Summary of the TNI Competency Task Force Meeting Wednesday, April 28, 2021 1:00 pm Eastern

1. Welcome and Roll Call

As the new Chair, Aaren Alger, was traveling and unable to moderate the call safely, Jerry agreed to manage the meeting and he welcomed everyone. Attendance is recorded in Attachment 1. The minutes of the March 24, 2021, meeting were approved by acclamation. NOTE: the date in the header was entered by the PA after approval, as it had been omitted earlier.

2. Clarifying the Distinct Role of the Technical Manager or Subject Matter Expert

Participants began the discussion with the intent to refine and agree upon a definition for the Subject Matter Expert. The March meeting ended with the following draft definition:

An individual who is the key resource for the generation of data in the lab, who is knowledgeable and competent to make decisions related to analytical results about whether those results are fit for use. This would involve knowledge of data and instruments, SOPs, calibration and much more, probably for a specific area of the lab (chemistry or microbiology, for example) and the individual would work with the Quality Manager to assure that data generated are truly fit for use, for the purpose required by the client (this is a distinction different than the "quality of data").

The group considered the various responsibilities but then realized that it is actually the Project Manager or Customer Service Manager that determines whether data are "fit for use", based on meeting the client's needs. With further discussion, this conclusion led to the recognition that the roles within a lab (particularly a large lab) are difficult to delineate with clear boundaries. This has led to a situation where the standard as written currently requires that an AB be able to determine the specific person who meets some title called Technical Manager with specific qualifications, even though the actual duties to be performed by the person holding that title are nowhere explicitly defined.

One assessor in the conversation pointed out that ISO/IEC 17025 never assigns titles or requires qualifications, it merely states what must be done, the requirement that must be met for accreditation to be granted. Discussion proceeded with reflections about how, since the early NELAC days, education was used in the standard as a surrogate or substitute for experience in order to establish a "qualification" for the employee assigned the title, Technical Manager. This surrogate has been used to avoid an AB having to evaluate detailed experience and performance measurements to establish that one lab staff is "competent". Over the past several years, all of TNI's Expert Committees have wrestled with how to update the required qualifications for this role, and none are satisfied that the education requirements ensure that the necessary experience exists in the applicant for an open position, but ABs are bound to decline approval of a potential hire if the stated qualifications are not met. It is widely observed in the laboratory community that the Technical Manager positions are becoming difficult to fill, as grandfathered staff retire and few experienced individuals with college degrees are willing to locate in often rural, low-income areas where labs are needed (particularly drinking water and wastewater labs). This limitation is especially hard for small businesses.

There are no qualification requirements in the standard for QA Manager or any of the other titles routinely used in laboratories (Laboratory Manager, Project Manager, etc.). A participant who assesses labs pointed out that, if there are many findings related to a lab's quality system, that supports a broader, overall finding under V1M2 §5.2 that the lab management has failed to ensure the competency of certain staff. A similar approach could be used if other responsibilities, such as the duties presently assigned to the Technical Manager, are not being performed

satisfactorily. The entire concept of a standard is to establish what must be done, not to prescribe "how" it gets accomplished.

From this realization came the suggestion that V1M2 §5.2.6 could be completely omitted from the standard. Assessors would still need to establish that some individual was meeting each of the requirements of the standard, and write a finding if that were not the case. Further, any NELAP AB could choose to establish personnel requirements in its regulations (five already have such requirements, see Attachment 3 of the March 24, 2021, Task Force minutes). One participant asked that some standard for competency be established, and there was general consensus that the Task Force should continue its work to develop KSAs for meeting the requirements of the standard. Another participant suggested that some language to ensure competency be included in the standard, but leaving the specifics up to the individual labs. To appease the ABs, a similar less prescriptive set of assessor qualifications could be offered.

A paradigm change such as this will obviously require obtaining buy-in from the ABs and the Expert Committees before changing the Quality Systems module of the standard, and all present agreed that a presentation should be made to the Accreditation Council about the concept. Lynn will draft a strawman proposal for Aaren and Jerry to work from, and then distribute it to Task Force members before the next meeting and possibly sooner.

Jerry remarked that the Task Force cut a Gordian knot with this breakthrough.

5. Next Meeting

The next meeting of the Competency Task Force will be on <u>May 26, 2021, at 1 pm Eastern</u>. 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
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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	Kirstin.daigle@pacelabs.com	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
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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	Yes	13
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Mike	Michaud	Mike.michaud@abilenetx.gov	City of Abilene	No	16
Mitzi	Miller	Mitzi.Miller@nv5.com	NV5	Yes	17
Jerry	Parr	jerry.parr@nelac-institute.org	The NELAC Institute	Yes	18
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