California Environmental Laboratory Accreditation Program

Environmental Laboratory

Technical Advisory Committee (ELTAC) Meeting

August 24, 2016

CALIFORNIA Water Boards
STATE WATER RESOURCES CONTROL BOARD
REGIONAL WATER QUALITY CONTROL BOARDS

Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD

NOTICE OF ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE (ELTAC) MEETING

August 24, 2016
10:00 a.m. – 5:00 p.m.
(or until completion of business)

California Environmental Protection Agency Building
1001 I Street, Sierra Hearing Room, 2nd Floor
Sacramento, CA 95814

The Environmental Laboratory Accreditation Program (ELAP) will host a meeting of its technical advisory committee, as noted above. The notice and agenda for this meeting and others can be found at www.waterboards.ca.gov/elap. For further information regarding this agenda, see below or contact ELAP at elapca@waterboards.ca.gov or (916) 323-3431.

This meeting is available via webcast at https://video.cal.epa.gov.

AGENDA

ITEM #1 - Call to Order/Roll Call

ITEM #2 - Public Comments on Items Not on Agenda
(The Committee will not take any action but will consider placing any item raised on the agenda at a future meeting.)

ITEM #3 – Summary of July 27, 2016 Meeting and Approval of Minutes

ITEM #4 – DELAPO Report

ITEM #5 – Unfinished Business – Laboratory Accreditation Standards

ITEM #6 – Close – Review Action Items

Action may be taken on any item on the agenda. The time and order of agenda items are

subject to change at the discretion of the ELTAC Chair and may be taken out of order. The meeting will be adjourned upon completion of the agenda, which may be at a time earlier or later than posted in this notice.

In accordance with the Bagley-Keene Open Meeting Act, all meetings of ELTAC are open to the public.

Government Code section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by ELTAC prior to ELTAC taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issue before ELTAC, but the ELTAC Chair may, at his or her discretion, apportion available time among those who wish to speak. Individuals may appear before ELTAC to discuss items not on the agenda; however, ELTAC can neither discuss nor take official action on these items at the time of the same meeting [Government Code sections 11125 and 11125.7(a)].

The meeting locations are accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Katelyn McCarthy at (916) 322-7902 or emailing katelyn.mccarthy@waterboards.ca.gov. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

Webcast Information

Webcast	https://video.cal.epa.gov

ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM
ELTAC MEETING
Wednesday, May 11, 2016 – 10:00 a.m.
1001 I Street
Sierra Hearing Room, 2nd Floor
Sacramento, CA 95814

Meeting Agenda

TIME	AGENDA ITEM	PRESENTER(S)
10:00am	Item #1 - **Call to Order** *Objective: Roll call.*	Andy Eaton, *Chairperson*
10:05am	Item #2 - **Public Comments on Items not on Agenda**	Open
10:10am	Item #3 – **Summary of May 11, 2016 Meeting & Approval of Minutes** *Objective: Recall previous assignments and amend or approve minutes.*	Andy Eaton
10:20am	Item #4 – **DELAPO Report** *Objective: Update members on recent developments and activities.*	Christine Sotelo
10:30am	Item #5 – **Structure for the day** *Objective: Present the agenda for the day.*	Christine Sotelo
10:40am	Item #5 cont. – **Presentation of Quality Management Systems Options -** 1. Standards in Existing Regulations 2. US EPA Quality Systems 3. The TNI Standard 4. The TNI Standard "Light" 5. Other *Objective: Provide information on quality*	1. Miriam Ghabour 2. David Kimbrough 3. Allison Mackenzie 4. Christine Sotelo 5. No scheduled speaker

	management systems to inform afternoon discussions.	
12pm-1pm	Lunch	
1:00pm	Item #5 cont. – **Recommendation on Quality Management System** *Objective: Formalize a recommendation to ELAP on which Quality Management System to include as a requirement for accreditation.*	All members
3:00pm	Item #5 cont. – **Implementation Schedule** *Objective: Formalize a recommendation to ELAP on an implementation timeline for standard recommendation.*	All members
4:00pm	Item #5 cont. – **Recommendation on Training and Assistance for Laboratories** *Objective: Formalize a recommendation to ELAP on necessary training and assistance for laboratory implementation of standard.*	All members
4:45pm	Item #6 – **Close** 1. Review Action Items *Objective: Review assignments generated during the meeting.*	Andy Eaton
5:00 pm	Adjourn	

Welcome Environmental Laboratory Technical Advisory Committee

August 24, 2016

Accomplishments from Last Meeting

- You reached a recommendation on FOT lists
  - ELAP should certify on a per-analyte basis from the list of published methods
  - Additions to the list should come from regulatory agencies
- You reached a recommendation on ELAP's technical standard
  - Will consist of all approved methods in the FOT lists and any additions by regulatory agencies
  - We have accepted
- Voted to support the development of a quality management system as a condition of accreditation for California
  - We agree
  - There are additional questions to answer today.

Primary Focus of Today's Meeting

- California's Quality Management System
  - Presentations on options
- Discussion and Recommendation
  - We need a finalized recommendation by the end of the day

ITEM 1
Call to Order/Roll Call

ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM
ELTAC MEETING
Wednesday, August 24, 2016 – 10:00 a.m.
1001 I Street
Sacramento, CA 95814

MEETING PACKET

AGENDA ITEM #1

Call to Order/Roll Call

Name	Affiliation	Type	Present
Christine Sotelo	ELAP	DELAPO	
Katelyn McCarthy	ELAP, Scribe	Scribe	
Mindy Boele	CWEA	Rep	
Jill Brodt	Brelje and Race Laboratories	Rep	
Bruce Burton	Division of Drinking Water	SRAE	
Gail Cho	CA Dept. of Fish and Wildlife	SRAE	
Stephen Clark	Pacific EcoRisk	Rep	
Ronald Coss	CWEA	Rep	
Huy Do	CASA	Rep	
Andy Eaton	Eurofins Eaton Analytical	Rep	
Miriam Ghabour	Metropolitan Water District of Southern California	Rep	
Bruce Godfrey	ACIL	Rep	
Anthony Gonzales	CAPHLD	Rep	
Rich Gossett	Physis Environmental	Rep	
David Kimbrough	Pasadena Water and Power	Rep	
Mark Koekemoer	Napa Sanitation District	Rep	
Bruce LaBelle	Dept. of Toxic Substances Control	SRAE	
Allison Mackenzie	Babcock Laboratories	Rep	
Guilda Neshvad	Positive Lab Service	Rep	
Renee Spears	State Water Resources Control Board	SRAE	

Abbreviation	Member Type
DELAPO	Designated ELAP Officer, nonvoting
Scribe	Minutes (non-member)
SRAE	State Regulatory Agency Employee, nonvoting
Rep	Representative Member, voting

ITEM 2
Public Comments on Items Not on Agenda

Public Comments on Items Not on Agenda

Members of the public may address the Environmental Laboratory Technical Advisory Committee (ELTAC) regarding items that are not contained in the meeting agenda at this time.

However, ELTAC may not discuss or take action on any item raised during this public comment session, except to decide whether to place the matter on the agenda of a future meeting [Government Code sections 11125 and 11125.7(a)].

ITEM 3
Summary of July 27, 2016 Meeting and Approval of Minutes

AGENDA ITEM #3

Approval of Minutes from July 27, 2016 Meeting

The Environmental Laboratory Technical Advisory Committee (ELTAC) is asked to review and approve the July 27, 2016 Meeting Minutes.

Attachment:
Draft Minutes from July 27, 2016 ELTAC Meeting

CALIFORNIA ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE (ELTAC)
COMMITTEE MEETING MINUTES
July 27, 2016

More information on the Environmental Laboratory Accreditation Program (ELAP) and previous ELTAC meetings can be found at http://www.waterboards.ca.gov/elap.

CALL TO ORDER

DELAPO Christine Sotelo called the meeting to order on July 27, 2016 at 10:00 a.m. at the California Environmental Protection Agency Headquarters, 1001 I Street, Conference Room 2540, Sacramento, CA and the Southern California Coastal Water Research Project, 3535 Harbor Blvd., Suite 110, Costa Mesa, CA 92626.

COMMITTEE MEMBERS PRESENT

DELAPO: Christine Sotelo
Representatives:
Mindy Boele
Jill Brodt
Stephen Clark
Ronald Coss
Huy Do
Andy Eaton
Miriam Ghabour
Anthony Gonzalez
Rich Gossett
David Kimbrough
Mark Koekemoer
Allison Mackenzie
Guilda Neshvad
State Regulatory Agency Employees:
Bruce Burton
Gail Cho
Bruce LaBelle
Renee Spears
Not Present:
Bruce Godfrey

OTHER STAFF PRESENT

Scribe: Katelyn McCarthy
ELAP: Maryam Khosravifard, Jacob Oaxaca
Division of Drinking Water: Robert Brownwood

ANNOUNCEMENT

- *Evacuation information in case the fire alarm goes off during the meeting.*
- *The Committee meeting is being webcast and recorded.*

COMMITTEE MEETING

PUBLIC FORUM

Any member of the public may address and ask question of the Committee relating to any matter within ELTAC's scope provided the matter is not on the agenda, or pending before the Advisory Committee.

No Comments

COMMITTEE BUSINESS

ITEM #1 - Call to Order/Roll Call

ITEM #2 - Public Comments on Items Not on Agenda
(The Committee will not take any action but will consider placing any item raised on the agenda at a future meeting.)

No Action Taken

ITEM #3 – Approval of Amended Minutes from June 15, 2016 Meeting

Motion: Member Gossett motioned to adopt the amended minutes.
Seconded by: Member Kimbrough
MOTION CARRIED: July 27, 2016

Aye:	Member Boele
	Member Brodt
	Member Clark
	Member Coss
	Member Do
	Member Eaton
	Member Ghabour
	Member Gonzales
	Member Gossett
	Member Kimbrough
	Member Koekemoer
	Member Mackenzie
	Member Neshvad
Nay:	None
Absent:	Member Godfrey
Abstain:	None

ITEM #4 – DELAPO Report

- ***DELAPO Christine Sotelo spoke about ELTAC's accomplishments from the last meeting:***
  - ***ELTAC recommended a process for agency and laboratory coordination when new regulatory needs emerge. The proposed process was verbally accepted by the Division of Drinking Water.***
  - ***ELTAC recommended a revised structure for the Fields of Testing Worksheets. ELAP accepted the recommendation.***
  - ***ELTAC agreed on a framework for discussing laboratory standards.***
  - ***ELTAC recommended ELAP require one Proficiency Test per year from laboratories. ELAP accepted the recommendation.***
- ***Sotelo discussed that ELAP's future training contract will include compliance assessments of drinking water laboratories where ELAP assessors will shadow a third-party contractor's experienced assessors.***
- ***Sotelo informed the committee that ELAP staff members are training to certify a new method for Shellfish. California will be the first state in the country to offer the certification.***
- ***Sotelo announced that ELAP currently has five vacant positions, four of which will be assessment staff.***
- ***Sotelo requested that ELTAC form a group to discuss and recommend a solution for improving ELAP's current Proficiency Testing scoring system.***
  - ***Action Item: It was decided the Field of Testing subcommittee would address this issue.***
- ***Sotelo requested feedback on a memo regarding new application requirements for aquatic toxicity laboratories.***
  - ***Action Item: ELAP staff member who authored the memo will confer with Member Clark on which tests the requirements apply to before sending to all ELTAC members.***
- ***Sotelo informed the committee that the formation of a subcommittee by official action would subject the subcommittee to the requirements of the Bagley-Keene Open Meeting Act.***

Motion: A motion was made by Member Boele to adjust the day's agenda by moving Member Kimbrough's presentations to 2:00pm.
Seconded by: Member Gossett
MOTION CARRIED: July 27, 2016

Aye:	Member Boele
	Member Brodt
	Member Clark
	Member Coss
	Member Do
	Member Eaton
	Member Ghabour
	Member Gonzales
	Member Gossett
	Member Kimbrough
	Member Koekemoer
	Member Mackenzie
	Member Neshvad
Nay:	None
Absent:	Member Godfrey
Abstain:	None

ITEM #5 – Committee Reports

1. Field of Testing (FOT) Subcommittee

Motion: A motion was made by Member Kimbrough to recommend that ELAP offer accreditation on a per analyte basis for all FOTs from the list of published methods, and additions to the FOTs may only be added in response to a request from the regulatory agencies.
Seconded by: Member Gossett
Amendment: Amend the recommendation to include the request that ELAP post the revised FOT lists to the program website, request public comments, and make necessary revisions prior to them becoming effective.
Seconded by: Member Boele
AMENDMENT CARRIED: July 27, 2016

Aye:	Member Boele
	Member Brodt
	Member Clark
	Member Coss
	Member Do
	Member Eaton
	Member Ghabour
	Member Gonzales
	Member Gossett
	Member Kimbrough
	Member Koekemoer
	Member Mackenzie
	Member Neshvad
Nay:	None
Absent:	Member Godfrey
Abstain:	None

