Summary of the TNI Competency Task Force Meeting
Wednesday, August 25, 2021 1:00 pm Eastern

1. Welcome and Roll Call

Aaren welcomed everyone to the meeting. Attendance is recorded in Attachment 1. The minutes from June 23 and July 28 were approved by acclamation.

2. Planning for San Antonio Conference

Jerry and Steve Arms are trying to meet with every committee prior to the September 8 Board meeting, to get feedback on the proposed conference in San Antonio. Due to rescheduling from 2020, the scheduled dates fall during the week of the Martin Luther King, Jr., holiday, so plans are to have the training courses on Monday (the holiday itself, which primarily impacts government employees) and then the conference sessions on Tuesday through Friday. The preliminary program should be ready by mid-October.

Jerry stated that a hybrid conference is not preferable, but current plans are to record each session/meeting and make those available to registrants after the meeting, so that people unable to travel can at least hear the discussions. Assuming that COVID-19 infection levels remain in a range where the conference can take place (per public health guidance and TNI's judgement), it's likely that in-person attendees will be required to provide proof of vaccination or a negative test result once they arrive on-site.

After a brief discussion, all agreed to have a Task Force meeting joint with the Quality Systems and Chemistry committees, to be scheduled after the individual committees have met.

3. Follow-Up to Conference Session

Aaren asked for feedback from her presentation of the Technical Director proposal at conference. Please see Attachment 2 below for the full document on which Aaren's presentation was based. This document was posted in the conference portal, so that individuals registered for the TNI track would have access to the entire proposal. Aaren noted that no written comments or complaints have been received on the proposal since the July Task Force meeting, even though she requested comments during her presentation.

Discussion points included the following:

- Some are skeptical about whether ABs will actually grant exceptions to requirements stated in the standard.
- The SME role should be the "go-to for questions" person in the lab/section.
- The language in 4.1.7.2.b should be the basis for the SME/TD role.
- ABs are not inclined to remove requirements.
- Someone must have the authority to issue a "stop work" order. This seems to be a false issue, as the QA Manager or the lab director would have that authority, not only the TD (as currently defined).
- It's unclear that current TDs are supervisors. More often, they are non-supervisory group leaders. Perhaps we could add a requirement that the SME "have access" to the QAM.
- Assessors may be reluctant to call out an individual as responsible and not performing to the requirements of the standard.
- ABs may be concerned about having "incompetent" people running the labs, while in reality, many fully competent people are excluded from these positions. There is a tendency to equate credential with competence, and it's far easier to measure an employee with a checklist instead of an actual performance evaluation.

- We may need targeted outreach to NELAP ABs in order to ease resistance to shifting the TD role to SME. Perhaps jointly done with Quality Systems?
- It might be helpful to provide training for SMEs as a way of credentialing them, in order to address the ABs' need to document competency.
- Some concern was expressed about what might happen if the TNI standard drops the term Technical Manager, as that term is explicitly used in California's regulations. Either CA would need new regulations to adopt a revised standard, anyway, or perhaps the Task Force could retain the TM/TD title but redefine it or add an SME as a separate position.

A more in-depth conversation took place about potential interaction(s) with the NELAP AC, to determine the level of opposition to removing supervisory responsibilities from the TD role, and to gain a clear idea of what changes the NELAP ABs will be willing to accept, but phrased in terms of what skill set (KSAs) is needed to meet the requirements of the standard. It seems clear to Task Force members, at least, that the KSAs needed will vary according to the scope of the lab, but the requirements put into the standard should be narrow. A lab can expand the personnel requirements according to its needs, based on the analyses being performed and the caliber of analysts employed.

Aaren noted that she has heard a concern that assessors may develop for themselves an inflexible concept of what "commensurate" education and experience is, so perhaps language such as "the lab shall define…" would be better. Lynn joked that the group has now come full circle from where we began.

Aaren will revise the proposal yet again, based on this discussion, and bring it back for the September meeting. Lynn noted that two points emerged from the conference presentation – that emerging contaminants need somehow to be addressed and that we should consider whether language about a shared position (i.e., two or more people sharing the SME responsibilities) needs to be added. At this point, time was expired.

4. New Business

None.

