TNI Board of Directors Meeting Summary
September 9, 2020

1.   Roll Call

Directors	Present
Jordan Adelson	X
Aaren Alger	X
Steve Arms	X
Justin Brown	X
Kristin Brown	X
David Caldwell	X
Stacie Crandall	X
Bob Di Rienzo	
Jack Farrell	X
Maria Friedman	
Myron Gunsalus	
Paul Junio	X
Judy Morgan	
Patsy Root	X
Debbie Rosano	
Scott Siders	X
Nick Slawson	X
Alfredo Sotomayor	X
Dave Speis	
Lem Walker	X
Curtis Wood	X
Past Chair	
Sharon Mertens	
Staff	
Lynn Bradley	X
Carol Batterton	X
Jerry Parr	X
Suzanne Rachmaninoff	X
Ilona Taunton	X
Janice Wlodarski	X
Bob Wyeth	X

2.   Approval of August Minutes

Motion to Approve: Patsy Root
Second: David Caldwell
Abstentions: Aaren Alger
Approved: Approved

3.   Program Reports (Attachment 1)

4.   San Antonio Meeting – Hybrid In-person and Virtual Meeting (Attachment 2)

After reviewing a number of options, the Advocacy Committee is recommending we go forward with an in-person meeting in San Antonio.

  - ➢ January 11-14, 2021.
  - ➢ Monday am: Plenary Session.
  - ➢ Monday pm to Wednesday pm: 3 concurrent sessions; 2 committee meeting slots and 1 special session.
  - ➢ Committee meetings subject to change based on input from staff and chairs and need for a face-to-face meeting.
  - ➢ Special sessions would start at 9:00 am (7:00 am Pacific) and be available as webinars.
  - ➢ Anticipate in-person drop off to around 100-150 attendees in-person.
  - ➢ Training Courses on Thursday.
  - ➢ Allow exhibitors to exhibit in-person or virtually.

We would retain the option to go entirely virtual if events dictate so. See Attachment 2 for a draft of the Conference at a Glance.

TNI will reach out to the exhibitors to see if they are planning to come to an in-person meeting. If not, then we will go fully virtual. If exhibitors say yes, then we will reach out to committees and see if they will come to an in-person meeting.

Recommendation is that we move forward as planned. We won't have a definitive answer until the October Board meeting.

5.   Quality System, Management System, or Quality Management System (Attachment 3)

In the August Board call, preliminary discussions were held regarding the use of the term Quality System in Module 2 of the TNI laboratory standard. A small group was tasked to discuss this topic in more detail. Attachment 3 contains a draft report from the group along with a strong counter opinion from one member.

Note: The document produced by this group also contains proposed changes to Module 2 by adding back in Section 1.3, Scope from the 2003 NELAC Standard. That issue is something the Quality Systems committee can address without Board intervention and is not discussed ion Attachment 3.

Discussion involved a lot of agreement about adding the word "Management" to the Quality System label. Maria made a great argument that we have been using the term Quality Systems for more than 20 years and maybe we shouldn't be too quick to replace it, that "Quality Systems" is a kind of TNI branding. Are there are negative connotations with change to "Quality Management System"?

  - • Could this change be seen as TNI's making a change simply to make the change, so people and organizations out there see that we're changing things up? No, we have more than enough information about why we are making the change to make this point a non-issue.

  - • Could this have a negative effect or impact by the Small Lab community?

  - • Maybe the only downside is that we will have some documents to change. The Quality Systems committee will still be titled "Quality Systems".

QMS vs QS Poll:
Jordan – QMS
Aaren – QS but could go either
Steve – QMS
Justin – QMS

David – QMS
Stacie – QMS
Jack – QMS
Kristine – Either way
Paul – QS but could go either
Scott – QMS
Nick – QMS
Curtis – QMS

Do we have a motion to adopt the term Quality Management System (vs Quality System):

Motion to Approve: Scott Siders
Second: Aaren Algers
Approved: Unanimous

Jerry will write an article for the newsletter.

6.   White Paper on the Value of Accreditation

For the past 6 months, the Advocacy Committee has been working on a White Paper on "Does Laboratory Accreditation Make a Difference?" This document was provided separately. Although SOP 1-122 indicates White Papers do not need Board approval, this one reflects a significant change in direction and Board guidance is appropriate.