MOTION CARRIED: July 27, 2016

Aye:	Member Boele
	Member Brodt
	Member Clark
	Member Coss
	Member Do

	Member Eaton
	Member Ghabour
	Member Gonzales
	Member Gossett
	Member Kimbrough
	Member Koekemoer
	Member Mackenzie
	Member Neshvad
Nay:	None
Absent:	Member Godfrey
Abstain:	None

Motion: A motion was made by Member Kimbrough to table Item 6 from the FOT Subcommittee update until a later meeting.
Seconded by: Member Gossett
MOTION CARRIED: July 27, 2016

Aye:	Member Boele
	Member Brodt
	Member Clark
	Member Coss
	Member Do
	Member Eaton
	Member Ghabour
	Member Gonzales
	Member Gossett
	Member Kimbrough
	Member Koekemoer
	Member Mackenzie
	Member Neshvad
Nay:	None
Absent:	Member Godfrey
Abstain:	None

Motion: A motion was made by Member Eaton to table the discussion of fee structure until a later meeting.
Seconded by: Member Kimbrough
MOTION CARRIED: July 27, 2016

Aye:	Member Boele
	Member Brodt
	Member Clark
	Member Coss
	Member Do
	Member Eaton
	Member Ghabour
	Member Gonzales
	Member Gossett
	Member Kimbrough
	Member Koekemoer
	Member Mackenzie
	Member Neshvad
Nay:	None
Absent:	Member Godfrey
Abstain:	None

ITEM #6 – Unfinished Business – Laboratory Accreditation Standard

1. State Agency Partner Report – Carol Wortham, DTSC

- ***An informal request was made by Member Clark that Carol Wortham amend her presentation to show that one partner agency dissented from the vote to recommend ELAP use the TNI Standard as California's laboratory accreditation standard.***

Motion: A motion was made by Member Kimbrough to move to the next item on the agenda.
Seconded by: Member Gossett
MOTION CARRIED: July 27, 2016

Aye:	Member Boele
	Member Brodt
	Member Clark
	Member Coss
	Member Do
	Member Eaton
	Member Ghabour
	Member Gonzales
	Member Gossett
	Member Kimbrough
	Member Koekemoer
	Member Mackenzie
	Member Neshvad
Nay:	None
Absent:	Member Godfrey
Abstain:	None

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2. Accreditation Standard Questions

Motion: A motion was made by Member Kimbrough that ELTAC recommend to ELAP that the technical standard for accreditation consist of all approved methods in the FOT lists and any additional technical requests to be recommended later by a regulatory agency.
Seconded by: Member Ghabour
MOTION CARRIED: July 27, 2016

Aye:	Member Boele
	Member Brodt
	Member Do
	Member Ghabour
	Member Gonzales
	Member Gossett
	Member Kimbrough
	Member Koekemoer
	Member Neshvad
Nay:	Member Coss
Absent:	Member Godfrey
Abstain:	Member Clark
	Member Eaton
	Member Mackenzie

Motion: A motion was made by Member Clark to have ELTAC support the development of a quality management system for California laboratories.
Seconded by: Member Eaton
Amendment: An amendment to the motion was made by Member Kimbrough to add that ELTAC support the development of a quality management system "*as a condition of accreditation by California ELAP*".

Seconded by: Member Clark
AMENDMENT CARRIES.

Aye:	Member Boele
	Member Brodt
	Member Clark
	Member Coss
	Member Do
	Member Eaton
	Member Gonzales
	Member Gossett
	Member Kimbrough
	Member Koekemoer
	Member Mackenzie
	Member Neshvad
Nay:	Member Ghabour
Absent:	Member Godfrey
Abstain:	None

MOTION CARRIED: July 27, 2016

Aye:	Member Boele
	Member Brodt
	Member Clark
	Member Do
	Member Eaton
	Member Gonzales
	Member Gossett
	Member Koekemoer
	Member Mackenzie
Nay:	Member Coss
	Member Ghabour
	Member Kimbrough
Absent:	Member Godfrey
Abstain:	Member Neshvad

Straw Poll: Should ELTAC recommend the TNI Standard as a foundation for ELAP's quality management system requirement for accreditation?
Yes: 5
No: 8

Motion: A motion was made by Member Kimbrough to schedule and August meeting of ELTAC in order to discuss quality management systems, implementation timelines, and implementation assistance for laboratories.
Seconded by: Member Coss
MOTION CARRIED: July 27, 2016

Aye:	Member Boele
	Member Brodt
	Member Clark
	Member Coss
	Member Do
	Member Eaton
	Member Ghabour
	Member Gonzales
	Member Gossett
	Member Kimbrough
	Member Koekemoer
	Member Mackenzie
	Member Neshvad
Nay:	None

Absent: Member Godfrey
Abstain: None

ITEM #9 - Close

- Review action items:
    a. The FOT Subcommittee will research the issue of ELAP's Proficiency Testing scoring system.
    b. ELAP staff will confer with Member Clark on the memo regarding new application requirements for toxicity laboratories prior to distribution to ELTAC members.
    c. The State Agency Partners Committee Report will be amended to show one agency dissention in the recommendation to use the TNI Standard.
    d. Katelyn McCarthy will send PDFs of all presentations directly to members following the meeting.
    e. ELAP will obtain copied of the TNI Standard for ELTAC members prior to the next meeting for discussion purposes.

ADJOURNMENT

The Committee adjourned at 5:03 pm.

ITEM 4
DELAPO Report

Christine Sotelo, CA ELAP

ELAP Progress

- Enhancing Resources
  - Assessment staff attended technical sessions at National Environmental Monitoring Conference (NEMC)
  - Emerging environmental laboratory accreditation assessor issues
- Communications
  - NEMC requested we hold a session to present different perspectives on the changes to CA ELAP
  - We were able to communicate with other state programs to gain perspective and learn

Upcoming Changes to Drinking Water reporting requirements

- Division of Drinking Water will change its reporting requirements

- Laboratories will be required to report directly to SDWIS within 3 years
  - New reporting formats will be necessary
  - “Write-On” is obsolete

- Phased in approach
  - Begin with lead and copper - 1st quarter 2017

AGENDA ITEM #4

Designated ELAP Officer (DELAPO) Report

ITEM 5
Unfinished Business

Laboratory Accreditation Standard

Structure for the Day

Structure for the day

- Before lunch - Quality Management Systems Presentations
  - Standards in Existing Regulations – Miriam Ghabour
  - US EPA Quality Systems – David Kimbrough
  - The TNI Standard – Allison Mackenzie
  - The TNI Standard – “Light” Version – Christine Sotelo
  - Other – No scheduled speaker
- After lunch - Discussion and recommendation

Recommendation Components

- Which Quality Management System should ELAP require as a condition of accreditation?
- What is an appropriate implementation schedule?
- What training and assistance should ELAP provide to laboratories?

Unfinished Business – Laboratory Accreditation Standard – Quality Management System

Attachments:

Standards in Existing Regulations

- Presentation slides, Miriam Ghabour, "Standards in Existing Regulations: Explicit & Implicit QMS Requirements", August 24, 2016
- Draft regulations, Miriam Ghabour, August 24, 2016

US EPA Quality Systems

- Presentation slides, "A Quality Management System for ELAP", David Kimbrough, August 24, 2016
- White Paper #4: *A Quality Management System for ELAP*, David Kimbrough, August 24, 2016

The TNI Standard

- Presentation slides, Allison Mackenzie, "TNI Standard & Work Plan Timelines", August 24, 2016
- White Paper, Allison Mackenzie, *In Support of Adoption of the TNI Standard*, May 11, 2016
- USEPA Memorandum, Comparison of TNI and OW Laboratory Assessment Standards, December 15, 2008
- The 2016 TNI Laboratory Accreditation Standard, Summary of changes to the 2009 version, Jerry Parr, August 4, 2016

The TNI Standard "Light"

- Presentation slides, Christine Sotelo, "TNI Light, August 24, 2016

Standards in Existing Regulations

Explicit & Implicit QMS Requirements

Current Regulations

- ELAP has Quality Management System requirements in Title 22
- Each program/agency that requires ELAP certification has additional guidance for Quality Management Systems
- Guidance documents are not explicitly referenced in Title 22, prompting ambiguity regarding the degree of their enforcement

Title 22

QMS Requirements:

- Laboratory Organization And Personnel Responsibilities
- Quality Assurance Objectives For Measurement Data
- Sampling Procedures
- Custody, Handling, And Disposal Of Samples
- Calibration Procedures And Frequency
- Analytical Procedures
- Acquisition And Reduction, Validation And Reporting Of Data
- Internal Quality Control Checks
- Performance And System Audits
- Preventive Maintenance
- Assessment Of Precision And Accuracy
- Corrective Action
- Quality Assurance Reports

Title 22

Technical Standard

- Quality assurance and quality control practices must be employed by the laboratory and shall, at least, include the quality assurance and quality control requirements specified in the test methods.
- Each piece of laboratory equipment shall meet all operational, quality assurance, quality control, and design criteria established in the method.
- Records shall be kept of all operational and maintenance activities associated with the operation of laboratory equipment.

Drinking Water Cert Manual, 5th ed.

QMS Requirements:

- Laboratory organization and lines of responsibility, including QA managers
- Training records and documentation that laboratory personnel have demonstrated proficiency for the methods they perform.
- Process used to identify clients' data quality objectives
- SOPs with dates of last revision
- Field sampling procedures
- Laboratory sample receipt and handling procedures ~ chain-of-custody procedures
- Instrument calibration procedures
- Data reduction, validation, reporting and verification
- Quality Control
- Internal and external system and data quality audits and inter laboratory comparisons
- Preventive maintenance procedures and schedules
- Corrective Action contingencies
- Record keeping procedures
- Sample rejection policy
- Control charts

Drinking Water Cert Manual, 5th ed.

Technical Standards

Detailed Requirements for the following disciplines:

- Chemistry
- Microbiology
- Radiochemistry
- Sample Collection

NPDES Compliance Inspection Manual

QMS Requirements:

- Sample handling procedures
- Approved analytical procedures ~ SOPs
- Initial Demonstration of Capability
- Records of reagent preparation, instrument calibration and maintenance, incubator temperature, and purchase of supplies
- QC checks are on materials, supplies, equipment, instrument calibration and maintenance, facilities, analyses, and standard solutions
- Documentation of any EPA-approved deviation from specified test procedures
- Standard and specific procedures for cleaning glassware and containers
- Standard operating procedures for daily operation of instruments and equipment
- Documentation of standards sources, traceable to a national standard
- Analysis run logs or instrument run logs
- Written troubleshooting procedures
- Documentation on equipment maintenance and service checks and schedules
- Control charts
- Corrective actions
- Procedures for correction of data entry errors

RCRA SW-846 Chapter 1, update 5

QMS Requirements ***(as applicable per each client's QAPP)***

- Data Quality Objectives
- Sample Custody SOP
- Sample Collection SOP
- Analytical Method SOP, including subsampling, sample preparation/cleanup, calibration, QC, and analysis
- Reagent/Standard Preparation and Traceability SOP
- Equipment Calibration and Maintenance SOP
- Corrective Action SOP
- Data Reduction SOP
- Data Reporting SOP
- Records Management SOP
- Waste Disposal SOP
- Internal QA Audits
- Data verification/validation
- Control Charts ~ "Data Quality Assessment"

NSSP Guide for the Control of Molluscan Shellfish, 2015 rev.

QMS Requirements:

- Organization and management structure of the laboratory
- Laboratory staff training program ensuring that all laboratory personnel are qualified, properly trained, and supervised
- Procedures and methods used to analyze samples ~ SOPs
- Quality control measures, their frequency and tolerance limits, for determining equipment performance
- Maintenance of records of analytical performance, quality control results, and equipment maintenance and calibration
- Internal assessment and participation in a recognized annual proficiency test program (FDA, NELEOM, etc.)
- Corrective action for any deficiencies found in the laboratory quality assurance program, laboratory operations, and laboratory performance

Conclusion

- If current QMS requirements are deemed insufficient, add more QMS requirements to ELAP regulations, such as a requirement for Data Integrity and Ethics training.
- To make the QMS stipulations found in supporting guidance documents mandatory requirements, explicitly cite them in the ELAP regulations.

Title 22:

Laboratory and Equipment.

(b) Each piece of laboratory equipment shall meet all operational, quality assurance, quality control, and design criteria established in the method(s) employed by the laboratory.

(c) Each piece of laboratory equipment shall be operated and maintained by the laboratory as required by the manufacturer's maintenance instructions for the equipment.

(d) Records shall be kept of all operational and maintenance activities associated with the operation of laboratory equipment.

Quality Assurance.

(a) Each laboratory shall develop and implement a quality assurance program to assure the reliability and validity of the analytical data produced by the laboratory. As evidence of such a program, the laboratory shall develop and maintain a quality assurance program manual.

(b) The quality assurance program manual shall address all quality assurance and quality control practices to be employed by the laboratory and shall, at least, include the quality assurance and quality control requirements specified in the test methods for which the laboratory holds, or seeks, certification. The manual shall include the following elements: laboratory organization and personnel responsibilities; quality assurance objectives for measurement data; sampling procedures (when the laboratory performs the sampling); custody, handling, and disposal of samples; calibration procedures and frequency; analytical procedures; acquisition and reduction, validation and reporting of data; internal quality control checks; performance and system audits; preventive maintenance; assessment of precision and accuracy; corrective action; and quality assurance reports.

