

## **Summary of the NELAP Accreditation Council Meeting July 6, 2021**

### **1. Welcome and Introductions**

Kristin welcomed everyone to the call. Attendance is noted in Attachment 1. The minutes of June 7, 2021, were approved unanimously.

This meeting was rescheduled from the normal first Monday due to that day being the official Independence Day holiday.

### **2. Discussion of Technical Director Proposal**

TNI's Competency Task Force has crafted a new concept to address the problematic Technical Manager (Technical Director, TD) qualifications issue, and the Task Force Chair, Aaren Alger, along with Jerry Parr joined the Council to discuss this proposed concept and get feedback from the NELAP ABs. Over the previous month, one of them met with each of the relevant expert committees to discuss it and get feedback which was incorporated into the proposal brought to the Council. See Attachment 2 for the white paper describing this in more detail.

Aaren explained how the TD discussion evolved within the Task Force, from the current inflexible education and experience qualifications to thinking in terms of a subject matter expert and then, after learning that very few labs actually use the person with the title of Technical Director for the role on which the qualifications and experience are based, moving into allowing task assignments to vary in accordance with the laboratory's needs. The expectation would be that each lab would define its operating structure and the qualifications of the staff responsible for meeting the requirements set forth in Volume 1 of the TNI ELS Standard, and that assessors would then determine whether the lab is meeting the requirements with the staffing structure it has chosen, and if not, that would be a finding under V1M2 §5.2 that the lab has not ensured the staff competence.

There is general agreement that some labs, particularly small labs in rural areas, are finding it impossible to hire anyone meeting the current TD qualifications, and recognize that this is causing those labs to either contract with off-site, part-time TD personnel or else close the operational area of the lab that fails to find a qualified hire.

Discussion points were raised as noted below:

- What about secondary accreditations? This is complex. Currently, mutual recognition relies upon all ABs doing the same things in the same way, which everyone understands is not the case. It is widely assumed that legacy staff can do the jobs they full, but as those individuals age out of the workforce, replacement staff will not have the same experience base. Some states have specific personnel requirements in regulation, and those states might have to enforce their regulations for the purposes of secondary accreditation if they choose not to accept simple reciprocity. The Task Force is open to additional suggestions for this issue.
- One possibility for addressing secondary accreditations would be a system of tiered requirements. At least 4 ABs expressed support for some sort of tiered system with tradeoffs between education and experience.

- The NELAP Mutual Recognition Policy 3-100 may be able to play some role in easing this transition, with regard to secondary accreditations.
- This is a huge change for state bureaucracy to accept all at once. Is there some less drastic way to approach the problem?
- ABs are likely to want more structure than “each lab hires according to its own stated qualifications”.
- Waiver authority is available in most states but cannot be reasonably granted on a widespread basis.
- In this electronic age, there are many ways beyond education and in-lab work experience for a staff person to gain the necessary knowledge, skills and abilities to perform in the various roles required, and it’s common to rely more on experience than knowledge gained in college classes.
- The current requirement for 24 hours of chemistry courses is archaic, as one can actually obtain a PhD with fewer hours of actual chemistry.
- Coursework is just the foundation – experience in a far more valuable commodity.
- Exceptions but with structure seems to be the ideal – fewer hours of chemistry required for labs with limited scopes and/or wastewater operators, or perhaps additional years of experience in an accredited lab to substitute for education. Such “exception” structure would need to be very explicit, as the difficulty of enforcement rises quickly with lack of specificity in the standard.
- The Competency Task Force is one component of TNI’s effort to develop (optional) training that could lead to a credential in each of the skill sets needed to meet the requirements of the standard. Such a credential could reasonably qualify as one option for meeting such an exception. There is a Credentialing Subcommittee of the Task Force looking at how to award a recognizable credential upon passing a specific test for various knowledge and skills, with or without an associated training course.
- A sole-source provider of such a credential could be problematic for state government ABs.
- ABs (indeed, government in general) are risk-averse, so this proposal is a quantum leap that may be too far. It may require several 5-year revisions of the standard to reach the desired state of affairs.
- Assessors vary widely, and some may be hesitant to insist that a lab change its personnel even when the lab is clearly not meeting the requirements of the standard. Assessor consistency is crucial.
- The important outcome is that the data quality are acceptable. If ABs cannot rely on their peers to ensure that, then the problem is beyond the capability of a Mutual Recognition Policy to fix.

