

Summary of the TNI Competency Task Force Meeting  
Wednesday, May 26, 2021 1:00 pm Eastern

1. Welcome and Roll Call

Aaren welcomed everyone to the meeting. Attendance is recorded in Attachment 1. Approval of the minutes from April 28 was postponed until the June meeting, due to some missing information as well as the lack of a quorum.

2. Updated from Credentialing Subcommittee

Jerry explained that this group, composed of members from both this Task Force and the Training Committee, had its first meeting in May. They reviewed a number of documents to understand the distinctions among various types of certification, from degrees to certificates (and including comprehensive programs, not just single course certificates). The group will explore a potential scheme whereby the requirements from the Quality Systems module, V1M2, are broken into individual pieces for training purposes, with each “piece” being awarded a digital badge. Then, some collection of badges (still to be determined) would qualify the trainee to become a certified environmental laboratory professional, with perhaps categories of specialization attached to that credential (such as PT, data integrity, QC, document control, measurement integrity, and so forth).

Comments made during the Task Force’s discussion of this concept included:

- A caution not to make the credentialing “too modular”. Jerry noted that there are no “management requirements” in the standard, but only technical requirements, so that grouping to some extent makes sense.
- This is potentially a model for assessors as well.
- Individuals gain competency through both experience and training.
- A variety of experience is important to develop perspective.

3. Review of the Technical Manager Proposal

As agreed during the April meeting, Lynn drafted and Jerry and Aaren edited a proposal to be presented to the expert committees and the NELAP AC. This draft was distributed with the meeting reminder and thoroughly reviewed by participants, who added a few additional “cons” as well as “pros” to the document. See Attachment 2 for the final document.

One participant noted that a non-NELAP state’s regulation specifically references particular sections of V1M2, and cautioned that TNI ought not to change or eliminate those sections. However, those refer to the 2016 Standard, and any later revision of the standard is unlikely to retain the same numbering, as the 2017 revisions to ISO/IEC 17025 involved a complete restructuring of the entire document. Also, any state having regulations that specifically reference a particular version of the TNI Standard (such as the 2009 or the 2016 standards) would need to adopt new regulations in order to move to any future revision, which will not be available for several years at least. Roughly half of the NELAP states already must do this for each revision.

4. Presenting the Proposal to TNI Expert Committees and the NELAP Accreditation Council

Participants next discussed which groups should be offered this proposal. The NELAP AC, obviously, but the Non-governmental ABs have consistently said that they will do whatever NELAP directs, so those NGABs will not require direct presentations. The Expert Committees, of course, as they have struggled with the Technical Manager qualification requirements for several years now, particularly Quality Systems. The two Chairs (QS and Micro) added as Associate Task Force members for this effort both favor the proposal but it seems preferable to have an “outsider” do the presentation.

Participants also determined that it would be best to have one person present to all of the committees, so that all of the feedback would reside in the same place, and to meet with the expert committees first, then incorporate their feedback before approaching the NELAP AC. Aaren offered that her month of June is relatively open and that, after looking at the committee meeting schedule on the TNI calendar, she can probably attend each of the expert committee meetings (QS, Asbestos, Chemistry, Microbiology, Radiochemistry and WET – there seems no need to present to PT, FAC or SSAS). Jerry indicated that he can substitute for Aaren if she's unable to attend any of those meetings.

Then, at the June 23 Task Force meeting, we can refine the proposal as needed, and be prepared to present to the NELAP AC at its July meeting. That Council meeting will be rescheduled from its normal first Monday, as July 5 will be the official Independence Day holiday, and it's not yet known when the reschedule will take place, but likely either July 6 or July 12.

Lynn agreed to notify the relevant expert committee chairs and the Program Administrators that the Task Force requests time on their June agendas for this presentation. A short introductory message and the proposal were sent on May 28, with a request that the Chairs notify Aaren of when their meeting date/time is set so that she can plan to attend.