5. Next Meeting

The next meeting of the Competency Task Force will be on **September 22, 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	Yes	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	No	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	No	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	Yes	20
Alfredo	Sotomayor	asotomayor@mmsd.com	MMSD	Yes	21
Elizabeth	Turner	Elizabeth.turner@pacelabs.com	Pace Labs, Inc.	No	22
Associate Members (for TM/TD activities):					
Debbie	Bond	DBOND@southernco.com	Alabama Power	Yes	24
Michelle	Wade	mwade@a2lawpt.org	A2LA Workplace Training	No	25
Program Administrator:					
Lynn	Bradley	The NELAC Institute	Lynn.bradley@nelac-institute.org	Yes	

Attachment 2 – Draft Proposal Provided to Conference Session Attendees

Competency Task Force Proposal to Revise Technical Manager Qualifications

July 28, 2021

This document is being provided to attendees to the 2021 Environmental Measurement Symposium to gather feedback. Please send any comments to Lynn Bradley at lynn.bradley@nelac-institute.org.

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. This is a topic with which both the Accreditation Council and the technical discipline Expert Committees have struggled, 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. The laboratory representatives on the Task Force and within the larger laboratory community expressed concern regarding the expectation that the Technical Manager shall "exercise actual day-to-day supervision of laboratory operations…" (see V1M2: 4.1.7.2.a). Often the individual who has the technical experience either does not have the requisite education or does not wish, desire, or have the skills to be a supervisor. 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, Director of Operations, Technical Manager, Quality Assurance Manager, Project Manager, Customer Service Manager and probably more. See Attachment 2.

Since 2003, the standard has defined qualifications for only the Technical Director/Manager position in a laboratory, primarily using education as a surrogate for years of experience, with a certain number of years working in a related lab activity required. It has become 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. The clause in Section 5.6.2.2(c) which allowed an exception is becoming less utilized as these individuals are retiring. (Note, the concept of giving an exemption for experienced individuals in and of itself confirms the belief that individuals without the requisite education, but with a solid background and experience, are acceptable to the industry and can be tasked with the responsibility to oversee accredited laboratories and be responsible for ensuring that laboratories meet the accreditation requirements.)

The Task Force attempted to define general roles within the laboratory and found that each laboratory operates and is structured so differently that establishing the knowledge, skills and abilities (KSAs) for even the role of a Technical Manager became an exercise in frustration and did not 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. This "risk-based" concept puts the responsibility on laboratory ownership and management to determine the individual laboratory's and client's needs, establish minimum qualifications for its own operations and personnel, and then be responsible for meeting those qualifications or else suffer the consequences if either the employee qualifications or the accreditation standards are not met (or both).

Section 6.2.2 of the 2017 version of 17025 requires laboratory management to "specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities."

A subcommittee of this Task Force, the Credentials Subcommittee, has noted the fact that individuals can gain competency by education, experience, training, or a certification program or by some combination of these.[1]

Initial Proposal

Remove the terms "Technical Manager", duties, qualifications, and exemptions from V1M2 4.1.7.2 and 5.2.6 and allow laboratories to establish the qualifications and experience of personnel to meet both the requirements of the standard and the organizational needs of the laboratory. The laboratory itself is then tasked with the responsibility to establish minimum qualifications for personnel performing tasks defined in the standard. [Note: Some states may choose to adopt into regulations specific educational or experience requirements for laboratory staff such as a Technical Manager, Quality Manager, Analyst, etc.] Attachment 1A shows what potential language might look like.

This approach would be to replace the language in 4.1.7.2 with this edited language from the drinking water certification manual (with "should" changed to "shall" and other minor edits):

> 4.1.7.2 The laboratory shall designate at least one individual who shall be a qualified professional with the technical education and experience commensurate with the size and type of the laboratory. This individual is ultimately responsible for ensuring that all laboratory personnel have demonstrated competencies for their assigned functions and that all data reported by the laboratory meet the required quality control (QC) criteria and regulatory requirements.

If any required tasks are not being performed satisfactorily, assessors would use V1M2 §5.2.1 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 findings around a particular requirement that demonstrates a lack of competency of the individual performing the task. This section states:

> "The laboratory management shall ensure the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports."

This evaluation is currently done for all other personnel (QA Manager, analysts, project managers, customer service representatives, sample collection personnel, etc.) and can be done for any other requirements in the standard. 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 some already have. See Attachment 3.
- Problem of legacy-qualified TD/TMs retiring and the difficulty finding replacement staff is more easily solved, particularly in rural and low-income areas across the nation.