(c) The Laboratory Director shall review, and amend if necessary, the quality assurance program and quality assurance program manual at least annually. The Laboratory Director shall also review and amend the quality assurance program and manual whenever there are changes in methods or laboratory equipment employed, in the laboratory structure or physical arrangements, or changes in the laboratory organization.

(d) A laboratory shall maintain records of the implementation of its quality assurance program, and provide those records upon request of the Department. Records shall be maintained for a minimum of three years.

Laboratory Personnel.

(a) Each laboratory shall designate a Laboratory Director. Except as provided in (b) below, no person shall be designated as a Laboratory Director unless he or she meets the following educational and experience requirements.

(1) Possesses at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science.

(2) Has at least three years experience in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples. The experience requirement shall be satisfied from relevant work experience prior to the person having obtained the position of Laboratory Director. A master's degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public hearing engineering, natural or physical science may be substituted for one year of the required experience. A doctorate in chemistry, biochemistry, environmental, sanitary or public hearing engineering, biology, microbiology, natural or physical science may be substituted for two years of the required experience.

(d) A Laboratory Director shall be responsible for:

(1) all analytical and operational activities of the laboratory, including those of any auxiliary or mobile laboratory facilities; and

(2) supervision of all personnel employed by the laboratory, including those assigned to work in any auxiliary or mobile laboratory facilities, and those persons designated as Principle Analysts; and
(3) the accuracy and quality of all data reported by the laboratory, including any auxiliary or mobile laboratory facilities.
(e) If, for any reason, a Laboratory Director leaves and is not replaced within 15 days by a person meeting the requirements specified in (a) or (b), whichever applies, a person or persons with lesser qualifications may serve as a temporary director for a period not to exceed ninety days, provided that the laboratory notifies the Department, pursuant to Section 1014(d) of the Health and Safety Code, describing the qualifications of the temporary director and receives written confirmation from the Department. An additional extension of no more than ninety days beyond the original 90-day period may be granted by the Department, provided the laboratory can document that its good-faith efforts to recruit a qualified director were unsuccessful for reason beyond its control.
(f) A Laboratory Director shall assume the position of, or shall designate another person as Principal Analyst whenever there is use of a sophisticated laboratory instrument as defined in Section 64801(k). No person shall be a Principal Analyst for a laboratory unless he or she is:
(1) the user of the sophisticated laboratory instrument; or
(2) the supervisor of the users of the sophisticated laboratory instrument.
(g) Except as provided in (h) below, no person shall be a Principal Analyst unless he or she meets the following educational and experience requirements.
(1) Possesses at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science; or
(2) Possesses a certification of participation in, and completion of, a course taught by the manufacturer of the particular sophisticated laboratory instrument which is being used or supervised by the Principal Analyst; and
(3) Has at least six months experience in the operation of a sophisticated laboratory instrument in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples, or food. This experience requirement must be satisfied from experience gained prior to obtaining the position of Principal Analyst.

Drinking water cert 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.
10.3 Quality Assurance Manager
The QA manager should be independent from the laboratory management, if possible, and have direct access to the highest level of management. The QA manager should have a bachelor's degree in science, training in quality assurance principles commensurate with the size and sophistication of the laboratory, and at least one year of experience in quality assurance. The QA manager should have at least a working knowledge of the statistics involved in quality control of laboratory analysis and a basic understanding of the methods which the laboratory employs.

11. Laboratory Quality Assurance Plan

All laboratories analyzing drinking water compliance samples must adhere to any required QC procedures specified in the methods. This is to ensure that routinely generated analytical data are scientifically valid and defensible, and are of known and acceptable precision and accuracy. To accomplish these goals, each laboratory should (EPA Order 5360.1 A2) prepare a written description of its QA activities (a QA plan). It is the responsibility of the QA manager to keep the QA plan up to date. All laboratory personnel need to be familiar with the contents of the QA plan. This plan should be submitted to the auditors for review prior to the on-site visit or should be reviewed as part of the on-site visit.

The laboratory QA plan should be a separately prepared text. However, documentation for many of the listed QA plan items may be made by reference to appropriate sections of this manual, the laboratory's standard operating procedures, (SOPs) or other literature (e.g., promulgated methods, Standard Methods for the Examination of Water and Wastewater, etc.). The QA Plan should be updated at least annually (EPA Order 5360.1 A2).

At a minimum, the following items should be addressed in each QA plan:

11.1 Laboratory organization and responsibility

• include a chart or table showing the laboratory organization and lines of responsibility, including QA managers;

• list the key individuals who are responsible for ensuring the production of valid measurements and the routine assessment of measurement systems for precision and accuracy (e.g., who is responsible for internal audits and reviews of the implementation of the plan and its requirements);

• reference the job descriptions of the personnel and describe training to keep personnel updated on regulations and methodology, and document that laboratory personnel have demonstrated proficiency for the methods they perform.

11.2 Process used to identify clients' Data Quality Objectives

11.3 SOPs with dates of last revision

- The laboratory should maintain SOPs that accurately reflect all phases of current laboratory activities
- keep a list of SOPs
- ensure that current copies of SOPs are in the laboratory and in the QA Managers files;
- ensure that SOPs are reviewed annually and revised as changes are made;
- ensure that SOPs have signature pages and revisions dated.

11.4 Field sampling procedures

• describe the process used to identify sample collectors, sampling procedures and locations, required preservation, proper containers, correct sample container cleaning procedures, sample holding times from collection to analysis, and sample shipping and storage conditions;

• ensure that appropriate forms are legibly filled out in indelible ink or hard copies of electronic data are available. See Chapters IV, V, and VI for specific items to be included;

• describe how samples are checked when they arrive for proper containers and temperature and how samples

are checked for proper preservation (e.g., pH, chlorine residual) before analysis;

• ensure that sampling protocol is written and available to samplers.

11.5 Laboratory sample receipt and handling procedures

• bound laboratory note books, if used, should be filled out in ink; entries dated and signed (A secure, password protected, electronic data base is acceptable);

• store unprocessed and processed samples at the proper temperature, isolated from laboratory contaminants, standards and highly contaminated samples and, sometimes, each other; holding times may not be exceeded;
• maintain integrity of all samples, (e.g., by tracking samples from receipt by laboratory through analysis to disposal);
• require Chain-of-Custody procedures for samples likely to be the basis for an enforcement action (see Appendix A);
• specify criteria for rejection of samples which do not meet shipping, holding time and/or preservation requirements and procedures for notification of sample originators.

11.6 Instrument calibration procedures (may reference SOP)

• specify type of calibration used for each method and frequency of use;
• describe calibration standards' source, age, storage, labeling;
• perform data comparability checks;
• use control charts and for radiochemistry, report counting errors with their confidence levels.

11. 7 Analytical procedures (may reference SOP)

• cite complete method manual;
• describe quality control procedures required by the methods that need to be followed.

11.8 Data reduction, validation, reporting and verification (may reference SOP)

• describe data reduction process: method of conversion of raw data to mg/L, picocuries/L, coliforms/100 mL,etc.;
• describe data validation process;
• describe reporting procedures, include procedures and format;
• describe data verification process;
• for radiochemistry, describe reporting of counting uncertainties and confidence levels;
• describe procedure for data corrections.

11.9 Type of quality control (QC) checks and the frequency of their use (see Chapters IV, V and VI).(may reference
SOP)

Parameters for chemistry and radiochemistry should include or reference:
• instrument performance check standards;
• frequency and acceptability of method detection limit (MDL) calculations;
• frequency and acceptability of demonstration of low level capability;
• calibration, internal and surrogate standards;
• laboratory reagent blank, field reagent blank and trip blank;
• field and laboratory matrix replicates;
• quality control and proficiency testing samples;
• laboratory fortified blank and laboratory fortified sample matrix replicates;
• initial demonstration of method capability
• use of control charts;
• qualitative identification/confirmation of contaminants.

Parameters for microbiology should include or reference:
• positive and negative culture controls;
• confirmation/verification of presumptive total coliform positive samples;
• sterility controls;
• proficiency testing and quality control samples.

11.10 List schedules of internal and external system and data quality audits and inter laboratory comparisons (may

reference SOP)

11.11 Preventive maintenance procedures and schedules

• describe location of instrument manuals and schedules and documentation of routine equipment maintenance;
• describe availability of instrument spare parts in the laboratory;
• list any maintenance contracts in place.

11.12 Corrective action contingencies

• describe response to obtaining unacceptable results from analysis of PT samples and from internal QC checks;
• name persons responsible for the various corrective actions;
• describe how corrective actions taken are documented;

11.13 Record keeping procedures

• describe procedures and documentation of those procedures;
• list length of storage, media type (electronic or hard copy);
• describe security policy of electronic databases;
• all electronic data should have software support so it may be regenerated.

If a particular item is not relevant, the QA plan should state this and provide a brief explanation. A laboratory QA plan should be responsive to the above items while remaining brief and easy to follow. Minimizing paperwork, while improving dependability and quality of data, are the intended goals.

12. Chain-of-Custody Procedures

Certified laboratories, when requested to process a sample for possible legal action against a supplier, should use an adequate chain-of-custody procedure. An example of such a procedure is found in Appendix A. The State or Region should seek input from its attorney general's office to ensure that the laboratory's procedures are adequate. The procedure used should be documented.

Chemistry of drinking water

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.

Before beginning the analysis of compliance samples, the analyst must adhere to any required QC procedures specified in the methods for blanks, precision, accuracy, sensitivity, specificity and

satisfactory analysis on unknown samples. This should be documented according to the laboratory's QA Plan.

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.

Before beginning the analysis of compliance samples, the technician must adhere to any required QC procedures specified in the methods for blanks, precision, accuracy, sensitivity, specificity and satisfactory analysis on unknown samples. This should be documented according to the laboratory's QA Plan.

1.4 Sampling Personnel

Personnel who collect samples should be trained in the proper collection technique for all types of samples which they collect. Their technique should be reviewed by experienced sampling or laboratory personnel.

1.6 Training Records

Training records should be maintained for all personnel. These should include all job-related formal education and training taken by the analyst which pertains to any aspect of his/her responsibilities, including but not limited to analytical methodology, laboratory safety, sampling, quality assurance, data analysis, etc.

4. General Laboratory Practices

4.1 General

4.1.1 Chemicals/reagents: Chemicals and reagents used must meet any requirements specified in the methods.

If not specified, then "Analytical reagent grade" (AR) or American Chemical Society (ACS) grade chemicals or better should be used for analyses in certified laboratories. Consult the currently promulgated editions of *Standard Methods for the Examination of Water and Wastewater*, part 1070 for more detailed information on reagent grades.

4.2 Inorganic Contaminants

4.2.1 Reagent water: The laboratory must have a source of reagent water having a resistance value of at least 0.5 megohms (conductivity less than 2.0 micromhos/cm) at 25 oC when required by the method. High quality water meeting such specifications may be purchased from commercial suppliers. Quality of reagent water is best maintained by sealing it from the atmosphere. Quality checks to meet specifications above should be made and documented at planned intervals based on use. Individual analytical methods may specify additional requirements for the reagent water to be used. Inorganic methods require distilled or deionized water free of the analyte(s) of interest and trace metals methods require ASTM Type 1 water.

4.2.2 Glassware preparation: Glassware cleaning requirements specified in the methods must be followed. If no specifications are listed, then glassware should be washed in a warm detergent solution and thoroughly rinsed first with tap water and then with reagent water. This cleaning procedure is sufficient for general analytical needs.

It is advantageous to maintain separate sets of suitably prepared glassware for the nitrate and mercury analyses due to the potential for contamination from the laboratory environment. Table IV-1 summarizes the cleaning procedures specified in the EPA methods.

4.3 Organic Contaminants

4.3.1 Reagent water: Reagent water for organic analysis must adhere to any required QC specified in the methods.

Most methods specify the reagent water not contain analytes of interest above their respective method detection levels (MDLs). It may be necessary to treat water with activated carbon to eliminate all interferences. Reagent water requirements of individual methods must be followed.

4.3.2 Glassware preparation: Glassware cleaning requirements specified in the methods must be followed.

Table IV-1 summarizes the cleaning procedures specified in the EPA methods.

6. Sample Collection, Handling, and Preservation

The manner in which samples are collected and handled is critical to obtaining valid data. It is important that a written sampling protocol with specific sampling instructions be available to and used by sample collectors and available for inspection by the certification officer. (Appendix A, Chain-of-Custody).

6.1 Rejection of Samples

The laboratory's rejection criteria should be documented in writing in the laboratory's QA Plan or in an SOP. The laboratory should reject any sample taken for compliance purposes which does not meet the criteria in 6.2 through 6.6.

The laboratory must (141.23(a)(4)(i))notify the authority requesting the analyses and ask for a resample. If resampling is not possible and the sample is analyzed, the sample data should be clearly identified in the data package as being unusable for its intended purpose. In addition, the inadmissibility of these sample data need to be clearly communicated to all end data users.