5. General Prerequisites for Training

This discussion was begun but not completed. The general thinking was that any prerequisites ought not to be elaborate and that the instructor(s) should have some authority over who is admitted to the training, but that it is equally important that trainees be pre-screened in order to ensure effectiveness of the training, as a class member who continually needs "catch-up" information would be detrimental to everyone involved. Another perspective was that the individuals unable to perform after training would be identified during assessments.

This discussion will continue in June.

6. Next Meeting

The next meeting of the Competency Task Force will be on **June 23, 2021, at 1 pm Eastern**. An agenda and any necessary documents will be sent in advance of the meeting.

**Attachment 1**

**Competency Task Force Roster**

NAME		EMAIL	AFFILIATION	Present?	
Aaren	Alger	aaren@alger-consulting.com	Alger Consulting & Tech.	Yes	1
Paul	Banfer	paul.banfer@eisc.net	EISC	No	2
Kenneth	Brown	kbrown@escondido.org	City of Escondido	Yes	3
Julia	Caprio	JKlensCaprio@Geosyntec.com	Geosyntec	No	4
Patricia	Carvajal	pmcarvajal@sara-tx.org	San Antonio River Authority	No	5
Yumi	Creason	ycreason@pa.gov	Pennsylvania DEP	Yes	6
Kirstin	Daigle	<a href="mailto:Kirstin.daigle@pacelabs.com">Kirstin.daigle@pacelabs.com</a>	Pace Laboratories	No	7
Bob	Di Rienzo	Bob.DiRienzo@ALSGlobal.com	ALS Global	No	8
Steve	Drielak	drielak-associates@usa.net	Drielak & Associates	Yes	9
Amanda	Dutko	adutko@fairwaylaboratories.com	Fairway Laboratories	No	10
Stacey	Fry	sfry@babcocklabs.com	Babcock Laboratories	Yes	11
Kitty	Kong	Kitty.Kong@chevron.com	Chevron	No	12
Kimberly	Kostzer	kkostzer@coca-cola.com	Coca-Cola	No	13
Silky	Labie	elcatllc@centurylink.net	ELCAT	No	14
Harold	Longbaugh	Harold.Longbaugh@houstontx.gov	City of Houston	Yes	15
Mike	Michaud	Mike.michaud@abilenetx.gov	City of Abilene	No	16
Mitzi	Miller	Mitzi.Miller@nv5.com	NV5	No	17
Jerry	Parr	jerry.parr@nelac-institute.org	The NELAC Institute	Yes	18
Sharon	Robinson	Sharon.Robinson@doh.nj.gov	New Jersey DOH	No	19
Joann	Slavin	Joann.slavin@health.ny.gov	NY ELAP	No	20
Alfredo	Sotomayor	asotomayor@mmsd.com	MMSD	Yes	21
Elizabeth	Turner	Elizabeth.turner@pacelabs.com	Pace Labs, Inc.	No	22
Curtis	Wood	curtis_wood@waters.com	ERA, A Waters Company	No	23
<b>Associate Members</b> (for TM/TD activities):					
Debbie	Bond	DBOND@southernco.com	Alabama Power	Yes	24
Kasey	Raley	kasey.raley@pacelabs.com	Pace Laboratories	Yes	25
<b>Program Administrator:</b>					
Lynn	Bradley	The NELAC Institute	Lynn.bradley@nelac-institute.org	Yes	

## Competency Task Force Proposal to Revise Technical Manager Qualifications

### Background

TNI's Board of Directors established the Competency Task Force after adopting its most recent Strategic Plan, to explore and make recommendations regarding programs to document competencies for Quality Managers, Technical Managers, Assessors, Samplers and others as appropriate. The Task Force initially chose to address assessor competency, but when comments on the Draft Standard V2M1 suggested that the initial language should be revised, the group set aside assessor training until the language of the standard is settled. The Task Force then moved to the next category it had chosen to address at the outset, competency for Technical Managers. You are all aware that this is a topic where both the Accreditation Council and the technical discipline Expert Committees have struggled with, as they try to update the Quality System module V1M2.