As you will see, this paper argues for moving away from our 25-year guiding principle, "data of known and documented quality," to a principle of "data you can trust," of which the old principle is now one of several.

Based on the Board's decision on Agenda item 3, this document may need to be revised to reflect that decision.

After much discussion about the language that we use in the paper, Jerry will review again and present another draft to the Board in October.

Attachment 1
PROGRAM REPORTS

CONSENSUS STANDARDS DEVELOPMENT

- TNI has submitted its final version of the Corrective Action Plan (CAP) in response to the ANSI audit. The CAP will be reviewed by the ANSI Executive Standards Council for consideration of TNI's re-accreditation. Also submitted to ANSI were all of our revised operational SOPs. These documents will be reviewed by ANSI for compliance with *ANSI Essential Requirements*. These SOPs will also be publicized in *Standards Action* for public comment. Any public comments received from the posting will have to be addressed and resolved prior to any re-accreditation.

- The TNI Glossary work group has begun activities by preparing a comparison document of all definitions presented in TNI documents and the current glossary as completed last year. Relevant ISO standards definitions are also being included but copyright restrictions need to be ascertained and addressed if necessary. The ultimate direction (i.e., guidance document, module of the standard, etc.) as to use of the glossary has yet to be addressed.

- Revisions to training materials for committee chairs and committee members has commenced and a preliminary draft is being prepared. This effort will be directed at training for all TNI committee in addition to the expert committees and is scheduled to be ready for implementation by early 2021.

- Committee chairs have also been requested to review their committee rosters and determine the potential need for new members in 2021 which will be advertised in appropriate TNI media for solicitation of committee candidates. Committee chairs will be asked to make attempts to bring expert committee to the full complement of 15 voting members.

- The **Chemistry** committee has begun initial efforts regarding modifications to Module 4, specifically as relates to Initial and Continuing Demonstration of Capabilities for the laboratory and individual analysts. The Committee is also working on a new SIR 387 concerning the use of pre-calibrated equipment and their use for accredited analysis. The committee is also addressing its future leadership as the current chair is rotating off the committee and the current vice-chair has indicated that he will be unavailable to assume the role of chair. Volunteers and nominations are being solicited and accepted for consideration and ultimate committee approval.

- The **Proficiency Testing** committee continues to develop a work plan focusing on needed changes to Module 1, including review of ISO 17011, 17025 and 17034 for consistency with the TNI standard. The committee reviewed "invalid SIRs" to ensure that any modifications made to their module will address all outstanding issues. The committee discussed at length the Whole Effluent Toxicity (WET) testing committees' issue with the efficacy of the current PT program. The committee supports the position that WET PT should evaluate the competency of the laboratory which at this point in time is questionable. A meeting of the PTEC, PTPEC and the WET committee is being planned with a joint meeting, including the CSDEC and the AC at the winter meeting is also being proposed. The PTEC is attempting to expand its membership to a full 15 voting member group. The underrepresented "Other" and "AB" stakeholder groups create balance issues when trying to fill committee positions. The question of reclassification of "others" working for and basically representing NGAB and/or AB as member of the "AB" stakeholder group was suggested to help alleviate this problem.

- The **Asbestos** committee is in the process of developing their summary document. Upon committee approval of this summary, the Draft Standard and the Summary will be posted and announced consistent with Rev. 3.2 of SOP 2-100. This announcement will be directed to all relevant TNI committee chair as well as the non-TNI interested parties. Jan is assisting in development of the TNI and non-TNI outreach distribution process.

Attachment 1
PROGRAM REPORTS cont.

- The **Laboratory Accreditation Body** Committee has worked through all of the comments submitted after its April 2019 publication of the outline of proposed changes and draft revised module. The committee now is addressing the recommendations of the Field Activities Task Force. It looks possible that a Draft Standard may be issued for comment by the end of calendar 2020.

- The **WET** committee members continue working on the various issues underway while the Chair and AB representatives are focusing on attaining closure about an acceptable process for analyst initial demonstrations of competency.