6.2 Sample Containers and Preservation

The type of sample container and the required preservative for each inorganic and organic chemical contaminant are listed in Table IV-6. The laboratory must measure and record the temperature of the sample when it arrives when temperature preservation is required by the method. The use of "blue ice" is discouraged because it generally does not maintain the temperature of the sample at 4°C ±2°C or less. If blue ice is used, it should be frozen at the time of sampling, the sample should be chilled before packing, and special notice taken at sample receipt to be certain the required temperature (4°C) has been maintained.

6.5 Sample Collector

The sample collector should be trained in sampling procedures and have complete written sampling instructions (SOPs) for each type of sample to be collected. The samplers are to be able to demonstrate proper sampling technique.

6.6 Sample Report Form

The sample collection report form should contain, at a minimum, the ID, location, date and time of collection, collector's name, preservative added and shipping requirements, container and volume, sample type, analysis, and any special remarks concerning the sample. Indelible ink should be used.

7. Quality Control

7.1 General Requirements

***7.1.3 Balances and Weights*:** Balance range should be appropriate for the application for which it is to be used.

Drinking water chemistry laboratories should use balances that weigh to at least 0.0001 g. The balances should be calibrated at least annually with ASTM Type I, Class 1 or 2 weights. (ASTM, 1916 Race St., Philadelphia, PA 19103) This may be done by laboratory personnel or under contract by a manufacturer's representative. We strongly recommend that laboratories have a contract to calibrate balances due to the expense of the calibration weights, and to serve as an outside QC check of the weights and balances. Weights meeting ASTM Type I, Class 1 or 2 specifications should be recertified at least every five years or if there is reason to believe damage (corrosion, nicks) has occurred.

Each day the mechanical or digital balance is used, a verification should be performed. The verification consists of a check of a reference mass at approximately the same nominal mass to be determined.

Verifications should be done each weighing session unless it can be shown that fluctuations in the environment do not affect the calibration.
Weights meeting ASTM Type 1 specifications may be used. These should be calibrated annually against the reference weights at time of balance calibration. The checks and their frequency should be as prescribed in the laboratory's QA Plan. A record of all checks should be kept and be available for inspection.
7.1.4 Color Standards: Wavelength settings on spectrophotometers should be verified at least annually with color standards. The specific checks and their frequency should be as prescribed in the laboratory's QA documents. A record of these checks should be kept as prescribed in the laboratory's QA documents and be available for inspection.
7.1.5 Temperature Measuring Devices Liquid bearing thermometers such as mercury or alcohol thermometers need to be traceable to NIST calibration and verified at least annually and whenever the thermometer has been exposed to temperature extremes. The correction factor should be indicated on the thermometer and the date the thermometer was calibrated and the calibration factor should be kept as prescribed in the laboratory's QA documents and be available for inspection. The NIST thermometer should be recalibrated at least every five years or whenever the thermometer has been exposed to temperature extremes.
Digital thermometers, thermocouples and other similar electronic temperature measuring devices should be calibrated at least quarterly. The date the thermometer was calibrated and the calibration factor should be kept as prescribed in the laboratory's QA documents and be available for inspection.
When an infrared detection device is used to measure the temperature of samples, the device should be verified at least every six months using a NIST certified thermometer over the full temperature range that the IR thermometer will be used. This would include ambient (20-30°C), iced (4°C) and frozen (0 to -5°C). Each day of use a single check of the IR should be made by checking the temperature of a bottle of water at the temperature of interest that contains a calibrated thermometer. Agreement between the two should be within 0.5°C, or the device should be recalibrated.
7.1.6 Traceability of Calibration: Calibrations of all measurement devices need to be traceable to national standards whenever applicable.
7.2.2 Quality Control Samples: At least once each quarter, the laboratory should analyze a quality control sample for the analytes they are determining in that quarter. The sample should be prepared from a source other than that from which their working standards are prepared. The sample should be in the same concentration range as the drinking water calibration curve. If errors exceed limits required in the methods, corrective action must be taken and documented, and a follow-up quality control sample analyzed as soon as possible to demonstrate the problem has been corrected.
7.2.3 Calibration Curve: Calibration requirements in the methods must be followed. If there are no calibration requirements in the method, the following are guidelines to be used. At the beginning of each day that samples are to be analyzed, a calibration curve covering the sample concentration range and all target analytes should be generated according to the approved SOP. Depending on concentration ranges, the curve should be composed of three or more points. Field measurements (e.g. pH and chlorine residual) need to be made on instruments which have been properly calibrated as specified in the method or instrument manual and checked each day of use. The less precise the measurement, the greater the number of concentrations which should be included in the calibration curve.
7.2.4 Calibration Check: The calibration for some methods is so time-consuming that 7.2.3 is impractical on a daily basis. Where the determinative time is extensive such as Methods 508/508.1, 515.1, 524.2, 525.2, etc. and the instrument is very stable, the calibration curve should be initially developed as specified in 7.2.3.
Thereafter, each day analyses are performed, this curve should be verified by analysis of at least one standard for each of the target analytes at the expected concentration range. This verification should be

done at both the beginning and end of the analyses. All checks must be within the control limits required in the method or the system is to be recalibrated as specified in 7.2.3. The concentration of the check standard should vary from day to day across the range of analyte concentrations being measured. For some methods an initial conditioning injection is to be made to deactivate active sites that may have developed overnight. Depending on the method, the blank may be appropriate for this. Specific calibration requirements in the methods must be followed if different than the above.

7.2.5 Blanks: Requirements in the methods must be followed. A laboratory reagent blank should be carried through the full analytical procedure with every sample batch. In general, results from laboratory reagent blanks should not exceed the laboratory's Minimum Reporting Limit, the lowest concentration of standard used for quantitation. (MRL).

7.2.6 Laboratory Fortified Blanks: Requirements in the methods must be followed. LFBs should be analyzed at the level specified in the method. Some methods require that a laboratory fortified blank at ten times the MDL or a mid level concentration be analyzed with each batch of samples. Precision and accuracy data should be documented for this determination. In addition, the analyst should routinely verify the minimum reporting limit for each analyte by analyzing a laboratory fortified blank at the minimum reporting level.

7.2.7 Laboratory Fortified Sample Matrix: Laboratory fortified sample matrix requirements in the methods must be met. If there are no laboratory fortified sample matrix requirements in the method, the following are guidelines to be used. The laboratory should add a known quantity of analytes to a percentage (to be described in the approved SOP) of the routine samples to determine sample matrix interference. The fortified concentration should not be less than the concentration of the sample selected for fortification unless specified by the method. If the sample concentration is unknown or less than detectable, the analyst should choose an appropriate concentration (e.g., a percentage of the MCL or mid point in the calibration range). **Over time, samples from all routine sample sources should be fortified. The procedure should be described in the SOP.** If any of these checks are not within the criteria specified in the method or control limits specified in 7.2.7, and the laboratory performance is in control, the result for that sample should be flagged to inform the data user that the results are suspect due to matrix effects.

7.2.8 Control Charts: Control charts for accuracy and precision, generated from laboratory fortified blanks (LFBs) should be maintained and used by the laboratory. Until sufficient data are available from the laboratory, usually a minimum of 20 to 30 test results on a specific analysis, the laboratory should use the control limits specified in the methods. If there are no control limits specified in the method, the limits may be statistically calibrated using the procedure below...

7.2.9 Initial Demonstration of Capability: Requirements in the methods must be followed. Before beginning the analysis of compliance samples, an initial demonstration of capability (IDC) must be performed for each method as required in the method. The IDC includes a demonstration of the ability to achieve a low background, the precision and accuracy required by the method, and determination of the method detection limit (MDL) (see below). An IDC should be performed for each instrument. It is also recommended that an IDC be performed by each analyst. In addition, it is recommended that the IDC also address the variability introduced if more than one sample preparation technician is used. Precision, accuracy and MDL should be similar for each technician. The analyst should recalculate IDCs when a change in the method, analyst or instrument is made which could affect the precision or accuracy or sensitivity. Minor changes should prompt a check to ascertain that the precision, accuracy and sensitivity have been maintained.

7.2.11 MDL Calculation: Requirements in the methods must be followed. Most methods require initial MDL calculations for all analytes and certification officers should require the laboratories to calculate their detection limits for all regulated contaminants. If there is no procedure to determine the detection

limits in the method, it should be determined in accordance with the procedure given in 40 CFR 136, Appendix B.
Sample preparation and analyses for the MDL calculation should be made over a period of at least three days to include day-to-day variation as an additional source of error. The analyst should determine MDLs initially, when any change is made which could affect the MDLs, or more frequently if required by the method. (Inorganic methods may require MDLs to be determined differently, and in all cases the methods must be followed.) In addition, the analyst must demonstrate low level capability on an ongoing basis through an MDL determination or repeated low level analyses (MRL).
7.2.12 Low Level Quantitation*:* The laboratory's minimum reporting limits (MRL) should be reported to the client along with the data. The reporting limit must be below the MCL. Laboratories should **run a LFB at their MRL every analysis day and should** not report contaminants at levels less than the level at which they routinely analyze their lowest standard. While this is a scientifically sound practice, whether it is an acceptable practice will depend on State and Federal reporting requirements. It is important for users of data to understand the statistical and qualitative significance of the data. Laboratories may be required by the States to achieve a specific MDL or quantitation limit more stringent than that required by EPA.
8. Records and Data Reporting
8.1 Legal Defensibility: Compliance monitoring data should be made legally defensible by keeping thorough and accurate records. The QA plan and/or SOPs need to (EPA Order 5360.1) describe the policies and procedures used by the facility for record integrity, retention and storage. If samples are expected to become part of a legal action, chain of custody procedures should be used (See Appendix A).
8.2 Maintenance of Records: **Public Water Systems** are required to maintain records of chemical analyses of compliance samples for 10 years (40 CFR 141.33) and lead and copper for 12 years (40 CFR 141.91). The laboratory should maintain easily accessible records for five years or until the next certification data audit is complete, whichever is longer. Changes in ownership, mergers, or closures of laboratories do not eliminate these requirements. The client water system should be notified before disposing of records so they may request copies if needed. This includes all raw data, calculations, and quality control data. These data files may be either hard copy, microfiche or electronic.
Electronic data should always be backed up by protected tape or disk or hard copy. If the laboratory changes its computer hardware or software, it should make provisions for transferring old data to the new system so that it remains retrievable within the time frames specified above. Data which is expected to become part of a legal action may need to be maintained for a longer period of time. Check with your legal counsel.
8.3 Sampling Records: Data should be recorded in ink with any changes lined through such that the original entry is visible. Data may also be kept electronically. Changes need to be initialed and dated. The following information should be readily available:
8.3.1 Date, location (including name of utility and PWSS ID #), site within the system, time of sampling, name, organization and phone number of the sampler, and analyses required;
8.3.2 Identification of the sample as to whether it is a routine distribution system sample, check sample, raw
or finished water sample, repeat or confirmation sample or other special purpose sample;
8.3.3 Date of receipt of the sample;
8.3.4 Sample volume/weight, container type, preservation and holding time and condition on receipt;
8.3.5 pH and disinfectant residual at time of sampling (if required) (from plant records);
8.3.6 Transportation and delivery of the sample (person/carrier, conditions).

8.4 Analytical Record: Data should be recorded in ink with any changes lined through such that original entry is visible. Changes need to be initialed and dated The following information should be readily available:

8.4.1 Laboratory and persons responsible for performing analysis;
8.4.2 Analytical techniques/methods used;
8.4.3 Date and time of analysis;
8.4.4 Results of sample and quality control analyses;
8.4.5 Calibration and standards information.
8.4.6 Analyst and technician Initial Demonstration of Capability documentation should be kept on file as well as results of proficiency testing.
8.5 Reconstruction of Data: Adequate information should be available to allow the auditor to reconstruct the final results for compliance samples and PT samples.
8.6 Computer Programs: Computer programs should be verified initially and periodically by manual calculations and the calculations should be available for inspection. Access to computer programs and electronic data need to be limited to appropriate personnel.

Drinking water cert manual also has additional microbiology, radiochemistry, & sample collection QMS requirements

NPDES Compliance Inspection Manual

Sample Handling Procedures

Proper sample handling procedures are necessary in the laboratory from the sample's receipt to its discard. Sample handling procedures for small permittees may differ from procedures for larger permittees because staff organizational structures and treatment facility designs vary from one facility to the next. However, proper sample handling procedures should be standardized, utilized and documented by all permittees. In evaluating laboratory sample handling procedures, the inspector should verify the following:

• The laboratory has a sample custodian.
• The laboratory area is secure and restricts entry to authorized personnel only.
• The laboratory has a sample security area that is dry, clean, and isolated, has sufficient refrigerated space, and can be locked securely.
• A minimum number of people handle the samples.
• The custodian receives all incoming samples, signs the chain-of-custody record sheet accompanying the samples and retains the sheet as a permanent record.
• The custodian performs or analyzes checks of proper preservation, container type, and holding times and documents results.
• The custodian ensures that samples are properly stored.
• Only the custodian distributes samples to personnel who are to perform analyses.
• Transfer of samples is usually document by the sample custodian.
• Care and custody records for handling samples are accurate and up-to-date.

