboratory Handbook. The committee is working through sections using Webex. The PT Expert Committee will be submitting their review and comments in April. The Chemistry section will be based on the current 2016 Standard and the areas being opened for Standard update will be noted and updated after the update to the Standard is complete. The Charter was finalized, but a change to format will require one more review and vote during the committee's April meeting. Work is continuing on the Assessor Checklist. A Draft is expected by later April.
- The Laboratory Accreditation Body Committee (LAB) approved its updated Charter, and has forwarded it to CSDEC. Committee members have begun discussing comments received at the LAB session in Houston. A formal response to comments tracking spreadsheet is in place and will be used even for this early, informal feedback. Committee membership stands at ten members, with several associate members not interested in becoming full members. Additional volunteers would be welcome, up to a full roster of fifteen individuals.
- The WET committee expects to approve its updated Charter at the April meeting. Plans are underway for a webinar to be offered to all NELAP assessors, based on information from the WET Assessment Forum session in Orange County. Presenters have consulted with Ilona about tips and tricks of using Webex, and the training is scheduled for May 24 in the afternoon. Committee members are beginning to work on revising the WET module of the standard, beginning with revising requirements for initial and ongoing demonstrations of competency. This is considered the most difficult piece, and will thus be tackled first.
- The Radiochemistry committee has completed a final review of the Small Laboratory Handbook with an expected handoff to Quality Systems in April. The 2016 Assessor Checklist is still in progress. The committee updated their Charter and it has been sent to the CSDP EC for final approval. New committee members, Candy Friday and Yoon Cha, have now been approved.
- The Microbiology committee handed off the Small Lab Handbook to Quality Systems. Quality Systems will review and send back any comments that need further work. The committee has split up the 2016 checklist and assignments for update are to be complete in April. The committee will then compile everyone's work with hopes to have a complete checklist by May. The committee is beginning work on their charter by email and will plan to approve it during their April meeting.

### NEFAP Executive Committee

- There were not enough members available to hold a regular meeting in March, but Kim did provide updates on various topics the committee is working on.

- The candidate information and voting details have been sent to IT to begin the voting process. The vote will close on April 23, 2017 and the new term for candidates will begin May 1, 2017. A new chair and vice-chair will be elected during the April meeting scheduled for 4/24/17.
- The PTP/NEFAP Evaluation Workgroup – see report under PTP.
- The TNI Board requested more specific information about the recommended “Task Force” or special committee to continue work on the TNI Strategic Initiative to develop and implement a plan for treatment of mobile labs among NELAP ABs and between NELAP and NEFAP. This effort is complete and is included with this monthly report.
- The Strategic/Marketing Subcommittee met late March and made updates to their plan. Marlene will begin work on laying out website updates needed, Ilona will prepare a request to IT to prepare a separate video of the first 20 minutes of the Scared Straight training to include on the website to provide background on “Why NEFAP”, Tracy is working on getting written testimonials from FSMOs and Kim and Tracy are working getting testimonials from FSMO clients.
- The committee is continuing review of SOPs for finalization and expects to vote on final versions during their April meeting.
- The committee could not finalize the Charter in March, but plans to complete it during the April meeting.
- The review of an old FAQ document will be on the May agenda.
- Two documents on the NEFAP website were submitted to the Policy Committee for approval as Guidance Documents. The proposals have been approved and the Policy Committee will begin reviewing the accreditation process review document. The other document is being worked on by the FAC and an update will be submitted to Policy for review mid-summer.
- “Why NEFAP?” video shorts are still needed from Kim and Justin to complete the first phase of this activity for the website. Kim’s portion will be pulled from the Scared Straight presentation done in Orange County. This request has been submitted to IT.

#### **Field Activities Expert Committee (FAC)**

- The Scope Guidance Subcommittee did not meet this last month.
- The committee approved the Standard update documents needed to get started and Ilona will forward this information to Ken Jackson to move things forward.
- The committee just needs to make a format change to the Charter and then it will be ready for final approval in April and submission to the CSDP Executive Committee.
- The FSMO Tools Subcommittee is being reformed to review and update the “priority” document for final submission to the Policy Committee.