- The **Radiochemistry** Committee met in August and started reviewing the public webinar feedback and recommended changes to their module. They should complete this review in October and possibly have a Draft Standard by the end of the year.

- The **Microbiology** Committee finalized their Summary of Changes document and are finalizing a date for their public webinar. They are targeting late September. They will not be meeting in September, but will begin working on language changes to their module in October.

- The **Quality Systems** Committee did one last review and completed work on their Summary of Suggested Changes to the Standard table to prepare for a public webinar to receive more input on the needed changes/additions to the Module 2 Standard. The Committee will be doing the webinar at 12pm EDT on September 25, 2020. Notifications will be going out this week. The Committee has set a goal to have a DRAFT Standard to present at the winter meeting so they can hit a target of August 2021 for an approved CSDP Module 2 Standard. The Committee is awaiting more input from Jerry to confirm they need to have an approved Standard that DoD can use.

- The **SSAS** Committee is continuing work on their SOPs to define how they will be able to provide audit samples at other concentrations. SOP 6-100 (Conducting Pilot Studies for New Concentration Ranges and Acceptance Limits for Source Sampling Audit Samples) has been finalized by the Policy Committee and an update to SOP 6-101 (SSAS Table Management) is still being worked on. The Committee is continuing to meet more frequently to try to finish up their last SOP and the Standard updates in hopes that these changes to the program will encourage another audit sample provider to apply.

NEFAP Executive Committee

- The two workgroups formed to begin addressing the training plan and marketing plan are continuing to meet.

  - The Training Workgroup found a memo (1/11/18) from the US Department of the Interior that has a directive to get training for sampling and field methods. They are looking at training needs for FSMO organizations and ABs. They want to see all classes have a test that gets scored.

  - The marketing workgroup is looking at updating the content of the website, use of marketing material like the trifold we currently have, identifying industry groups they can target for NEFAP presentations, and looking for persons they can contact in each state to understand their field needs. They have been added to the Advocacy Committee agenda to discuss options on social media, contacting states and ways advocacy can help.

    The two workgroups will meet this month to combine resources and present a plan to the NEFAP EC. The NEFAP EC is also beginning work on the metrics the Board asked about. The Committee will have an extra meeting this month in order to have a report to the Board for the October meeting.

Attachment 1
PROGRAM REPORTS cont.

- The Nominating Committee (Chair – Geneva Bowman from AIHA) is working on completing the slate of candidates. One FSMO member would like to serve a second term and they have one open spot.

- The Committee is continuing to delay the discussion regarding accreditation options for FSMO's until the Scope Guidance Document is complete. The Marketing Workgroup is aware of this discussion and may consider it during their discussions. Reminder: An interesting discussion was started in Milwaukee when someone asked if they could add an FSMO accreditation to their NELAP accreditation. This could work currently for an NGAB accrediting to the TNI Environmental Standard. This thought was incorporated into the TNI Strategic Plan recommendation as looking at ways to work with NELAP.

- The Committee is working on SOPs and updating its internal audit checklist.

Field Activities Expert Committee (FAC)

- The Committee is rescheduling its September meeting, but is continuing work on the DRAFT FSMO Standard that was developed by combining the 2014 Standard with the new ISO/IEC 17025:2017.

- Scott and Ilona will make progress next week on the Summary of Changes document to hopefully prepare for a public webinar in Fall.

NELAP

Accreditation Council

- The first remote site visit for an AB renewal of recognition is in process (New York) and four additional applications are in various stages of review. The NELAP Evaluation SOP 3-102 that was revised to accommodate remote site visits and is being used under Provisional status as it awaits Policy Committee review. NY is viewed as a pilot, with the Lead Evaluator and Program Manager working through process details as they progress through the remaining materials that would normally be addressed during a site visit. With the August 20 withdrawal of LA DOH from NELAP, there will be a gap in the 2-month cycle of renewal request letters, which should allow the Lead Evaluator to "catch up" on the existing applications that were backed up due to inability to perform in-person site visits.

- The Council considered carefully whether revisions to the Mutual Recognition SOP 3-100 and after several versions, was presented with a draft for adoption at its meeting on September 8. As NELAP cannot override state regulations, the revision focuses on early notification to NELAP of pending rule changes and when notifying labs, to advise that they apply to a different NELAP AB within two months.