Laboratory Analyses Techniques Evaluation

The permittee's laboratories or its contract laboratories must use uniform methods, thus, eliminating methodology as a variable when data are compared or shared among laboratories. The permittee's

laboratory must select by consulting 40 CFR Part 136 or EPA for approval of alternative methods. A permittee may only use alternative test procedures if the procedures have EPA approval, as specified by 40 CFR 136.4 and 136.5, and promulgated under Public Law (PL) 92-500.

Many standardized test procedures promulgated under 40 CFR Part 136 are covered in Methods for Chemical Analysis of Water and Wastes (USEPA 1979b). Revisions and new additions to this publication are made whenever new analytical techniques or instruments are developed. These are considered accepted after final publication in the Federal Register. The latest accepted edition of Standard Methods for the Examination of Water and Wastewater [American Public Health Association (APHA), American Water Works Association (AWWA), and Water Environment Federation (WEF)]. (The most current 40 CFR Part 136 may supersede any method or technique cited in this manual.) Other approved methods from United States Geological Survey (USGS), American Society for Testing and Materials (ASTM), and several commercial vendor methods are also reference in 40 CFR 136.

In evaluating laboratory analytical procedures, the inspector should verify the following:

• The lab follows analytical methods specified in the most current 40 CFR Part 136 and properly performs any deviations allowed by 40 CFR Part 136.

• The lab uses a QC system that conforms to the system specified in the permit or to that detailed in published Standard Methods (APHA, AWWA, and WEF) (e.g., initial demonstration of capability for organic analyses).

• The lab maintains a QC record on reagent preparation, instrument calibration and maintenance, incubator temperature, and purchase of supplies.

• The lab conducts QC checks are made on materials, supplies, equipment, instrument calibration and maintenance, facilities, analyses, and standard solutions.

• The lab maintains documentation of any EPA-approved deviation from specified test procedures.

Evaluation of Permittee Laboratory Facilities and Equipment

To verify that the proper analytical procedures are being followed, the inspector should have the responsible analyst describe each of the procedures. The inspector should be alert to any deviation from the specified analytical method. Any questions regarding the proper procedures can be resolved by referring to the cited methodology. Even simple analyses can yield invalid results if the methodology cited in 40 CFR Part 136 is not exactly followed. Certain required deviations from the approved method are cited in 40 CFR 136, notes.

Laboratory Services

The availability of laboratory services affects data reliability. The inspector should verify that the laboratory provides the following items:

• An adequate supply of laboratory pure water, free from chemical interferences and other undesirable contaminants. The lab should check water quality routinely and document it.

• Adequate bench, instrumentation, storage, and recordkeeping space.

• Clean and orderly work area to help avoid contamination.

• Adequate humidity and temperature control.

• Adequate lighting and ventilation.

• Dry, uncontaminated, compressed air when required.

• Efficient fume hood systems.

• Necessary equipment such as hot plate, incubator, water bath, refrigerator for samples, pH meter, thermometer, and balance.
• Electrical power for routine laboratory use and, if appropriate, voltage-regulated sources for delicate electronic instruments.
• Emergency equipment, fire extinguisher, eye wash station, shower, first aid kit, gloves, and goggles.
• Vibration-free area for accurate weighings.

The inspector should also check that the lab uses proper safety equipment (lab coats, gloves, safety glasses, goggles, and fume hoods) where necessary. The laboratory should have a fire extinguisher, eye wash station, shower, and first aid kit. The inspector should document any problems and refer to the proper authority [e.g., Occupational Safety and Health Administration (OSHA)].

Instruments and Equipment

Instrumentation is extremely important in the analytical laboratory. To a certain extent, analytical instrumentation is always developmental; manufacturers are continually redesigning and upgrading their products, striving for miniaturization, enhanced durability and sensitivity, and improved automation. In evaluating laboratory instruments and equipment, the inspector should verify the following:

• The lab follows standard and specific procedures for cleaning glassware and containers are followed. Chapter Two of EPA's *NPDES Compliance Monitoring Inspector Training Laboratory Analysis Module* (April 1990) contains detailed information on glassware cleaning.
• The lab has written requirements (e.g., standard operating procedures) for daily operation of instruments and equipment which are easily accessible and the staff follow them.
• Standards and appropriate blanks are available from suppliers to perform standard calibration procedures. The lab should use standard concentrations that closely bracket actual sample concentrations. Sources of standards are documented and where possible, traceable to a national standard [e.g., National Institute of Standards and Technology (NIST)].
• Records of each set of analysis performed including the order in which calibration, QA and samples were analyzed (i.e., analysis run logs or instrument run logs).
• Lab has written troubleshooting procedures are available to identify common equipment malfunctions.
• Lab follows written schedules for replacement, cleaning, checking, and/or adjustment by service personnel.
• Lab maintains documentation on equipment maintenance and service checks.

Commonly used analytical instruments include analytical balances, pH meters, dissolved oxygen meters, conductivity meters, turbidimeters, spectrophotometers, atomic absorption spectrophotometers, organic carbon analyzers, selective ion analyzers, gas-liquid chromatographs, titrimetric analyses, and temperature controls. Chapter Two of EPA's *NPDES Compliance Monitoring Inspector Training Laboratory Analysis Module*. (April 1990) includes a detailed discussions on these instruments.

Maintenance of laboratory facilities and equipment is an important factor in laboratory QA. Qualified service checks should be performed and documented.

<u>Supplies</u>

Chemical reagents, solvents, and gases are available in many grades of purity, ranging from technical grade to various ultrapure grades. The purity of the materials required in analytical chemistry varies with the type of analysis. The parameter being measured, the analytical method, and the sensitivity and specificity of the detection system determine the purity of the reagents required. Do not use reagents of lesser purity than that specified by the method. In evaluating laboratory supplies, the inspector should verify that the laboratory:

Uses the required reagent purity for the specific analytical method.
• Stores standard reagents and solvents according to the manufacturer's directions.
• Checks working standards frequently to determine changes in concentration or composition.
• Verifies concentrations of stock solutions before being used to prepare new working standards.
• Date supplies with limited shelf life upon receipt and observe shelf-life recommendations, including the discard date on the container and the storage requirements.
• Prepare and standardize reagents against reliable primary standards.
• Label standards and reagents properly including the date of preparation, concentration and the analyst's identification.
• Store standards and reagents in appropriate containers and under required method conditions. If conditions are not specified, standards and reagents are stored according to 40 *CFR* Part 136, Table II. See Chapter Five, Sampling, Table 5-3.
• Check the accuracy of purchased solutions as per method requirements.
• Use clean containers of suitable composition with tight-fitting stoppers or caps for storage.
• Discard reagents when signs of discoloration, formation of precipitates, or significant changes in concentrations are observed.
• Prepare stock solutions and standards using volumetric glassware.

Quality Assurance and Quality Control

Evaluation of the Precision and Accuracy of the Permittee Laboratory

The purpose of laboratory control procedures is to ensure high-quality analyses by the use of control samples, control charts, reference materials, and instrument calibration. The laboratory must initiate and maintain controls throughout the analysis of samples. Specifically, each testing batch must contain at least one blank, standard, duplicate, and spiked (as applicable) sample analysis. When a batch contains more than 10 samples, every tenth sample should be followed by a duplicate and a spike (as applicable).

The precision of laboratory findings refers to the reproducibility or degree of agreement among replicate measurements of the same quantity. The closer the numerical values of the measurements come to each other, the more precise are the measurements. In a laboratory QC program, precision is determined by the analysis of actual samples in duplicate. These may represent a range of concentrations and a variety of interfering materials usually encountered during the analysis. Accuracy refers to the degree of difference between observed values and known or actual values. The closer the value of the measurement comes to the actual value, the more accurate the measurement is. The accuracy of a method can be determined by analyses of samples to which known amounts of reference standards have been added (spiked samples).

In evaluating the precision of the measurement process, the inspector should verify that:
• The lab introduces control samples into the train of actual samples to monitor the performance of the analytical system. Control samples include any digestions, extractions, distillations and other sample preparations as for sample analyses.
• Perform duplicate analyses with each batch of samples to determine precision. In general, 10 percent of the samples should be duplicated.
• Prepare and use precision control charts or other statistical techniques for each analytical procedure. Develop precision control charts by collecting data from a minimum of 15 to 20 duplicate samples (run in controlled conditions) over an extended period (e.g., 10 to 20 days). Statistical methods include calculation of mean, standard deviation, and variance to define the range and variability of the data.
• Take corrective actions when data fall outside the warning and control limits.
• Document out-of-control data, the situation, and the corrective action taken.
In evaluating accuracy, the inspector should verify that the laboratory:
• The lab introduces spiked samples into the train of actual samples at least 10 percent of the time to monitor the performance of the analytical system.
• The lab uses spiked samples to monitor accuracy in each sample batch. -The amount of additive is appropriate to the detection limit and sample concentration.
• Prepare and use accuracy control charts for each analytical procedure. The lab should develop accuracy control charts by collecting data for a minimum of 15 to 20 samples over an extended period of time.
-Establish accuracy limits (as % recovery) based on standard deviations whose upper and lower control limits are established at three times the standard deviation above and below the central line.
-Establish the upper and lower warning limits at twice the standard deviation above and below the central line. Note: Some parameters have a defined warning limit required by 40 CFR Part 136.
-Take corrective actions when data fall outside the warning and control limits.
-Document out-of-control data or situation and the corrective action taken.
Evaluation of Permittee Data Handling and Reporting
An analytical laboratory must have a system for uniformly recording, correcting, processing, and reporting data. The inspector should verify that the laboratory:
• Uses correct formulas to calculate the final results.
• Applies round-off rules are uniformly.
• Establishes significant figures for each analysis.
• Cross-checking calculations provisions are available.
• Determine control chart approaches and statistical calculations for the purposes of QC and reporting.
• The laboratory report forms provide complete data documentation and permanent recording, and they facilitate data processing.
• The program for data handling provides data in the form/units required for reporting.
• Maintain laboratory records for a minimum of 3 years (or longer and made available if requested by EPA or the State).
Keeps laboratory notebooks or pre-printed data forms that are bound permanently to provide good documentation, including the procedures performed and the details of the analysis, such as the original value recorded, correction factors applied, blanks used, and the reported data values. The dated notes

indicate who performed the tests and include any abnormalities that occurred during the testing procedure. Laboratory maintains the notes as a permanent laboratory record.

• Procedures for correction of data entry errors are defined. Original data entries can be read and the individual(s) making the corrections are clearly identified.

• Back up computer data with duplicate copies (i.e., electronic and hardcopy).

• Proper data handling and reporting procedures are implemented by all contract laboratories performing sample analyses.

• Maintain data records that allow the recalculation of all results reported by the laboratory(ies) from the original unprocessed results (i.e., raw data) to the final results sent to EPA and the regulatory authority for a minimum of three (3) years.

Evaluation of Permittee Laboratory Personnel

Analytical operations in the laboratory vary in complexity. Consequently, laboratory should clearly define work assignments in the laboratory. All analysts should be thoroughly instructed in basic laboratory operations. Those persons performing complex analytical tasks should be qualified and properly trained. All analysts must follow specified laboratory procedures and be skilled in using the laboratory equipment and techniques required for the analyses assigned to them. In evaluating laboratory personnel, the inspector should consider the following factors:

• Adequacy of training

• Skill and diligence in following procedures

• Skill and knowledge of staff in using equipment and analytical methods (particularly for complex equipment such as gas chromatography)

• Precision and accuracy in performing analytical tasks

• Assignment of clearly defined tasks and responsibilities.

Evaluation of Contract Laboratories

When the permittee contracts with the laboratory to analyze samples, the inspector may need to evaluate the laboratory practices at the contracted laboratory. The practices can also be evaluated by other designated EPA inspectors. If a deficiency is identified at a contract laboratory, the permittee is responsible for the deficiency and will be notified.