### Introduction

For purposes of training and possible credentialing, the Competency Task Force initially set out to define the Technical Manager role as a Subject Matter Expert on the technical aspects of laboratory analysis -- the person who runs and troubleshoots various analytical methods and evaluates the QC performed. We quickly learned that, in different labs, various configurations of the necessary roles and responsibilities in operating a laboratory are assigned to titles that include Laboratory Manager, Technical Manager, Quality Assurance Manager, Project Manager, Customer Service Manager and probably more. See Attachment 1.

Since the early NELAC days, the standard has defined qualifications for only the Technical Manager position in a laboratory, primarily using education as a surrogate for details of experience, with a certain number of years working in a related lab activity required. It became increasingly obvious that finding staff who meet these qualifications and are willing to work for the salaries offered in rural, low-income areas is somewhere between frustrating and futile.

Without a clear definition of the role of Technical Manager (as separate from those other indistinct titles), establishing the knowledge, skills and abilities (KSAs) for the role will be an exercise in frustration and unlikely to yield usable results. Further, ISO/IEC 17025 does not set forth qualifications for *any* titled roles in a laboratory – not Technical Manager, not QA Manager, nor any other role. Rather, it establishes requirements for tasks or duties that must be accomplished, without regard for titles or the education or experience of the person performing those tasks, requiring the laboratory to ensure that each task is performed to satisfy the requirement, period.

### Proposal

Remove the Technical Manager duties, qualifications, and exemptions from V1M2 §§4.1.7.2.f and 5.2.6 and allow laboratories to determine the personnel needed (including their qualifications and experience) to meet both the requirements of the standard and the organizational needs of the laboratory. There is no inherent need to establish minimum qualifications for personnel performing tasks defined in the standard.

If any required tasks are not being performed satisfactorily, assessors may use V1M2 §5.2 to determine that laboratory management has not assured the competence of the staff assigned to perform any of the requirements of the standard, based on clusters of findings around that particular requirement. This is currently done for other personnel (QA Manager, for example) and can be done for the tasks associated with the Technical Manager position, as well. Every assessor has a list of tasks or duties required by the standard, and needs only to determine that **some individual** within the lab is satisfactorily performing each of those duties, regardless of what title that person might have.

Pros:

- States are free to set qualifications in regulation as five already have. See Attachment 2.
- Problem of “grandfathered” TD/TMs retiring and the difficulty finding replacement staff is more easily solved, particularly in rural and low-income areas across the nation.
- The TNI Standard would no longer include a specific requirement for education or experience qualifications of laboratory personnel or management which would remove any expectation or requirement for ABs to evaluate these personnel qualifications unless the AB includes such requirements in its state-specific regulations.
- The potential for conflict in how ABs evaluate and interpret the Technical Manager qualifications will be eliminated.
- Labs are allowed to manage their own risks from staffing choices with assessor oversight to ensure performance.

Cons:

- States are free to set their own education and experience/training qualifications in regulation, which could lead to inconsistent requirements or duplicative evaluations of secondary applicants. Note: Several NELAP ABs already have their own requirements for laboratory personnel in regulation. See Attachment 2.
- Assessor judgment will be required to determine whether number and severity of findings constitute personnel not meeting requirements.
- Assessors will need to more definitively oversee each lab’s risk management decisions.

The language below provides an example of how the requirements in the 2016 standard map to different individuals illustrating that the experience and education requirements for a Technical Manager is biased and overly prescriptive.