- The implementation status of all NELAP ABs is unchanged from the March Board meeting, and thus the table will not be displayed until changes occur, as discussed at the April Board meeting.

- A press release regarding the withdrawal of Louisiana DHH from NELAP was posted on the TNI website.

Laboratory Accreditation Systems Executive Committee

- LASEC was treated to an explanation of the updated SIR Tracking Spreadsheet, developed by Judy Morgan after extended discussions about the need to monitor timelines better and report regularly to LASEC as well as the Board about the status of SIRs moving through the review and approval process. After her presentation to the committee, Judy returned to the spreadsheet and made further revisions, so that it is ready for use. The recently revised SIR Management SOP 3-105 has been

Attachment 1
PROGRAM REPORTS cont.

withdrawn from the Policy Committee review queue so that a few additional details can be added, based on the presentation and discussion of SIR tracking reporting requirements.

- There was a slight delay in the quarterly reporting to the Board about SIR status, since changes to the spreadsheet were not made while it was undergoing revision, but those will be caught up in the near future.

PROFICIENCY TESTING

- The PTPEC did not meeting in August 2020. Work is continuing on the FoPT limit setting SOP through subcommittee meetings. The internal audit checklist will be updated in September.

ADMINISTRATION

Advocacy

- The Advocacy Committee discussed options for the January meeting with Jerry and recommended that we proceed with planning for a hybrid (in-person with a virtual component) meeting.

- The next newsletter will be published in mid-October. Zonetta English will be the editor.

- The Mentoring Subcommittee continued discussion on developing the overall structure of the program and the mentoring process. The initial questionnaire for labs who apply to be mentored has been significantly simplified. The mentoring agreement has also been simplified into a less formal document. Jerry is working on a draft web page to announce the program.

Policy Committee

- The Committee reviewed an additional change to SOP 2-100 (Procedures Governing Standards Development) and finalized it - the option of abstentions was added as requested by ANSI. The Committee completed the review of SOP 6-100 (Conducting Pilot Studies for New Concentration Ranges and Acceptance Limits for Source Sampling Audit Samples). Editorial changes were recommended and made by the SASS Expert Committee. This SOP is final. The Committee also reviewed the new TNI Training Committee charter and made some recommendations that will be reviewed by the Training Committee on Friday.

Training

- Training Committee:

    ➢ Policy reviewed the committee charter and forwarded some recommendations that the Committee will look at this Friday.

    ➢ The Committee also reviewed the DRAFT Knowledge, Skills and Abilities (KSAs) for Lab Assessors that the Competency Task Force is working on. Committee members were curious with how this document compares to what is being done today and they discussed how these types of documents will be used by the Training Committee.

Attachment 1
PROGRAM REPORTS cont.

> ➤ The Committee also discussed the possibility of training tracks and what a track might include. The started with a comprehensive list for a Quality Manager track and discussed what other tracks could be beneficial.

- Current Classes being worked on:

  > ➤ Good Laboratory Practice – Internal Audits – Part II (Matt Sica) – Comments sent to ANAB for review and update of the training. An email was sent to follow-up on this.

  > ➤ Ilona will work with ANAB on a new course they are proposing: Risk Based Thinking in the Environmental Laboratory.

  > ➤ Marlene and Ilona are still discussing evaluator training for the NEFAP/PTP Evaluations.

  > ➤ Scott Siders is working on turning a training he was going to give in Minneapolis into a Webinar training: Lowering the Cost of Poor Quality (CoPQ) with an Effective Quality Management System and Integrating Risk Management Principles. The course will be targeted for October.

  > ➤ Jerry is working with Judy Morgan on course based on a presentation they did during NEMC: History of Environmental Monitoring. Jerry plans to roll this out in October.

  > ➤ Silky is working on an update to her 2009 Standard Implementation class: Implementing the 2016 TNI Standard Series. Jerry expects this could be ready later this month.

  > ➤ Jerry is working on an update to the class: Theoretical and Practical Consideration for Establishing Sensitivity of Measurements. He plans to roll this class out in September.