Included is a LABORATORY QUALITY ASSURANCE CHECKLIST

RCRA SW-846 Chapter 1 & EPA Method 8000D

QSM and QC for haz waste labs

A Quality Management System for ELAP

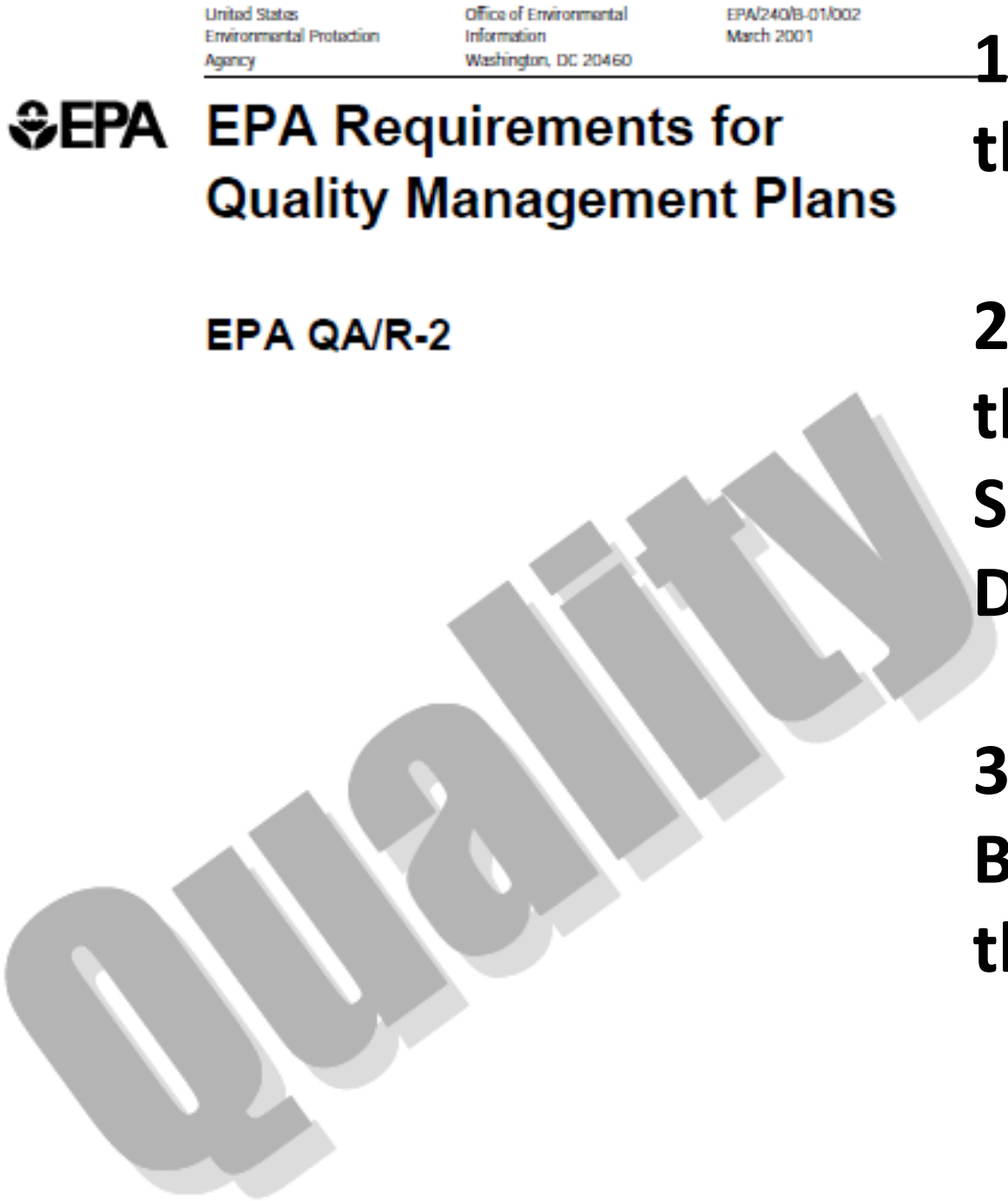
ELTAC Meeting August 24, 2016

ELTAC

- June Meeting – Only 1 PT Per Year which effectively excludes TNI as a QMS
- July Meeting
  - Technical Standard to be the Methods Only
  - Quality Management System
  - No TNI
- August Meeting
  - Non-TNI QMS
  - Strawman Based on USEPA QMS

Quality System

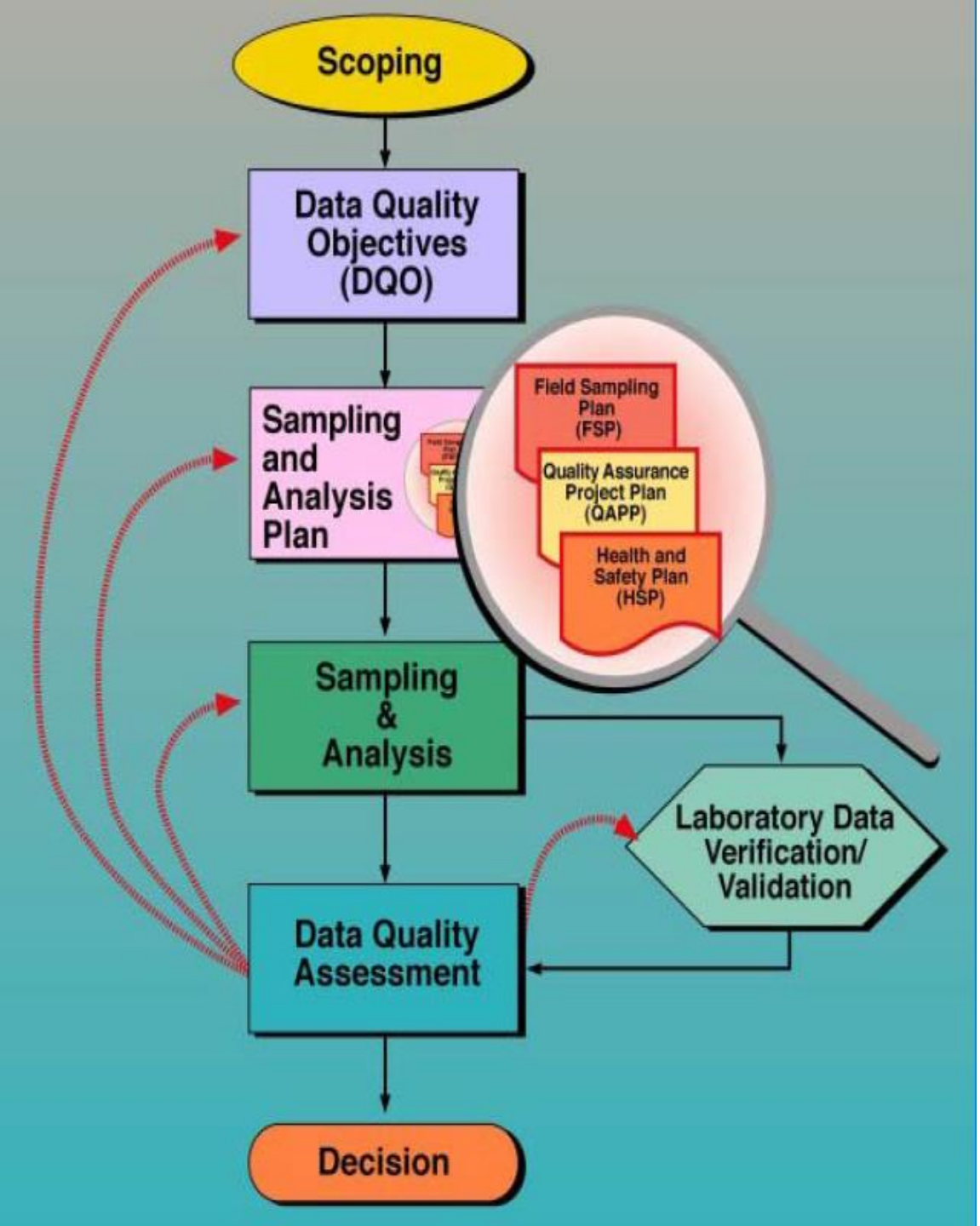
- USEPA
  - The EPA Quality System encompasses management and technical activities related to the planning, implementation, assessment and improvement of environmental programs that involve:
  - the collection, evaluation and use of environmental data
  - the design, construction and operation of environmental technology
- It is about providing Regulators with Data of Sufficient Quality to make Public Health Decisions



1) This is the QMS that USEPA Uses

2) This is the QMS that many of the SWRCB & DTSC Data users use

3) It makes sense to Base ELAP's QMS on this



1) The Starting Point of a Quality System Is the DQOs

2) The Axis on which a Quality System Turns is the DQA

3) Laboratory work is only one Part of the Quality System, Not Even the Majority

Quality Management System

For ELAP's QMS, Just Some Parts of the EPA's QMS need to be used, not all of it.

Objective

- Create an Accreditation Standard which allows laboratories to support the Quality Management Systems of the California Environmental Regulatory Agencies.
- Specifically require laboratories to incorporate Measurement Quality Objectives of Data Users into their activities

Sources

California's Current Regulations

California's 2005 Draft Regulations

EPA QA-R/2

Laboratory Certification Manual

Wisconsin's Regulations

Virginia's Regulations

Pennsylvania's Regulations

New Jersey's Regulations

Straw Man

Article A – Definitions
Article B – Purposes
Article C – Accreditation Process
Article D – Quality Management Systems
Article E – Measurement Quality Objectives
Article F – Personnel
Article G – Facilities and Equipment
Article H – Required Tests Methods
Article I – Fields of Accreditation
Article J – Quality Assurance Manual
Article K – Standard Operating Procedures
Article L – Records Retention
Article M – Standards
Article N – Sample Handling
Article O – Corrective Actions
Article P – Notification and Reporting
Article Q – On-Site Assessment

Article A - Definitions

1. **"Data User"** means an individual or group within a State regulatory agency that has unique data quality objectives and measurement quality objectives.
2. **"Measurement Quality Objective"** or "MQO" is an individual performance or acceptance goals for a laboratory determined by a data user.
3. **"State regulatory agency"** means an agency that requires the analysis of environmental samples that has been established under regulatory and/or statutory requirements by the State Water Resources Control Board (SWRCB), Regional Water Quality Control Boards (RWQCBs), the Department of Toxic Substances Control (DTSC), the California Environmental Protection Agency (Cal/EPA), the Department of Health Services (DHS), the Department of Food and Agriculture (DFA), Department of Fish and Wildlife (DFW), or any successor agencies.

Article B - Purpose

(1) The purpose of this chapter is to protect public health, safety, welfare and the environment by ensuring the accuracy, precision, representativeness, comparability, completeness, sensitivity, and reliability of data generated by environmental laboratories by establishing an accreditation program for environmental laboratories which report results to California state regulatory agencies.

(2) To link the data quality needs of the data users of the California state regulatory agencies to the laboratories that analyze sample through measurement quality objectives

(3) To establish an accreditation program for laboratories performing analyses for California state regulatory agencies;

(A) State Water Resources Control Board – Division of Drinking Water

(B) State Water Resources Control Board – Division of Water Quality / Regional Water Quality Control Boards

(C) Department of Toxic Substances Control

(D) Department of Food and Agriculture

(E) Department of Public Health

(F) Department of Fish and Wildlife (DFW)

Article C – Accreditation Process

SECTION 2 Application for Accreditation.

(a) To apply for an initial, renewed, or amended ELAP certificate, a laboratory shall submit an application to ELAP that includes the following:

(1) Details on the laboratory's type, location, contact information and ownership;

(2) Qualifications of personnel, addressing the requirements in Article F including, Laboratory Director, Supervisors, and Analytical Specialist(s);

(3) FoA(s) and/or UoA(s) for which accreditation is being requested;

(4) A list of all California State regulatory agencies and data users with unique measurement quality objectives.

(5) Quality assurance manual pursuant to Article I for ELAP accreditation

Article D – Quality Management System

(c) Laboratories shall conduct their analytical activities under a quality system that incorporates the provisions of this section. The quality system must incorporate the measurement quality objectives of the appropriate data user from California state regulatory agency.

(1) Laboratories accredited in Fields of Accreditation 101 – 106 and 129 shall use measurement quality objectives used by the data users of the State Water Resources Control Board - Division of Drinking Water Programs.

(d) Measurement quality objectives may vary with different projects and programs from different data users in different California state regulatory agencies may be found in Quality Assurance Project Plans, Sampling and Analysis Plans, or other similar documents.

(e) If no measurement quality objectives are available, laboratories shall use the measurement quality objectives identified in Article E.

Article E

(a) As identified in Article D of this chapter accredited laboratories are required to incorporate the measurement quality objectives of the data users in California state regulatory agency to which the results are to be reported. However not all data users and California state regulatory agencies have data quality objectives for every sample submitted for analysis. This Article establishes the measurement quality objectives for laboratories to use when the California regulatory agency or data user does not provide them.

(b) Laboratories will use the appropriate quality control procedures identified in the approved methods identified in unit of accreditation for which the laboratory is accredited and which the data user has requested.

Article E

(c) Those units of accreditation which identify methods that do not have their own quality control requirements shall use the following measurement quality objectives.

(1) Negative Controls shall be processed along with and under the same conditions, including all sample preparation steps, as the associated samples in a preparation batch. The purpose of negative controls is to identify contamination.

(Method Blanks, Negative Control Cultures, &c)

(2) Positive Controls shall be processed along with and under the same conditions, including all sample preparation steps, as the associated samples in a preparation batch. The purpose of positive controls is to identify contamination or loss of analyte.

(Laboratory Fortified Blanks, Positive Control Cultures, &c)

Article F - Personnel

(a) The laboratory shall have management and analytical staff with education, training or experience that allows them to comply with the requirements of this chapter and the **measurement quality objectives** of the particular **data user** or California **state regulatory agency** to which they are reporting results.

Article G – Facilities & Equipment

(a) Utilities are maintained to allow the laboratory equipment to function and produce analyses for each unit of accreditation for which the laboratory is accredited and meeting for the measurement quality objectives for the data users and California state regulatory agency to which the results are to be reported to;

(b) Ventilation and environmental control are maintained to ensure that analytical results do not exceed quality control limits as specified in the approved test methods or in the laboratory's quality assurance manual consistent with Article I and meeting for the measurement quality objectives for the California state regulatory agency to which the results are to be reported to;

(c) The potential for sample contamination is minimized; and

(d) Analytical equipment conforms to analytical method requirements and allows compliance with the appropriate measurement quality objectives.