[1] *Understanding Certifications,* Corporation for a Skilled Workforce, https://workcred.org/Documents/Understanding-Certifications-Report-Dec-2020.pdf

- 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.
- Laboratories are allowed to manage their own risks from staffing choices with assessor oversight to ensure performance.
- Laboratories would no longer be naming an individual who is technically ”qualified” as the TD/TM on an application or paperwork to the AB in order to achieve or maintain accreditation when that person does not actually perform the responsibilities of the position (e.g., Technical Director/Manager in name only).
- Compliance with the standard requirements related to the quality of the data would be the focus and there would be no need to determine times when the TD/TM is not in the laboratory and name a substitute during the individual’s absence (as is now required).

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 accreditation applicants. Note: California and Louisiana already have their own unique requirements for laboratory personnel in regulation. See Attachment 3.
- Assessor judgment will be required to determine whether the number and severity of findings constitute personnel not being competent to ensure the requirements of the standard are met. (This is not new but might become a priority or new focus for the assessor.)
- Assessors will need to focus more definitively on oversight of each laboratory’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

Requirement	Responsible Individual
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/or calibrations and a record of the evidence of compliance with this International 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	Subject Matter

required of the application for which this equipment is used. Expert

Feedback to Date and Other Possible Options

The Task Force presented this concept to the relevant TNI Expert Committees and the NELAP Accreditation Council. Based on that feedback, the Task Force developed two other options that we hope will address the concerns expressed by those groups.

The first option was to modify 4.1.7.2(b) to make it more generic and revise 4.1.7.2(c) to more clearly specify the duties. See Attachment 1B.

The other possible option would be to keep much of the current language, change Technical Manager to Subject Matter Expert, retain degree requirements but remove hours of a particular science, clarify the duties, and have a revised section for granting waivers for education. Revised 4.1.7.2(d) as unlikely a SME would ever be in more than one laboratory. This option also removes "management" requirements, as the SME may not be a supervisor. See Attachment 1C.

Attachments 4 and 5 contain additional language that are relevant to this discussion.

Looking Ahead

Individuals can gain competency through education, experience, and training. It is up to laboratory management to evaluate the competency of their staff and decide what if any additional, education, experience, and/or training may be needed. TNI's role should be to ensure that relevant and suitable courses are available for the KSAs that meet such competencies. It is not TNI's role 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 which, if any, of the proposals offered herein are acceptable.

Attachment 1A: Language in Original Proposal

4.1.7.2 The laboratory shall designate at least one individual who shall be a qualified professional with the technical education and experience commensurate with the size and type of the laboratory. This individual is ultimately responsible for ensuring that all laboratory personnel have demonstrated competencies for their assigned functions and that all data reported by the laboratory meet the required quality control (QC) criteria and regulatory requirements. ~~The laboratory's technical manager(s), however named, and/or his/her designee(s) shall:~~

~~a) be a member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results.~~

~~b) be experienced in the fields of accreditation for which the laboratory is seeking accreditation.~~

~~c) have duties that include:~~

~~i. monitoring standards of performance in QC and QA, and~~

~~ii. monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.~~

d) not be the technical manager(s) of more than one accredited environmental laboratory without authorization from the primary Accreditation Body. Circumstances to be considered in the decision to grant such authorization shall include:

i. the extent to which operating hours of the laboratories to be directed overlap,
ii adequacy of supervision in each laboratory, and
iii the availability of environmental laboratory services in the area served.

e) if absent for a period of time exceeding fifteen (15) consecutive calendar days shall designate another staff member meeting the qualifications of the technical manager(s) to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing; and

~~f) meet qualification requirements as specified in Section 5.2.6.1.~~

Delete Section 5.2.6 entirely.