- Marlene decided to do the upcoming PA assessor class via Webex instead. She allowed the addition of 6 more students and will have a class of 20. She has asked Ilona to help with the breakout sessions in addition to regular assistance.

National Environmental Monitoring Conference

- We ended up with 588 attendees, but this include some exhibitors that only had access to the exhibit hall and some presenters and chairs that only attended their session.

- Feedback has been very positive, and a virtual component will be a feature of all future meetings.

- The NEMC Portal will be open thru October 31 and we are going to try and get more registrations.

- NEMC 2021 will be in Bellevue, WA, from August 2-6, 2021 with a virtual component and then a second week that will be virtual only.

- The theme will be *Hitting Reset*.

NGAB

- IAS Evaluation: Working on updating procedures to accommodate virtual observations.

Attachment 1
PROGRAM REPORTS cont.

MEMBERSHIP

- Active Members: 1067
- 54 New and Renewed Memberships
- 17 Expired Memberships
- There were 2 committee applications received in August: 1 – SSAS, 1 – LASEC.

TASK FORCES AND OTHER GROUPS

Competency Task Force

- At its August meeting, the group affirmed its July work on TNI-specific assessment competencies and the general content of assessor training, then moved into considering generic assessment competencies. At least one more session will be needed to complete that portion of the competency criteria. Next, the group will move on to considering professional and foundational competencies, but it is anticipated that those categories will be best evaluated during the interview and probationary employment phases of an assessor's career. The final portion of the competencies will address technical training (assessing the PT and QS modules of Volume 1 plus assessing to the analysis-specific modules) and technical module training (specific technologies and methods used in Modules 3-7).

Consumables Task Force

- The Task Force is continuing to "brainstorm" on characterization of supplies, products and services. Specifically addressing common consumables across all laboratories and types of analysis. This information collection effort is utilizing a previously Task Force approved spreadsheet for this purpose. Inputs from all Task Force members are being received and collated by the Task Force Chair.

Environmental Monitoring Coalition (EMC)

- The EMC has scheduled a meeting with Dan Hautman to discuss topics related to drinking water including IDOC requirements, adoption of recently approved methods, and ICPMS reaction/collision cell technology for drinking water.

- David Friedman has prepared a study plan on acrolein and acrylonitrile preservation and pH and he will take the lead on this topic.

- Jerry is following up with Richard Burrows for a better understanding of the issues related to user-generated mass spec library acceptance criteria.

- Jerry presented a draft proposal to EPA that he and David Friedman had worked on for a collaborative effort to address this issue.

end

Attachment 2
Conference at a Glance: 2021 FORUM
January 11-14, 2021
Hyatt Regency San Antonio

Time	Monday: 1/11	Tuesday: 1/12	Wednesday: 1/13	Thursday: 1/14
7:00-8:00	Continental Breakfast	Continental Breakfast	Continental Breakfast	Continental Breakfast

8-12 AM	8:30 Tools and Resources for Implementation **9:00 TNI Annual Meeting**
	
	10:30 New Initiatives
	   Competency
	   Consumables
	   Mentor
	   Training
		- Quality Systems
		- Assessment Forum
		- WET
			- Chemistry
			- Micro
			- Accreditation Body Perspectives on Laboratory Improvement Under NELAP
				Training Courses
				TNI Staff mtg

12-1	Lunch on Own	Lunch Provided	Lunch Provided	
1-5 PM	- Quality Systems **- How TNI Accreditation Improved my Lab** - FAC	- LASEC/NELAP AC - PTPEC/PT **- Mentor Session**	**- Advocacy Committee** - LAB - Radiochemistry **- Committee Reports 4 pm**	Training Courses
Evening	Reception			

Exhibit program runs from 3:00 pm Monday to 3:30 pm Tuesday
Sessions in **bold** held concurrently as a virtual event

Attachment 3
Quality System, Management System, or Quality Management System

Background

At the first NELAC meeting in February 1995, a newly formed Quality System Committee, chaired by Silky Labie, presented the first version of the Quality System Standard (Chapter 5) as published in the *Federal Register* on December 2, 1995.