**Table 1. Examples of Requirements for Laboratory Staff**

<b>Requirement</b>	<b>Responsible Individual</b>
Have managerial and technical personnel who have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests, and to initiate actions to prevent or minimize such departures	Laboratory Manager
Ensure that authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed.	Technical Manager
Maintain a register of all subcontractors that it uses for tests and a record of the evidence of compliance with this Standard for the work in question.	Quality Manager
Use test methods which meet the needs of the customer and which are appropriate for the tests it undertakes.	Project Manager
The results of any calibration or verification shall be within the specifications required of the application for which this equipment is used.	Subject Matter Expert

Looking Ahead

Discussion within the Task Force crystalized the thought that individuals can gain competency through education, experience, and training. It is up to each Accreditation Body to evaluate the competency of their assessor and decide what if any training courses may be needed. It is up to each laboratory to

ensure the competency of their staff and decide what if any training courses may be needed. TNI's role should be to ensure that relevant courses are available, but not to require specific training for any individual.

The Competency Task Force will still work to establish the KSAs needed to meet the technical requirements of the standard, in order for trainers to develop classes for individuals to learn how to meet the requirements, using those KSAs. At present, the positions of Assessor, Technical Manager and QA Manager were chosen for training and possible credentialing, but if this proposal is accepted, then it becomes likely that KSAs will be established for performing the requirements rather than for the job titles themselves. That part cannot be settled until we see whether the proposal is acceptable.

## **Attachment 1: Definitions of Laboratory Staff**

**Laboratory Manager** (Owner, Laboratory Director, Department Head, General Manager): The individual responsible for the overall management of the laboratory. This individual could be a scientist, but could also be an attorney, accountant, engineer, or any other individual that meets the qualifications of the position. This person does not need to be skilled in laboratory technical issues. The Laboratory Manager may be the Technical Manager.

**Technical Manager** (Laboratory Director, Operations Manager): The individual responsible for the technical management of the laboratory, including implementation of the Quality Management System, overseeing personnel, and ensuring the laboratory facilities and equipment are adequate for activities required. Note: This individual does not need to be an expert in every test.

**Subject Matter Expert** (Technical Specialist, Group Leader): The individual who is the key resource regarding all processes involved in generating data from a specific area (e.g., microbiology, inorganic non-metals). This individual requires education and experience commensurate with the type of testing involved and must have detailed knowledge and experience in the fundamentals of each test he/she is responsible for including sample preparation, instrument calibration, analysis, quality control, identification and quantitation, reporting, and may also act as a resource to assure that data generated are fit for the purpose required by the client. This individual may have supervisory responsibilities, but this is not required.

**QA Manager** (QA Director, QA Officer): The individual responsible for the Quality Assurance aspects of the laboratory.

**Project Manager** (Customer Service Manager): The individual(s) responsible for specifying the work to be performed and reviewing the final report to ensure customer's requirements were met.

## **Attachment 2: NELAP Regulations Relating to Technical Manager**

Note: Florida, Illinois, Kansas, Minnesota, New Hampshire, Oklahoma, Oregon, Texas, and Utah have no specific regulations.

### **Louisiana**

#### **4901. Laboratory Staff for All Programs Covered by These Regulations**

A. Managerial Staff. The laboratory shall have the managerial staff with the authority and resources needed to discharge their duties. The technical director or his/her designated representative shall be a full-time member of the laboratory staff who has the authority to exercise the day-to-day supervision of the laboratory policies and procedures. The laboratory shall be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times.

#### **B. Laboratory Technical Director**

1. Academic Training. The laboratory technical director must have a bachelor's degree in science or a minimum of four years' equivalent experience in a related field.
2. Experience. The laboratory technical director must have a minimum of two years' experience in the area of environmental analysis.

#### **C. Quality Assurance Manager**

1. Academic Training. The quality assurance manager must have a minimum of a bachelor's degree in science or four years' equivalent experience in a related field.
2. Experience. The quality assurance manager must have a minimum of two years' environmental laboratory experience.
3. Reporting Authority. The quality assurance manager must have direct access to the highest level of management for decisions regarding laboratory quality assurance policy and resources. He or she must have independent authority regarding quality assurance oversight and implementation of the quality assurance program. This organizational position must not report through the technical management of the laboratory. The quality assurance manager must have the opportunity and freedom to evaluate data objectively without influence from technical or financial management.
4. Technical Knowledge. The quality assurance manager must have a general knowledge of all analytical methods that are performed by the laboratory.
5. Small Laboratories. In smaller laboratories (staff less than 10 total employees), the quality assurance manager's responsibilities may be performed by an upper level technical or operational manager of the facility. Academic and experience requirements apply.