Attachment 1B: Language in Optional Proposal 2

4.1.7.2 The laboratory's technical manager(s), however named, and/or his/her designee(s) shall:

a) be a member of the staff of an environmental laboratory who has exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results.

b) be a qualified professional with the technical education and experience commensurate with the size/type of the laboratory. ~~experienced in the fields of accreditation for which the laboratory is seeking accreditation.~~

c) have duties that include:

i. serving as the primary contact for laboratory personnel related to sample preparation, instrumental analysis, and quality control so that all data reported by the laboratory meet the required quality assurance (QA) criteria and regulatory requirements ~~monitoring standards of performance in QC and QA~~, and

ii. having at least a working knowledge of quality assurance principles. ~~monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.~~

d) not be the technical manager(s) of more than one accredited environmental laboratory without authorization from the primary Accreditation Body. Circumstances to be considered in the decision to grant such authorization shall include:

i. the extent to which operating hours of the laboratories to be directed overlap,
ii. adequacy of supervision in each laboratory, and
iii. the availability of environmental laboratory services in the area served.

e) if absent for a period of time exceeding fifteen (15) consecutive calendar days shall designate another staff member meeting the qualifications of the technical manager(s) to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing; and

~~f) meet qualification requirements as specified in Section 5.2.6.1.~~

Delete all of Section 5.2.6.

Attachment 1B: Language in Optional Proposal 3

4.1.7.2 The laboratory's subject matter expert(s)~~technical manager~~(s), however named, ~~and/or his/her designee(s)~~ shall:

~~a) be a member of the staff of an environmental laboratory who has exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results.~~

b) be a qualified professional with the technical education and experience commensurate with the size/type of the laboratory that meets the qualification requirements as specified in Section 5.2.6.1. ~~experienced in the fields of accreditation for which the laboratory is seeking accreditation.~~

c) have duties that include:

i. serving as the authority for analysis and instrumentation, sample preparation, and quality control from a specific area (e.g., microbiology, inorganic non-metals) to ensure that all data reported by the laboratory meet the required quality assurance (QA) criteria and regulatory requirements ~~monitoring standards of performance in QC and QA~~, and

ii. having at least a working knowledge of quality assurance principles. ~~monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.~~

d) not be the subject matter expert(s)~~technical manager(s)~~ of more than one accredited environmental laboratory without authorization from the primary Accreditation Body. ~~Circumstances to be considered in the decision to grant such authorization shall include:~~

~~i. the extent to which operating hours of the laboratories to be directed overlap,~~
~~ii adequacy of supervision in each laboratory, and~~
~~iii the availability of environmental laboratory services in the area served.~~

e) if absent for a period of time exceeding fifteen (15) consecutive calendar days shall designate another staff member meeting the qualifications of the subject matter expert(s) ~~technical manager(s)~~) to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing; and

f) meet qualification requirements as specified in Section 5.2.6.1.

5.2.6.1 Subject Matter Expert ~~Technical Manager~~ Qualifications

The applicable requirements for subject matter experts ~~technical managers~~ are given below.

a) Any subject matter expert ~~technical manager~~ of an accredited environmental laboratory engaged in chemical analysis shall be a person with an earned bachelor's degree from an accredited institution in the chemistry, environmental sciences, biological sciences, physical sciences or engineering, or equivalent~~, with at least twenty-four (24) college semester credit hours in chemistry~~, and at least two (2) years of experience in the ~~environmental~~ analysis of representative inorganic and organic analytical technologies ~~analytes~~ for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

b) Any subject matter expert ~~technical manager~~ of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree from an accredited institution in chemistry, environmental, biological sciences, physical sciences or engineering, or equivalent ~~chemical, physical or environmental sciences~~, or two (2) years of equivalent and successful college education, ~~with a minimum of sixteen (16) college semester credit~~

~~hours in chemistry~~ and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytical technologies for which the laboratory seeks or maintains accreditation. ~~In addition, such a person shall have at least two (2) years of experience performing such analysis.~~

~~c)~~ Any subject matter expert ~~technical manager~~ of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelor's degree from an accredited institution in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering, or equivalent with at least one college-level microbiology laboratory course and at least two (2) years of experience in the analysis of samples representative of the analyses for which the lab seeks and maintains accreditation inorganic and organic analytical technologies for which the laboratory seeks or maintains accreditation. ~~a minimum of sixteen (16) college semester credit hours in general microbiology and biology and at least two (2) years of experience in the environmental analysis of representative analytes for which the laboratory seeks to obtain or maintains accreditation~~n. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