Article H – Test Methods

(a) Any laboratory requesting accreditation from the ELAP for Units of Accreditation in Fields of Accreditation 101 through 106 and/or 128 as identified in Article J, shall employ those methods identified in H&SC 100852 or as identified by the Division of Drinking Water for regulatory compliance purposes.

Article I – Quality Assurance Manual

(c)The quality assurance manual shall address all quality assurance and quality control practices to be employed by the laboratory and shall at least, include the quality assurance and quality control requirements specified in the test methods in the UOAs for which the laboratory holds, or seeks, certification. The quality manual shall include, address or refer to, at a minimum, the following elements:

(1) A description of the Quality Management System consistent with Article D, including.

(A) A list of all FoAs and UoAs consistent with Articles H and J.

(B) A list of all data users from California state regulatory agencies to which the laboratory submits results consistent with the information in the application for accreditation in Article C.

(C) A list of all measurement quality objectives consistent with Article E

(D) A list of all SOPs consistent with Article K

Article J – Fields of Accreditation

Article J Fields of Accreditation

Pursuant to Article C of this Chapter, a laboratory seeking accreditation shall specify the individual units of accreditation (UoAs) within the Fields of Accreditation (FoAs) in Table 1

Table 1

Fields of Accreditation

FOA	State Regulatory Agency	FOA Name
101	SWRCB – Division of Drinking Water	Microbiology
102	SWRCB – Division of Drinking Water	General Physical and Inorganic Tests
103	SWRCB – Division of Drinking Water	Spectroscopy and Ion Chromatography
104	SWRCB – Division of Drinking Water	Volatile Organic Compounds
105	SWRCB – Division of Drinking Water	Semi-Volatile Organic Compounds
106	SWRCB – Division of Drinking Water	Radiochemical Techniques
107	SWRCB – RWQC – DFW	Microbiology
108	SWRCB – RWQC – DFW	General Physical and Inorganic Tests
109	SWRCB – RWQC – DFW	Spectroscopy and Ion Chromatography
110	SWRCB – RWQC – DFW	Volatile Organic Compounds
111	SWRCB – RWQC – DFW	Semi-Volatile Organic Compounds
112	SWRCB – RWQC – DFW	Radiochemical Techniques
113	SWRCB – RWQC – DFW	Whole Effluent Toxicity
114	Department of Toxic Su (Ctrl) ol	Spectroscopy and Ion Chromatography
115	Department of Toxic Substances Control	Waste Extraction Test
116	Department of Toxic Substances Control	Volatile Organic Compounds
117	Department of Toxic Substances Control	Semi-Volatile Organic Compounds
118	Department of Toxic Substances Control	Radiochemical Techniques
119	Department of Toxic Substances Control	Whole Effluent Toxicity
120	Department of Toxic Substances Control	Physical Properties of Hazardous Waste
121	Department of Toxic Substances Control	Bulk Asbestos Analysis of Hazardous Waste
122	Reserved	
123	Department of Food and Agriculture	Inorganic Chemistry
124	Department of Food and Agriculture	Pesticide Residues by GC-MS
125	Department of Food and Agriculture	Pesticide Residues by GC
126	Reserved	
127	Department of Public Health	Shellfish Sanitation
128	Reserved	
129	SWRCB – Division of Drinking Water	Cryptosporidium

Article K – Standard Operating Procedures

(a) To obtain and maintain ELAP accreditation, each laboratory shall establish, have available for review by ELAP, and implement a quality management system consistent with Article D for all UoA for which it seeks, or is maintaining, accreditation which is summarized and described in a quality assurance manual:

(c)The quality assurance manual shall address all quality assurance and quality control practices to be employed by the laboratory and shall at least, include the quality assurance and quality control requirements specified in the test methods in the UOAs for which the laboratory holds, or seeks, certification. The quality manual shall include, address or refer to, at a minimum, the following elements:

(1) A description of the Quality Management System consistent with Article D, including.

(A) A list of all FoAs and UoAs consistent with Articles H and J.

(B) A list of all data users from California state regulatory agencies to which the laboratory submits results consistent with the information in the application for accreditation in Article C.

(C) A list of all measurement quality objectives consistent with Article E

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Article L - Records

(a) The laboratory shall establish procedures to control and manage all records and documents that form part of its quality system and that are required to demonstrate compliance with this chapter.

(b) The procedures shall be written and consistent with Article K and be part of the Quality Assurance Manual described in Article I.

(c) Each laboratory shall maintain comprehensive records of all laboratory activities, including original observations, calculations and derived data, calibration records and copies of test reports for a minimum of five (5) years

(d) The department may require in writing that records be retained for a longer period than that specified in paragraph (c) if ELAP or a data user from a California state regulatory agency has initiated legal action involving test results or the certification or registration status of the laboratory.

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Article M - Standards

(a) The laboratory shall ensure that results of analyses can be linked to all the standards and reagents used to derive results. Standards and reagents used in analyses shall conform to the purity specifications contained in approved methods identified in the units of accreditation for which the laboratory is accredited. When approved methods do not specify the purity of the standards and reagents to be used, the laboratory shall choose standards and reagents of sufficient purity to ensure the results consistent with **measurement quality objective** identified in Article E.

(b) The laboratory shall certify the accuracy of all reference materials used to calibrate or verify the calibration of analytical support equipment. Reference materials shall be calibrated by a body independent of that in charge of analytical operations that can provide traceability to primary standards maintained by National Institute of Standards and Technology.

(c) When reference materials traceable to NIST are not produced, manufactured or commercially available, the laboratory shall use materials of a quality that will ensure the accuracy of the calibrated or verified support equipment for its intended use and consistent with the **measurement quality objectives** in Article E.

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Article N – Sample Handling

(a) The laboratory shall have and follow a written policy that clearly outlines the conditions under which samples will be accepted or rejected for analysis, or under which associated reported results will be qualified. The policy shall be in the format of a standard operating procedure consistent with Article K and be part of the quality assurance manual as described in Article I. The policy will be provide procedures to ensure that the measurement quality objectives of the data user from a California state regulatory agency for which the samples are being analyzed are met or if no such MQOs exist, the measurement quality objectives of Article E are met.

(b) The policy shall describe how samples received by a laboratory for analysis shall:

(1) Be assigned a unique identification code. This code may be as simple as a location and a date or equivalent so long as it is unique.

(2) The unique identification code shall be placed on a sample container as a durable label.

(3) The unique identification code shall be used as a link to associate samples with their complete history, including treatment and analysis, while in the laboratory's possession.

(4)Chain−of−custody documentation shall be required for samples collected for compliance with this chapter.

Article O – Corrective Action

(1) The laboratory shall take corrective action when:

(a) Departures from established policies and procedures in the quality management system consistent with Article D and codified in the Quality Assurance Manual in Article I are identified or become apparent.

(b) Measurement quality objectives consistent with Article E, including measurement quality objectives required by data users from California state regulatory agencies, the individual methods identified in the UoAs for which the laboratory is accredited, or the Article E itself.

(c) Quality control samples and procedures, including proficiency testing samples, fail established acceptance limits or evaluation criteria.

Article P - Notification

(a) Laboratories certified for FoAs 101, 102, 103, 104, 105 and/or 106 shall conform to the following reporting and notification requirements.

(1) Laboratories reporting bacterial quality results as required by Title 22, California Code of Regulations, Section 64423.1 shall submit a bacterial monitoring report including information required in Title 22, California Code of Regulations, Sections 64423.1(c)(2) and (c)(3) directly to the Department.

(2) The laboratory shall notify a water supplier's designated contact person as soon as possible, but within 24 hours, and record the method and time of notification or attempted notification, whenever any of the following occur:

(A) The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli) is confirmed.

(B) A bacterial sample is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b).

Article Q – On-Site Assessment

(a) Each laboratory shall be subject to an on-site assessment to obtain its initial certificate and every two years thereafter by ELAP to verify the information submitted with its ELAP certificate application pursuant to Article C, including compliance with requirements in:

(1) Methods used for each UoA for which the laboratory seeks accreditation consistent with Article H;

(2) Quality Management Systems consistent with Article D

(3) Measurement quality objectives consistent those listed in the application described in Article C and with Article E

(4) Personnel Requirements consistent with Article F

(5) Quality Assurance Manual consistent with Article I

(6) Standard Operating Procedures consistent with Article K

(7) Record keeping and retention consistent with Article L

(8) Standards and traceability consistent with Article M

(9) Sample handling procedures consistent with Article N

(10) Corrective action policy and practice consistent with Article O

(11) Notification and Reporting practice consistent with Article P

Comparison

USEPA

- Amendable
- 33 Pages
- Specific to California
- Tied to Specific MQOs
- Free and Public
- Detailed and Specific
- Higher Quality

TNI

- Unamendable
- 186 Pages (Volumes 1 & 2)
- Not Specific to Any State
- DQO/MQOs generic
- Hidden Behind Paywall
- Vague and General
- Lower Quality

Negative Controls

USEPA

- **Article E**

(c)1(D) A sample in a batch shall be reanalyzed or qualified if the concentration of an analyte of interest in the associated method blank exceeds the highest of any of the following values:

(i) For FOAs 102 – 105 the Detection Limit for Reporting or Minimum Reporting Level where they exist and the Method Detection Limit where they do not.

(ii) five percent (5%) of the Maximum Contaminant Level or Action Level.

TNI

- **Module 4**

1.7.4.1 While the goal is to have no detectable contaminants, each method blank shall be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch. The source of contamination shall be investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed or data shall be appropriately qualified if:

a) the concentration of a targeted analyte in the blank is at or above the reporting limit as established by the method **or** by regulation, **AND** is greater than 1/10 of the amount measured in the sample;

b) the blank contamination otherwise affects the sample results as per the method requirements **or** the individual project data quality objectives; and

Positive Controls

USEPA

- **Article E**
- (c)2(A) For FOAs 102 – 105, For FOAs 107 – 111, and FOAs 114-117 Laboratory Fortified Blanks shall be processed along with and under the same conditions, including all sample preparation steps, as the associated samples in a preparation batch as positive controls.
- (B) Laboratory Fortified Blanks are not appropriate or required for analysis of pH, alkalinity, conductivity, disinfectant residuals, color, or odor.
- (C) Laboratory Fortified Blanks shall be processed at a frequency of at least one per preparation batch.
- (D) The recovery of analytes should be between 50% and 150%.

TNI

- **Module 4**
- 1.7.3.2.1 The LCS is used to evaluate the performance of the total analytical system, including all preparation and analysis steps. Results of the LCS are compared to established criteria and, if found to be outside of these criteria, indicates that the analytical system is "out of control." Any affected samples associated with an out of control LCS shall be reprocessed for re-analysis or the results reported with appropriate data qualifying codes.

Summary

1. The proposed QMS would well serve the interests of the data users in the state regulatory agencies as it would tie the performance of individual laboratories to the data quality needs of the individual projects and programs through the MQOs.

2. The proposed QMS would well serve the interests of ELAP as it would provide a standard that would easy to implement while robust enough to be enforceable and specific to California's needs.

3. The proposed QMS would well serve the interests of the accredited laboratory community well as it is comparatively short, simple, and publically available for free.

White Paper #4: A Quality Management System for ELAP

By David Kimbrough, Pasadena Water & Power

Presented to the Environmental Laboratory Technical Advisory Committee, August 24, 2016

The Environmental Laboratory Technical Advisory Committee voted to recommend to the Environmental Laboratory Accreditation Program to adopt a Quality Management System that was not based on documents of The NELAC Institute. This paper is a straw man for how such a Quality Management System would look.

1) Introduction

The Environmental Laboratory Accreditation Program (ELAP) posed four questions to the Environmental Laboratory Technical Advisory Committee (ELTAC) in regards to creating a new Accreditation Standard.

a) What should the standard be for Performance Testing Samples (PTS) in terms of how many studies per year should a laboratory participate in?

b) What should the Technical Standard be?

c) Should ELAP require laboratory have a Quality Management System (QMS) as a condition of accreditation?

d) If a QMS is required, which one should be required?

At the June meeting of ELTAC a vote was taken and the committee recommended that only one PTS study per year. This effectively eliminated using The NELAC Institute (TNI) documents as a whole for a QMS as the TNI documents require the two PTS studies per year.

At the July meeting, ELTAC voted that the Technical Standard of the overall Accreditation Standard should be made up of the requirements of the test methods themselves and nothing from other sources. ELTAC also voted that it wanted to recommend ELAP require a QMS as condition of accreditation. Since TNI as whole had been excluded by the June vote, the question was raised as to which non-TNI QMS should be recommended. The suggestion was raised that a "TNI Lite" QMS could be recommended but a straw poll showed that the Committee was not interested in such a proposal. The Committee voted to hold a meeting in August to propose a QMS for ELAP.

This paper is proposal for a QMS based upon the Quality Systems used by the United States Environmental Protection Agency and California State Regulatory Agencies.