#### **NELAP**

##### **Accreditation Council**

- The final renewal from the 2014-2016 round of evaluations is now approved. For the current round, six renewal letters have been issued thus far, with another to be sent this month. Five applications have been received. The remaining AB, LA DHH, is in process of replacing its sole staffer and will submit its renewal application as soon as possible.
- Council members met with Steve Arms (in his roles as Lead Evaluator and Chair of the Advocacy Committee) to discuss possible use of a list of items identified by EPA that the Agency requires for state primacy recognitions. Not all ABs can enforce all items on that list, particularly those not in regulation even though considered “required” by the Drinking Water Certification Manual (which is non-regulatory guidance.) The final decision was that the list will not be used in any way during the current round of evaluations, but some ABs may choose to use it for their internal audits. Donna



Ringel, EPA's Liaison to the AC, will provide a final version of the list that will be posted to the "documents and presentations" section of the NELAP AC web page.

- The Chemistry committee asked both LASEC and the NELAP AC for some form of approval of the edits made, to know that the version going into revision has only the two issues documented thus far to be addressed. While LASEC indicated its approval, the Council asked for clarified wording on two items; Chemistry agrees that those will be addressed.
- The AC voted to accept the LASEC's recommendation approving the edits to the PT module in Volume 2 (V2M2) made to match the already approved edits to reviewed proposed revisions to the 2016 PT module in Volume 1 (V1M1.)
- Council members are reviewing a draft revised charter for approval at the May 1 meeting.

### Laboratory Accreditation System Executive Committee (LAS EC)

- Revisions to the LASEC Charter await final approval at the April meeting.
- LASEC reviewed edits to the Chemistry module and found them acceptable. It also approved a recommendation to the NELAP AC, to accept the edits to V2M2, made to match the changes approved for V1M1.
- Now that the work of reviewing standards is at a lull, LASEC is making sound progress on policy development for the NELAP AC. A draft policy addressing method selection for assessment as well as documentation of preparatory methods is undergoing review and awaits finalization of some details about the particular fields of accreditation.

### PROFICIENCY TESTING

- Shawn Kassner and Ilona will begin working on updating only the SASS portion of the PTPA Evaluation checklist in June. The format will be based on information provided by the PTP/NEFAP Evaluation Workgroup.
- Analyte Request Application (ARA) – NPW/SCM Qualitative PCB Analysis: Maria sent a request to the Chair of the Chemistry FoPT Table Subcommittee for specific needs so data can be collected from the PT Providers. The actual request to providers should be out by the end of April.
- The radiochemistry and microbiology data have now been masked. The Chemistry FoPT Subcommittee will begin working on the data in April and the subcommittee should begin meeting sometime in May. The Microbiology subcommittee has forwarded the data to a statistician who will compile it and send it back the committee. A time frame has not been determined yet.
- Maria still needs to forward the NPW and SCM FoPT tables for posting to the TNI website with an implementation date of 7/24/17. This should be complete this week.
- The NELAP AC reviewed the DW FoPT table updates and asked that Footnote 15 be reconsidered. At least one member of the NELAP AC stated they would have to provide a veto vote because they could not implement the footnote in their State. The footnote stated: *The Low Level Analytes' concentration ranges and acceptance criteria are specifically intended for technologies/methods that can achieve the listed PTRL.* After discussion, the committee determined that the footnote could be deleted and the table is being sent back to the NELAP AC for approval. This issue mainly related to EDB and DBCP.
- SOP 4-105 (Voting) has been finalized and approved. It will be forwarded to the Policy Committee for review. SOP 4-102 comments are still be reviewed and the SOP is being updated and prepared for finalization in April.
- The final internal audit checklist will be completed in April after completion of SOP 4-102.

- The PTP/NEFAP Evaluation Workgroup had their third meeting. The Program Comparison document review has been completed and decisions have been documented:
  - no office visit unless determined to be needed after the “desktop audit”,
  - witnessing will continue,
  - ISO/IEC 17011 training can be part of the evaluation training process that is taught through TNI,
  - there will be one application that will include a list of needed documents that are common to both programs and additional items specific to each program,
  - time frames for final reports and corrective action were agreed upon,
  - evaluations will include non-conformances, concerns and comments, and
  - renewals will be 4 years until the workgroup meets again after this evaluation cycle to add TNI Environmental Standard Recognition to the application and then renewal cycles will be discussed again.
- The workgroup continued to discuss the make-up of the evaluation team and is leaning towards having a TNI staff member act as lead evaluator with volunteer technical evaluators who will perform the witnessing. Ilona discussed this possibility with Jerry and a decision will be made by email before the next meeting. The workgroup will meet again in two weeks to also finalize an implementation plan and then begin work on preparing any documentation needed to combine the evaluations with a goal to have an application ready to distribute by early August.
- The SOP subcommittee looked at how to add new FoPT table update procedures to existing SOPs and determined that the updates can be done and a new SOP number is not needed. The subcommittee will determine a schedule for these updates after it finalizes some SOPs already in progress. Maria still plans to send out a request for information from stakeholders to finalize the new process for updating FoPT tables.
- More work is needed on the Charter and it will be finalized during the April meeting.