A person with an associate's degree from an accredited institution in an appropriate field of the sciences or applied sciences, with a minimum of four (4) college semester credit hours in general microbiology and at least one (1) year of experience in the analysis of representative analytical technologies for which the laboratory seeks or maintains accreditation may be the subject matter expert ~~technical manager~~ of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, E. coli, and standard plate count. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. ~~In addition, each person shall have one (1) year of experience in microbiological analyses.~~

d) Any subject matter expert ~~technical manager~~ of an accredited environmental laboratory engaged in radiological analysis shall be a person with a bachelor's degree from an accredited institution in chemistry, environmental, biological sciences, or physical sciences or engineering, or equivalent and at least two (2) years of experience in the analysis of representative radiological analytical technologies for which the laboratory seeks or maintains accreditation. ~~with twenty-four (24) college semester credit hours of chemistry with two (2) or more years of experience in the radiological analysis of environmental samples~~. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year experience.

5.2.6.2 Subject Matter Expert ~~Technical Manager~~ Qualification Exceptions

a) The Accreditation Body may waive the need for the above specified academic credentials, on a case-by-case basis, for highly experienced analysts. The laboratory may seek an educational waiver if the proposed subject matter expert meets the following experience criteria:

i. A SME with an earned associate's degree instead of the requisite bachelor's degree shall have at least four (4) years of experience in the analysis of representative analytical technologies for which the laboratory seeks or maintains accreditation.

ii. A SME with no degree shall have at least five (5) years of experience in the analysis of representative analytical technologies for which the laboratory seeks or maintains accreditation.

b) The Accreditation Body may also waive the need for the above specified analytical experience, on a case-by-case basis, for subject matter expert(s) of a laboratory associated with a facility that only analyze samples from that facility.

c) If such a waiver is granted based on paragraphs a) or b), the Accreditation Body will prepare a written and signed justification for such a waiver.

d) Notwithstanding the educational and experience requirements in 5.2.6.1, an individual who has been credentialed as a technical manager by an organization such as the American Water Works Association (AWWA), the Water Environment Federation (WEF) or The NELAC Institute (TNI) shall be considered to possess the requisite management capability.

Attachment 2: 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 are met.

Attachment 3: California and Louisiana Regulations Relating to Technical Manager

California

§ 64812.00. Laboratory Personnel.

A laboratory shall designate a Technical Manager. Except as provided in subdivisions (b) and/or (c), below, the Technical Manager shall have at minimum:

(1) A baccalaureate degree in chemistry, biochemistry, biology, microbiology, natural or physical science, environmental engineering, sanitary engineering, or chemical engineering; and
(2) Three (3) years' experience in the analysis of chemical, biological, or microbiological samples in an environmental laboratory, prior to being designated Technical Manager, subject to the following allowances:

- A master's degree in chemistry, biochemistry, biology, microbiology, natural or physical science, environmental engineering, sanitary engineering, or chemical engineering may be substituted for one (1) year of the required experience;
- A doctorate in chemistry, biochemistry, biology, microbiology, natural or physical science, environmental engineering, sanitary engineering, or chemical engineering may be substituted for two (2) years of the required experience.

An employee of a drinking water or wastewater treatment facility, who holds a valid CWEA Laboratory Analyst certification or CA- NV/AWWA Water Quality Analyst certification, shall be deemed to meet the qualifications of Technical Manager if the grade of certification has educational and experience requirements appropriate to the scope of analytical testing in the facility's laboratory. Table 3 below states the grades of certification and the required training or experience to obtain for each grade.

Table 3: Analyst Certification grades and Required Training or Experience

CA-NV AWWA	CWEA	Required Training or Experience
I	I	Microbiological Methods
		Solids Methods
		Biochemical Oxygen Demand (BOD)
		Carbonaceous BOD Methods
II	II	Titrimetric Methods
		Methods using Specific Ion Electrode Technologies
		Colorimetric Methods
III	III	Methods using ton Chromatography
		Methods using Flame Atomic Absorption
		Methods using Graphite Furnace Atomic Absorption
IV	IV	Methods using Gas or Liquid Chromatography Technologies
		Methods using Inductively Coupled Plasma Technologies

The following shall be exempt from meeting the requirements in subdivisions (a) and (b), above:

- An individual who has continuously held the position of Technical Manager at an environmental testing laboratory since the laboratory was first accredited, provided that the accreditation date was on or before December 31, 1994; and
- A director of a public health laboratory, pursuant to Health and Safety Code sections 101150 and 101160.