#### **D. Supervisors**

1. Academic Training. Supervisors must have a minimum of a bachelor's degree or a minimum of four years' experience in a related field.
2. Experience. Supervisors must have a minimum of one year of experience in the area to be supervised, preferably with a minimum of six months' supervisory experience.
3. Radiochemistry. If the individual is supervisor of a radiochemistry laboratory, the individual must have a minimum of four years' experience in the field/area of radiochemistry; however, each year of additional college level training in related fields may substitute for one year of experience, up to a maximum of two years.

#### **E. Instrument Operators**

1. Academic Training. Instrument operators must have a minimum of a high school diploma or equivalent and satisfactory completion of a short course or structured in-house equivalent on the



operation of the instrument (by equipment manufacturer, professional organization, university, or other qualified training facility).

2. Experience. Instrument operators must have a minimum of six months' experience in the operation of the instrument with documentation that acceptable results are achieved by the operator (performance evaluation and quality control samples successfully analyzed).

3. On-the-Job Training. During on-the-job training to fulfill the requirement for experience, the data produced by the operator shall be deemed acceptable when validated and reviewed by a qualified instrument operator and/or laboratory supervisor.

#### F. Analyst

##### 1. Chemistry Procedures

a. Academic Training. An analyst must have a minimum of a high school diploma or equivalent, plus proper training in a methods training course or by a qualified analyst.

b. Experience. An analyst must have a minimum of six months' laboratory experience with the analysis procedure(s) with documentation that acceptable results are achieved by the analyst (performance evaluation and quality control samples successfully analyzed).

c. On-the-Job Training. During on-the-job training to fulfill the requirement for experience, data produced by the analyst shall be deemed acceptable when validated and reviewed by a qualified analyst and/or laboratory supervisor.

##### 2. Microbiological Procedures

a. Academic Training. An analyst must have a minimum of a bachelor's degree in science or four years' experience in a related field. He or she must have training in water analyses for total coliform and fecal coliform, a minimum of a high school diploma, or the equivalent, and satisfactory completion of a short course or structured inhouse equivalent on the proper techniques of analysis.

b. Experience. An analyst must have a minimum of six months' experience in microbiological analysis and techniques.

##### 3. Radiological Procedures (Gross Alpha, Gross Beta, and Specific Radionuclides)

a. Academic Training. An analyst must have a minimum of a high school diploma or equivalent, plus specialized training in standards and sample preparation, instrument calibration, calculations, and data handling.

b. Experience. An analyst must have a minimum of six months of on-the-job training. An analyst may assist in routine sample preparation and radioanalytical procedures provided that the work is supervised and validated by a qualified analyst and/or laboratory supervisor.

##### 4. Biomonitoring Procedures

a. Academic Training. An analyst must have a minimum of a high school diploma, or the equivalent, and documented training by a qualified analyst. EPA video training tapes should be utilized where available.

b. Experience. An analyst must have six months of on-the-job training with documentation of acceptable results from standard reference toxicant tests performed by the analyst.

c. On-the-Job Training. During on-the-job training to fulfill the requirements for experience, data produced by the analyst shall be deemed acceptable when validated and reviewed by a qualified analyst and/or laboratory supervisor.

G. Information on the relevant qualifications, training, and experience of the technical staff shall be maintained by the laboratory.

H. The laboratory shall provide additional training as needed in order to keep personnel current with new procedures, changes in existing procedures, and/or equipment changes or improvements.