## **ADMINISTRATION**

### **Advocacy Committee**

- The next newsletter is in review and will be published very soon.
- The committee discussed the possibility of assisting the California program with the clarifications/guidance that stakeholders have requested. Many of these issues have already been addressed by TNI in SIRs, the small lab handbook, and the quality manual template. Jerry will consider the options.
- The committee discussed incorporation of the essential items provided by the EPA DW program into NELAP AB evaluations since this issue was an item on the Advocacy Committee’s strategic plan tasks. The Committee agreed that no further action by Advocacy is needed. See NELAP AC report.

### **Non-Governmental Accreditation Bodies**

- The working group proposes to delay finalizing the SOP for disputes and appeals until such time as a uniform SOP can be developed for all NGAB programs.
- The TNRC’s work is complete for now, and no further action will be needed from them until 2020 unless there is a new applicant.
- The NGAB working group will delay any further actions until after the NEFAP PTPA evaluation process is complete.
- A small group can continue to finish out work as needed.
- No further meetings are scheduled.

## **Policy Committee**

- Policy has reviewed and approved updates to the SOP for awarding Continuing Education Credits from TNI training (SOP 1-117) as well as the NELAP Evaluation SOP 3-102. These are provided to the Board today, for endorsement.
- During review of the committee internal audit checklists, a number of details in various administrative SOPs and policies were identified as needing update to match the recently adopted TNI Quality Management Plan. Policy will work through these and all other documents older than five years, as timing permits. Current modifications and new documents will take priority in the review queue.

## **Training**

- A vendor presentation is planned for April 21, 2017 to discuss the Corporate Sponsor Program that includes opportunities to advertise during TNI training events.
- An Assessor Refresher course took place 3/6/17 – Marlene Moore, ASI. There were 51 participants including both individual and group registrations.
- A TNI Standard Implementation for Small Laboratories Series will start-up April 18<sup>th</sup> and run through August 1, 2017. The series consists of 10 two hour courses and is being taught by Marlene Moore. Response has been great with over 75 sign-ups and a week to still sign-up. 95+% have signed up for all 10 courses.
- There are two courses in the planning phase:
  - Understanding WET Testing. This course will be held May 24, 2017 for 4 hours and include a 20 question test. It is being taught by 3 members of the WET Expert Committee.
  - Implementing and Assessing the Environmental Laboratory Standard Interpretations. This course is being planned for Spring and will be 2-4 hours long. It is being taught by Marlene Moore.

## **NEMC**

- Over 150 abstracts have been received for the NEMC portion of the summer meeting. Work is well underway towards finalizing the sessions.
- Kay and Jerry have conducted a site visit and Jerry is making final space assignments.
- The draft conference brochure will be ready this month and letters are going out notifying speakers of acceptance.

## **Membership Report**

- There were 3 new committee applications that have been forwarded to the committee chairs and Program Administrators. One was for Radiochemistry Expert, one for LASEC, and one for Chemistry Expert.
- Active Members: 893

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### Attachment 3 Additional Information on Cannabis

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#### Part A: AOAC and Industry Partners to Set Voluntary Consensus Standards for Cannabis Potency

AOAC and industry are partnering to develop *Standard Method Performance Requirements* (SMPRs®) in an effort to find fit-for-purpose method(s) for cannabis potency. The AOAC Stakeholder Panel on Strategic Foods Analytical Methods (SPSFAM), chaired by Erik Konings of Nestlé, endorsed a fitness-for-purpose statement, and draft SMPRs are underway. Quantitative methods are needed for various measurements of cannabinoids in raw materials, extracts, topical applications, and foods.

“Analytical testing in the cannabis sector is greatly suffering from a lack of standardization and appropriately vetted methods that have been rigorously evaluated,” said **Susan Audino** of S.A. Audino & Associates and chair of the AOAC SPSFAM Working Group on Cannabis Potency. “The result is diminished consumer safety and insufficient knowledge about a legally acquired and purchased commodity.”