The Technical Manager, and/or their designee, shall be responsible for:

- All analytical and operational activities of the laboratory, including activities of satellite or mobile laboratories under the same certificate of accreditation;
- Supervision of all personnel employed by the laboratory, including personnel assigned to work in satellite or mobile laboratories under the same certificate of accreditation; and
- The accuracy and quality of all data reported by the laboratory, including data from satellite or mobile laboratories under the same certificate of accreditation.

A laboratory shall designate a Principal Analyst(s) to be a user of Sophisticated Technology, defined in Section 64801.00(v), or a supervisor of the users of Sophisticated Technology. The Principal Analyst shall:

- Possess at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, natural or physical sciences, environmental engineering, sanitary engineering, or chemical engineering; or
- Possess a certificate of completion in a course taught by the manufacturer of the Sophisticated Technology being used or supervised by the Principal Analyst: and
- Have at least six months experience in the operation of Sophisticated Technology in the analysis of environmental samples prior to obtaining the position of Principal Analyst.

Sophisticated Technology in the laboratory shall be operated by either the Technical Manager, Principal Analyst, or other personnel designated by the Technical Manager.

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-today 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.

Attachment 4: Excerpts from the Drinking Water Certification Manual

10.1 Laboratory Personnel
The laboratory should have sufficient supervisory and other personnel, with the necessary education, training, technical knowledge, and experience for their assigned functions.

10.2 Laboratory Director/Manager or Technical Director
The laboratory director/manager should be a qualified professional with the technical education and experience, and managerial capability commensurate with the size/type of the laboratory. The laboratory director/manager is ultimately responsible for ensuring that all laboratory personnel have demonstrated proficiency for their assigned functions and that all data reported by the laboratory meet the required quality assurance (QA) criteria and regulatory requirements.

Critical Elements for Chemistry

1. Personnel

1.1 Laboratory Supervisor
The laboratory supervisor should have at least a bachelor's degree with a major in chemistry or equivalent, and at least one year of experience in the analysis of drinking water. The laboratory supervisor should have at least a working knowledge of quality assurance principles. The laboratory supervisor has the responsibility to ensure that all laboratory personnel have demonstrated their ability to satisfactorily perform the analyses to which they are assigned and that all data reported by the laboratory meet the required quality assurance and regulatory criteria.

1.2 Laboratory Analyst
The laboratory analyst should have at least a bachelor's degree with a major in chemistry or equivalent, and at least one year of experience in the analysis of drinking water. If the analyst is responsible for the operation of analytical instrumentation, he or she should have completed specialized training offered by the manufacturer or another qualified training facility or served a period of apprenticeship under an experienced analyst. The duration of this apprenticeship should be proportional to the sophistication of the instrument. Data produced by analysts and instrument operators while in the process of obtaining the required training or experience are acceptable only when reviewed and validated by a fully qualified analyst or the laboratory supervisor.

1.3 Technician
The laboratory technician should have at least a high school diploma or equivalent, complete a method training program under an experienced analyst and have six months bench experience in the analysis of drinking water samples.

1.5 Waiver of Academic Training Requirement
The certification officer may waive the need for specified academic training, on a case-by-case basis, for highly experienced analysts.

~~Chapter V~~

Critical Elements for Microbiology

1. Personnel

1.1 Supervisor/Consultant
The supervisor of the microbiology laboratory should have a bachelor's degree in microbiology, biology, or equivalent. Supervisors who have a degree in a subject other than microbiology should have had at least one college-level microbiology laboratory course in which environmental microbiology was covered. In addition, the supervisor should have a minimum of two weeks training at a Federal agency, State agency, or academic institution in microbiological analysis of drinking water or 80 hours of on-the-job training in water microbiology at a certified laboratory, or other training acceptable to the State or EPA. If a supervisor is not available (and a waiver not granted per paragraph 1.3), a consultant having the same qualifications may be substituted, as long as the laboratory can document that the consultant is acceptable to the State and is present on-site frequently enough to satisfactorily perform a supervisor's duties.

The laboratory supervisor has the responsibility to ensure that all laboratory personnel have demonstrated their ability to satisfactorily perform the analyses to which they are assigned and that all data reported by the laboratory meet the required quality assurance and regulatory criteria.