## **New Jersey**

### 7:18-2.10 Environmental laboratory personnel requirements

(a) A certified environmental laboratory shall employ qualified personnel who possess the education, training, and experience required under this section. The laboratory shall maintain current employee records that include a resume and college transcript documenting each employee's training, experience, duties, and dates of relevant employment. The laboratory shall include at least the following personnel:

1. An environmental laboratory manager, who shall be the individual in responsible charge of the laboratory;
2. One or more supervisors, who shall be qualified in accordance with the applicable provisions of (b) below to perform the tests and analyses within the Category or Categories for which the environmental laboratory is certified, or seeks certification. The environmental laboratory manager may also serve as a supervisor provided that the manager meets the qualifications for supervisor;
3. A Quality Assurance (QA) officer. For a laboratory that is certified or seeks to be certified in any of Categories CLP01 through 6, the QA officer shall meet the applicable requirements of (b)9 below. For any other laboratory, the QA officer shall meet the applicable requirements of (b) below for a supervisor in any Category, provided however, that an individual who meets only the requirements for a supervisor in the Categories listed in (b)2 below may serve as the QA officer only in those Categories; and
4. If required under (b) below, technical support staff, who shall be qualified in accordance with the applicable provisions of (b) below for the tests and analyses within the Category or Categories for which the environmental laboratory is certified, or seeks certification.

## **New York**

Each environmental laboratory shall appoint one or more technical directors, who shall be full-time members of the laboratory's staff, and who shall exercise actual day-to-day supervision of laboratory operations, including the reporting of results. The designation of a lead technical director shall be documented; and each technical director shall have the requisite credentials and experience for an area of analysis, such as microbiology, organic chemistry, inorganic chemistry, and radiochemical analysis, and shall supervise only the areas of environmental analysis for which he or she meets the qualifications specified in this item.

Responsibilities A technical director's responsibilities shall include, but not be limited to, development and implementation of a quality system, including: monitoring standards of performance in quality control and quality assurance; monitoring the validity of analyses performed and data generated to ensure reliable data; ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory; and providing educational direction to laboratory staff.

## **Pennsylvania**

### 252.301. Laboratory supervisor.

(a) The Department will consider the laboratory supervisor of an environmental laboratory as the individual listed on the laboratory's application for accreditation for which the Department has reviewed and approved the individual's qualifications.

(b) Testing, analysis and reporting of data by an environmental laboratory shall be under the direct supervision of a laboratory supervisor.

(c) The laboratory supervisor shall certify that each test or analysis is accurate and valid and the test or analysis was performed in accordance with all conditions of accreditation. A laboratory supervisor may certify a test or analysis by signing the final laboratory report. A laboratory may use other mechanisms to certify a test or analysis, provided the mechanism is documented in the laboratory quality manual.

(d) The laboratory supervisor shall ensure that the records required by this chapter are maintained.

(e) The Department may disqualify a laboratory supervisor who is responsible for the submission of inaccurate test or analysis results.

(f) The Department will disqualify a laboratory supervisor convicted of any crime or offense related to violations of State or Federal laws or regulations related to the provision of environmental laboratory services or reimbursement for the services.

(g) An environmental laboratory may appoint one or more laboratory supervisors for the appropriate fields of accreditation for which they are seeking accreditation.

(h) An environmental laboratory shall designate another staff member meeting the qualifications of a laboratory supervisor and who is approved by the Department as described in subsection (a) to temporarily perform this function when a laboratory supervisor is absent for a period of time exceeding 21 consecutive calendar days. If this temporary absence exceeds 30 consecutive calendar days, the environmental laboratory shall notify the Department in writing under § 252.708 (relating to reporting and notification requirements).

### **Virginia**

"Technical manager (however named)" means the person who has overall responsibility for the technical operation of the environmental laboratory and who exercises actual day-to-day supervision of laboratory operation for the appropriate fields of testing and reporting of results. The title of this person may include but is not limited to laboratory director, technical manager, laboratory supervisor, or laboratory manager.