At that time, the language in the standard stated:

> Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures, which shall be delineated in a QA Plan to help ensure and document the quality of the analytical data. These shall include QA policies, which will establish essential QC procedures applicable to environmental laboratories regardless of size and complexity. The laboratory shall meet any additional or more stringent requirements as specified by the analytical methods, specific programs or Agencies.

By 1997, NELAC had moved to Guide 25, and in 2002, moved to ISO 17025: 1999. The language remained unchanged until the final 2003 NELAC Standard. The 2009 (and 2016) TNI Standard was revised to contain some, but not all, of the language contained in the 2005 version of 17025 but eliminated a lot of language from 2003 NELAC, including all of Section 1.3.

These documents use the terms management systems, quality systems, and quality management systems somewhat interchangeably. Also used is technical management system and "technical, managerial, and documentation requirements."

The 2005 version of ISO 17025, contains a definition (in a Note):

> The term 'management system' means the quality, administrative and technical systems that govern the operations of a laboratory.

This definition is very consistent with the TNI Board call on August 12, where the Board indicated items such as financial performance, personnel, and health and safety are outside the scope of TNI's Module 2.

The 2009 TNI Standard contains this definition:

> **Quality System:** A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC activities.

The 2017 version of 17025 takes a very different approach, organized as follows:

Section 4　　　General Requirements

1) Impartiality
2) Confidentiality

Section 5　　　Structural Requirements

Section 6　　　Resource Requirements

1) Personnel
2) Facilities
3) Equipment
4) Traceability
5) Externally provided services

Attachment 3
Quality System, Management System, or Quality Management System cont.

Section 7   Process Requirements

1) Reviews of requests, tenders, and contracts
2) Selection, verification and validation of methods
3) Sampling
4) Handling test items
5) Technical records
6) Measurement uncertainty
7) Ensuring the validity of results
8) Reporting results
9) Complaints
10) Non-conforming work
11) Control of data

Section 8   Management Requirements

1) Management system documentation
2) Control of management system documents
3) Control of records
4) Actions to address risks and opportunities
5) Improvement
6) Corrective actions
7) Internal audits
8) Management reviews

In looking at all of this it is important to note that Section 1 is informative only. It does not impose any requirements for laboratories but helps set the stage for the importance of the requirements contained in Sections 4 through 8 of ISO 17025:2017.

Note: ISO has published close to 100 "management" standards. Some of these could be used laboratories, or organizations that have laboratories. Examples include:

- 24518 – Crisis management of water utilities
- 30401 – Human resource management
- 41001 – Facility management
- 14001 – Environmental management systems
- 35001 – Biorisk management for laboratories

Because of the variety of "management" standards, TNI should use quality management to ensure no confusion with the other management standards.

Proposed Changes to Module 2, Section 1.0

1. The TNI definition says a quality system is a management system. Nonetheless, there is confusion over all of these terms, and to be consistent with efforts of TNI's Advocacy committee, the term Quality Management System (QMS) is preferred.

2. Because of the new Section 4 in ISO 17025:2017 is titled "General Requirement," this module needs to be renamed to Quality Management System Requirements.

3. Section 1 of Module 2 should be revised to be more consistent with the new 17025 while still keeping relevant language from earlier versions of the NELAC/TNI standards and 17025:2005 and the Note in 17025 should be moved into section 3.1, Definitions and combined with or reworded with the TNI definition of Quality Systems.

Attachment 3A
A Counter Opinion

An emphasis on quality and a "Quality System" has been hammered home by NELAC and TNI for the past 25 years. In my view, to break from that usage now would be detrimental to the mission of TNI. I therefore agree that we should not change "Quality System" to "Management System."

Having said that, I do not think we need to adopt "Quality Management System" language. Quality Systems has been a kind of brand of TNI for many years, and we must take caution when considering any change to that brand. It also seems incongruous to make that particular change at this time. ISO 17025:2005 used the term "Quality Management System" in its Introduction and Scope sections, but we did not use it in the TNI 2009 or 2016 standards. Now that ISO 17025:2017 removed the term, is now the time to add it to the TNI Standard? I do not see a problem with continuing the use of "Quality System" as the overall descriptor of the elements adopted by labs to assure quality, while adopting the ISO nomenclature for specifics such as structural requirements, management requirements, and so on.