1.2 Analyst (or equivalent job title)

The analyst should perform microbiological tests with minimal supervision and have at least a high school education. In addition, the analyst should have a minimum of at least three months of bench experience in water, milk, or food microbiology. The analyst should also have training acceptable to the State (or EPA for non-primacy States) in microbiological analysis of drinking water and a minimum of 30 days of on-the-job training in drinking water microbiology under an experienced analyst. Analysts should take advantage of workshops and training programs that may be available from State regulatory agencies, professional societies, and manufacturers. Before analyzing compliance samples, the analyst should demonstrate acceptable results on unknown samples.

1.3 Waiver of Academic Training

The certification authority may waive the need for the above specified academic training, on a case-by-case basis, for highly experienced analysts. The certification authority may also waive the need for the above specified training, on a case-by-case basis, for supervisors of laboratories associated with drinking water systems that only analyze samples from that system. If such a waiver for supervisor training is granted, the certification authority will prepare a written and signed justification for such a waiver and have it available for inspection. Laboratories should also keep a copy of the waiver.

~~Chapter VI~~

Critical Elements for Radiochemistry

1. Personnel

1.1 Laboratory Supervisor

At a minimum, the laboratory supervisor should have a bachelor's degree in chemistry or an equivalent degree, and one year of experience in the measurement of radioactive analytes in drinking water. The laboratory supervisor is required to have a working knowledge of Quality Assurance (QA) and Quality Control (QC) principles and apply it to all radiochemical practices and procedures conducted in his or her laboratory. The laboratory supervisor is responsible for ensuring that all laboratory personnel have demonstrated their ability to satisfactorily perform the analyses to which they are assigned and that all data reported by the laboratory meet the required quality assurance criteria.

1.2 Laboratory Analyst

At a minimum, the laboratory analyst should have a bachelor's degree in chemistry or an equivalent degree, and one year of experience in the measurement of drinking water for radiochemical parameters. If the analyst is responsible for the operation of analytical instrumentation, he or she is required to have completed specialized training offered by the manufacturer, another qualified training facility, or served a period of apprenticeship under an experienced analyst. The duration of this apprenticeship is proportional to the sophistication of the instrument. Completion of this apprenticeship period for instrumentation should be documented and maintained in a training file.

1.3 Technician

At a minimum, the laboratory technician should have a high school diploma or its equivalent. Prior to working independently on drinking water samples, technicians should have at least 6 months bench experience in drinking water analyses and have completed method training programs in the methods they will use on a daily basis. Their completed method training should be recorded in a training file.

1.7 Waiver of Academic Training

The certification officer may waive the need for specified academic training, on a case-by-case basis, for highly experienced analysts.

Attachment 5: Excerpts from the DOD/DOE Quality Systems Manual

4.1.5 (j) At a minimum, the following laboratory management staff (however named) shall be considered key managerial personnel:

i) Management (e.g., President, Chief Executive Officer, Chief Operating Officer, Laboratory Director);
ii) Technical Managers (e.g., Technical Director, Section Supervisors);
iii) Quality Managers;
iv) Support Systems and Administrative Managers (e.g., Laboratory Information Management System (LIMS) manager, purchasing manager, project managers); and
v) Customer Services Managers.

4.2.3 Top management (including 4.1.5 j) i) through iii)) shall be responsible for:

a) defining the minimum qualifications, experience, and skills necessary for all positions in the laboratory;

b) ensuring that all laboratory technical staff have demonstrated capability in the activities for which they are responsible. Such demonstration shall be recorded;

c) ensuring that the training of each member of the technical staff is kept up-to-date (on-going) by the following:

i) each employee training file must contain a certification that the employee has read, understands, and is using the latest version of the management system records relating to his/her job responsibilities;
ii) training courses or workshops on specific equipment, analytical techniques, or laboratory procedures shall all be recorded; and
iii) review of analyst work by relevant technical managers on an on-going basis is recorded or another annual demonstration of capability is performed by one of the following:
    a. acceptable performance of a blind sample (single or double blind to the analyst);
    b. at least four consecutive laboratory control samples with acceptable levels of precision and bias. The laboratory must determine the acceptable levels of precision and bias prior to analysis; or
    c. if the above cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst.

d) recording all analytical and operational activities of the laboratory;

e) ensuring adequate supervision of all personnel employed by the laboratory;

f) ensuring that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored; and

g) recording the quality of all data reported by the laboratory.