Even though cannabis remains illegal at the federal level, individual states have developed legislation for testing certain components, but the testing has not been standardized across states. The goal of the working group is to develop SMPRs that are applicable for industry and regulators alike.

Standards development activities for cannabis potency are supported by [AOAC Organizational Affiliate](#) (OA) companies **SPEX**, **Sigma-Aldrich**, **GW Pharmaceuticals**, **SCIEX**, **CEM Corp.**, and **SC Labs** through AOAC’s working group initiative.

“The working group initiative is a valuable opportunity for stakeholders to raise standard needs, and the food panel is an excellent forum to initiate this work,” Konings said.

Added AOAC Executive Director **James Bradford**, “This approach offers companies opportunities to solve challenges without waiting on priorities of existing stakeholder panels. The goal is to engage current and potential OAs in the important work of AOAC. OAs can solve immediate needs shared across their industry through standards development and fit-for-purpose methods.”

Perhaps the most significant analytical issue facing the cannabis industry is the lack of consensus or standard test methods. Results can vary greatly from laboratory-to-laboratory, leading to lack of confidence in analytical results.

Of the 15 compounds of interest, the working group narrowed the focus to five cannabinoids required for the initial SMPR, THC, THCA, CBD, CBDA, and CBN. Based on fitness-for-purpose, draft SMPRs were developed by the working group, and are posted on the AOAC website at [SPSFAM SMPRs for Public Comment: Cannabis and Proanthocyanadins in Cranberries](#) and is open for public comment. All interested parties are encouraged to submit comments by January 27, 2017. Comments will be compiled and reviewed, and the SMPRs revised, if necessary, based on the comments received.

#### Part B: PJLA Newsletter Article on FDA Accreditation

The Food Safety Modernization Act (FSMA) gives FDA important new tools to better ensure the safety of foods while directing it to build an Integrated Food Safety System (IFSS) in partnership with State and local T authorities. The Partnership for Food Protection (PFP) initiated by the FDA in 2008 is the vehicle to fully implement the Integrated Food Safety System through mutual reliance. In the effort to establish national laboratory standards and implement a fully IFSS, laboratory accreditation has been identified as a critical element by PFP for ensuring the integrity and accountability of laboratory analytical testing. In addition, Section 202 of FSMA requires that laboratories accredited by FDA-recognized accreditation bodies be used to test food under certain specified circumstances.

In 2012, FDA entered into five-year cooperative agreements with 31 state food-testing laboratories to either attain ISO/IEC 17025:2005 accreditation (23) or expand/maintain existing ISO accreditation (8). In 2015, an additional 26 food/feed testing laboratories were awarded funding to obtain ISO/IEC 17025 accreditation. FDA

also awarded a five-year cooperative agreement to the Association of Public Health Laboratories (APHL) in collaboration with the Association of Food and Drug Officials (AFDO) and the Association of American Feed Control Officials (AAFCO) to support laboratory accreditation. One of the major goals of this association cooperative agreement is to facilitate long-term improvements to the national food and animal feed safety system by strengthening collaboration and supporting laboratories seeking accreditation to the ISO 17025 standard.

Collaborative efforts between FDA and above mentioned three associations have been made to promote and enhance laboratory accreditation for the Nation's food and feed testing laboratories since 2012. In addition to providing funding to support laboratory accreditation, a structured laboratory accreditation support program has been established within the FDA's Office of Regulatory Affairs/Office of Regulatory Science to provide guidance and technical assistance to state laboratories seeking ISO/IEC 17025 accreditation or to enhance the scope of already accredited laboratories. The major activities of this program include:

1. conducting on-site assessments to assist the labs to identify gaps and set priorities;
2. institute a mentor-mentee program in which an accredited lab serve a mentor for non-accredited mentee;
3. conduct one-to-one calls to provide technical assistance as needed (e.g. provide resource such as FDA testing method and ISO related, etc.);
4. review mid-year and end of year report and provide evaluation and recommendation based on the performance;
5. collaborate and provide oversight on the associations effort for promoting accreditation

#### **Part C: About the AOAC Accreditation Guidelines for Laboratories (ALACC)**

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The "Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals – An Aid to the Interpretation of ISO/IEC 17025:2005 (2015)" (ALACC Guidelines) provide detailed information to aid in assessing the essential quality requirements for performing microbiological and chemical analyses of food, dietary supplements, and pharmaceuticals. The revision includes dietary supplements for the first time. The document is closely aligned with ISO/IEC 17025 and provides a section-by-section interpretation of the general ISO/IEC 17025 requirements.