And the biggest unanswered question is, what about the drinking water program? The concept will be presented to the entire TNI community at conference and with that final feedback, the Task Force expects to approach the Office of Groundwater and Drinking Water’s Technical Support Center to discuss the proposal.

Aaren asked for any additional thoughts and feedback to be sent to her, Jerry and Lynn by email, prior to the next Task Force meeting on July 23. She explained that no suggestions are rejected yet but that the presentation at conference may not include all suggestions on the table, as a way of not narrowing down the possibilities for additional ideas.

Kristin thanked Aaren and Jerry for their presentation and they departed the call.

### 3. PTRL Issue

Travis stated that he has met with the small workgroup comprised of himself, Paul, Victoria and Carl to create a short document requesting that PTPEC issue a unified interpretation of FoPT tables for all, and advising PTPEC that the ABs want clear delineation of minimum required PTs for labs on FoPT tables, so that labs will know which PT to use for the method being accredited. He asked for feedback by email once the document is distributed to the Council.

## **5. New Business**

Cathy noted that Footnote 85 in the most recent Method Update Rule has been found to need further clarification based on comments in the TNI-hosted MUR webinar that were in conflict with the footnote, and advised that ABs be aware of this situation as plans are made for an implementation date. She indicated that information shared in the TNI-hosted MUR webinar was that the Standard Methods publication plans to issue a clarification.

With no further new business and time expired, the meeting was adjourned.

## **8. Next Meeting**

The next meeting of the NELAP AC will be during the second, virtual week of conference, on Monday, August 9, at 3:15 pm Eastern. State AB representatives who do not plan to register for conference should contact Lynn for information about how to participate in this meeting.

A special session (3<sup>rd</sup> Monday) teleconference meeting is planned for Monday, August 16, to consider the veto vote on SIR 390. Justification for the veto vote and any other materials needed for this session will be sent prior to the meeting.

The next regularly scheduled teleconference meeting will be on Tuesday, September 7, 2021, at 1:30 pm Eastern. This is a rescheduled date due to the Labor Day holiday falling on Monday of that week. The agenda and documents will be provided in advance.

**Attachment 1**

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	Altérnate: Elizabeth West E: <a href="mailto:elizabeth.west@la.gov">elizabeth.west@la.gov</a>	Yes
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California	Christine Sotelo <a href="mailto:Christine.Sotelo@waterboards.ca.gov">Christine.Sotelo@waterboards.ca.gov</a>	No
Guests:	Aaren Alger, Chair, TNI Competency Task Force <a href="mailto:Aaren.s.alger@gmail.com">Aaren.s.alger@gmail.com</a>  Jerry Parr, TNI Executive Director and Past Chair, TNI Competency Task Force <a href="mailto:Jerry.parr@nelac-institute.org">Jerry.parr@nelac-institute.org</a>	

## Attachment 2

### 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 1.

Since the early NELAC days, 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 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. The grandfathering clause in Section 5.6.2.2(c) which allowed an exception is becoming less utilized as these grandfathered individuals are retiring. (Note, the concept of 'grandfathering' 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 to 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 suffer the consequences if either the qualifications are not met 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.<sup>1</sup>

### Proposal

Remove the term '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

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

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.] One possible optional 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. for example) 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 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.
- 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 maintain accreditation but who does not 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 thus eliminate time taken to determine times when the TD/TM is not in the laboratory.

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 2.
- Assessor judgment will be required to determine whether the number and severity of findings constitute personnel not being competent. (This is not new but might become a priority or new focus for the assessor.)
- Assessors will need to more definitively focus 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**



<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/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 required of the application for which this equipment is used.	Subject Matter Expert

### 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 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: 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 Ion 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-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.

## **Attachment 3: 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 4: 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.