2) Quality Management System

a) The USEPA QMS necessarily begins with the needs of the data users. The data users for this case are the California State Regulatory Agencies of the State Water Resources Control Board (SWRCB) - Division of Drinking Water (DDW), the SWRCB - Division of Water Quality (DWQ, including the Regional Water Quality Control Boards - RWQCB), the Department of Toxic Substances Control (DTSC), and the Department of Fish and Wildlife (DFW). Frequently at least some of these agencies already use the USEPA QMS. Therefore it is only logical that this be the basis for ELAP's QMS.

b) Data Quality Objectives - QMSs begin with the Data Quality Objectives (DQOs). DQOs are qualitative and quantitative statements that, among other things, specify tolerable limits on decision errors which will be used as the basis for establishing the quantity and quality of data needed to support the decision. The DQO Process helps ensure that data users are assured that the type, quantity, and quality of environmental data appropriate for the intended application. Sampling and analysis plans can be developed from DQOs. Variables such as precision, accuracy, representativeness, data completeness, comparability, and sensitivity are commonly used in environmental monitoring. Depending on the nature of the project, different data quality needs might be emphasized over others. For example if regulatory compliance with threshold concentration is the goal, accuracy and precision might be more important than comparability. The activities of laboratories are only a very small part of DQOs.

c) Data Quality Indicators - Data Quality Indicators provide quantitatively assessable measures of DQOs. For example accuracy can be assessed by the use of reference materials, continuing calibration verification standards (CCVS), matrix spikes and other similar tools. For each DQO, a DQI can be determined and used to assess the quality of the data generated.

d) Measurement Quality Objectives - Measurement Quality Objectives (MQOs) are the specific laboratory based measures to determine acceptance or rejection of data. For the DQO of accuracy and

the DQI of Continuing Calibration Verification Standards, the MQO could be a recovery of 25%. For the DQO of precision and the DQI of laboratory duplicates the MQO could be the relative percent difference of 20%.

e) The DQOs, DQIs, and MQOs are found in Quality Assurance Project Plans (QAPP), Sampling and Analysis Plans (SAP), but also in other documents.

f) Data Quality Assessment - The core of QMS is the Data Quality Assessment (DQA). The data users examine the entire universe of laboratory results, including MQOs, and determine if the data is of sufficient quality to allow him or her to make the needed decisions. If not, changes to the QS have to be made and more samples collected and analyzed. Attachment A shows a typical QMS used by the USEPA in their Clean Air Act program.

g) As can be seen, only a small part of the QMS actually involves laboratories, mainly the MQOs. So for ELAP to create a QMS that will be a requirement for laboratory accreditation, is should only include those parts of the QMS that impact laboratory functions.

3) ELAP Required QMS

a) The proposed QMS was not designed to be a separate "add-on" feature separate from the larger Accreditation Standard but is rather it was rather woven into the fabric of the Accreditation Standard at each point. The core elements of the QMS are found in almost every part of the Accreditation Standard

b) While the QMS has many elements, there were three core elements that hold it all together:

i. "*Data User*" means an individual or group within a State regulatory agency that has unique data quality objectives and measurement quality objectives.

ii. "*Measurement Quality Objective*" or "*MQO*" is an individual performance or acceptance goals for a laboratory determined by a data user.

iii. "State regulatory agency" means an agency that requires the analysis of environmental samples that has been established under regulatory and/or statutory requirements by the State

Water Resources Control Board (SWRCB), Regional Water Quality Control Boards (RWQCBs), the Department of Toxic Substances Control (DTSC), the California Environmental Protection Agency (Cal/EPA), the Department of Health Services (DHS), the Department of Food and Agriculture (DFA), Department of Fish and Wildlife (DFW), or any successor agencies.

c) The proposed QMS is divided up into Articles and numbered in a fashion similar to how California regulations are organized except that Articles are numbered rather than lettered.

Article A – Definitions
Article B – Purposes
Article C – Accreditation Process
Article D – Quality Management Systems
Article E – Measurement Quality Objectives
Article F – Personnel
Article G – Facilities and Equipment
Article H – Required Tests Methods
Article I – Fields of Accreditation
Article J – Quality Assurance Manual
Article K – Standard Operating Procedures
Article L – Records Retention
Article M – Standards
Article N – Sample Handling
Article O – Corrective Actions
Article P – Notification and Reporting
Article Q – On-Site Assessment

d) In each article, the requirements placed upon laboratories as a condition of accreditation are defined relative to the MQOs of the data users in the California state regulatory agencies. If the data users do not provide any MQOs, the quality control and quality assurance requirements in the test methods are still required. If there are no quality control requirements found in the test methods themselves, default MQOs are found in Article E.

i. These three core elements are defined in Article A.
ii. In Article B, the purpose of ELAP and laboratory accreditation is defined relative to the needs of data users from state regulatory agencies as expressed as MQOs.
iii. Article C requires that when a laboratory applies for accreditation it has to list the data users, state regulatory agencies, and MQOs that it is to use.

iv. Article D and Article I require that the laboratory include the MQOs of the data users be incorporated into the day to day activities of the laboratory.
v. Article K requires that the MQOs be incorporated into the SOPs of the laboratory.
vi. Article P indicates that when an on-site assessment is to be performed, the assessor will review the laboratory for compliance with the MQOs of the data users.
vii. Other Articles incorporate the MQOs in different ways.

e) At each point in the process of accreditation, ELAP ensures that accredited laboratories are complying with the MQOs of the data users.

4) Recommendations

a) The proposed QMS would well serve the interests of the data users in the state regulatory agencies as it would tie the performance of individual laboratories to the data quality needs of the individual projects and programs through the MQOs.

b) The proposed QMS would well serve the interests of ELAP as it would provide a standard that would easy to implement while robust enough to be enforceable and specific to California's needs.

c) The proposed QMS would well serve the interests of the accredited laboratory community well as it is comparatively short, simple, and publically available for free.

Article A Definitions

"Acceptable Results" means proficiency testing (PT) study findings that the PT study provider or ELAP has determined meet acceptance criteria specified for the study undertaken.

"Accuracy" means the closeness of a measured value to an accepted reference value or standard.

"Accreditation" A determination by ELAP that an environmental laboratory is capable of performing one or more units of accreditation in accordance with this chapter for California state regulatory agencies.

"Accredited laboratory" means a laboratory that has been granted certificate of accreditation by the agency directly or through reciprocal recognition under this chapter.

"Analyte" means the chemical substance, physical property

or organism analyzed in a sample.

"Analytical Specialist" means a person who either supervises the activities of others in, or is otherwise responsible for the results produced by, the analysis of environmental samples using sophisticated laboratory instruments, such as gas chromatograph/mass spectrometers (GC/MS), inductively coupled plasma atomic emission spectrometers (ICP-AES), inductively coupled plasma mass spectrometers (ICP-MS), liquid chromatograph/mass spectrometers (LC-MS), atomic absorption spectrophotometers (AA), gas chromatographs (GC), alpha particle or gamma ray spectrophotometer, electron microscopes (EM), polarized light microscope (PLM), high performance liquid chromatographs (HPLC), ion chromatography (IC), or liquid scintillation counter (LSC), or bioassay testing.

"Analytical staff" includes, but is not limited to, laboratory directors, supervisory personnel, quality assurance personnel, technicians, chemists, biologists, personnel performing extractions and analysts.

"Assessor" means the person who performs on-site assessments of laboratories' capability and capacity for meeting the requirements under this chapter by examining the records and other physical evidence for each one of the tests for which certification has been requested.

"Batch" means a set of samples prepared or analyzed together under the same process, instrumentation, personnel, and lots of reagents. An analytical batch refers to a set of any number of prepared samples, such as extracts, digestates or concentrates or samples requiring no preparatory steps analyzed together as a group in an uninterrupted sequence, and may consist of samples of various quality system matrices. A preparation batch refers to a batch of samples, excluding quality control samples, of the same quality system matrix which can be processed simultaneously using the same equipment, reagents and staff. Preparation batch processing shall be completed in a 24−hour period from the start of the processing of the first sample to the start of the processing of the last sample. For laboratories that do not analyze more than 7 samples for a given test and quality system matrix per week, a preparation batch may consist of up to 7 samples, excluding quality control samples, processed during the course of no more than a week.

“Bias” means the consistent deviation of measured values from a true value caused by systematic errors in a procedure or a measurement process.

“Chain of custody” means the procedures and records that document the possession and handling of samples from collection through disposal. A chain−of−custody form is used to document, with a signature, date and time, transfer of the sample from collector to transport/delivery service and then to the laboratory staff receiving the samples.

“Corrective Action Report” means a report documenting actions taken by a laboratory following the identification of non-compliance with the requirements of this Chapter.

“Data User” means an individual or group within a State regulatory agency that has unique data quality objectives and measurement quality objectives.

“Deficiency” means an existing nonconformity, defect or other undesirable inconsistent with the requirements of this chapter.

“Demonstration of technical capability” means a document that provides to ELAP the information necessary to determine whether a laboratory has the capability to conduct the analysis for a specific UoA, including:

“ELAP” means the California Environmental Laboratory Accreditation Program.

“Environmental sample” means a collected volume of potable or not-potable surface or ground water, soil, sediment, hazardous waste, or any other material analyzed for a State regulatory agency.

“Facilities” means fixed or portable building(s), including storage areas, that contain the analytical and ancillary operating equipment, supplies and space necessary to perform the analyses in the FoAs for which a laboratory is accredited.

“Field of Accreditation” or “FoA” means a group of UoAs related by which state regulatory agency results to be reported to and analytical technology or analyte type.

“Interim certificate” means a temporary certificate of ELAP accreditation listing UoAs that a laboratory has requested be added to its existing certificate, that allows the laboratory to report analyses for regulatory purposes for the additional UoAs.

“Laboratory” means a facility that performs tests in connection with a agency which requires data from a certified or registered laboratory. A facility consisting of a principal laboratory and annexes within 5 miles of the principal laboratory may be considered a single laboratory at the discretion of the department.

“Laboratory director” means the laboratory staff person who is responsible for actual day-to-day supervision of all technical, analytical and data reporting operations in the laboratory for the fields of accreditation listed on the laboratory’s certificate.

“Laboratory equipment” means any support equipment or analytical instrument necessary to or involved in generating the results of an analysis.

“Laboratory management” The individuals responsible for the overall operation, all personnel

and the physical plant of an environmental laboratory which includes a laboratory supervisor.

Laboratory supervisor—A technical supervisor of an environmental laboratory who supervises laboratory procedures and reporting of analytical data.

“MCL” means maximum contaminant level and is the maximum permissible level of a contaminant in water which is delivered to any user of a public water system.

“Measurement Quality Objective” or “MQO” is an individual performance or acceptance goals for a laboratory determined by a data user.

“Method blank” means a sample of a matrix devoid of or having a consistent concentration or amount of the analytes of interest processed simultaneously with and under the same conditions, preparatory and analyses steps as the associated samples. A method blank is a negative control sample for chemistry UOAs.

“Negative Control” is a quality control procedure to identify if samples as subject to contamination.

“Negative Control Sample” is a sample analyzed for a given UOA which is expected to produce a negative or zero response and is used as part of negative control procedure.

“Not Acceptable” means that the PT study provider or ELAP has determined that the PT study findings do not meet acceptance criteria specified for the study undertaken.

"On-Site Assessment" means a systematic evaluation by ELAP staff of a laboratory’s compliance with the requirements of this chapter.

“Owner” means any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.

“Owner's agent” or “agents of owners” or “officer”, means those persons who have been designated by the Owner(s) of the laboratory to act in its behalf for purposes of complying with this chapter or the statutes under which this chapter has been adopted.

“Quality control” means the overall system of technical activities designed to measure and control the quality of a product or service that meets the stated needs of users.

“Quality management system” means a structured and documented management arrangement describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products and services.

“Revocation” means cancellation of a laboratory’s certification of accreditation on permanent basis

“State regulatory agency” means an agency that requires the analysis of environmental samples that has been established under regulatory and/or statutory requirements by the State Water Resources Control Board (SWRCB), Regional Water Quality Control Boards (RWQCBs), the Department of Toxic Substances Control (DTSC), the California Environmental Protection Agency (Cal/EPA), the Department of Public Health (DPH), the Department of Food and Agriculture (DFA), Department of Fish and Wildlife (DFW), or any successor agencies.

“Support equipment” means devices that may not be analytical instruments, but that are necessary to support laboratory tests and operations. These devices include, but are not limited to, autoclaves, balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices, sample preparation devices and volumetric dispensing devices when quantitative results depend on the accuracy of the support equipment.

“Suspension” means a temporary cancellation of a laboratory’s certificate of accreditation.

“Test method” means an analytical testing technique or procedure that a State regulatory agency requires to be used to determine the level of a designated analyte in an environmental sample for the purposes of assessing compliance with its statutes, regulations and/or permits.

“Unit of accreditation” or “UoA” means a specific combination of: (a) for ELAP accreditation, a State regulatory agency, or for NELAP accreditation, a matrix, (b) a test method or technology, and (c) a designated analyte or analyte group for which accreditation may be obtained.

ARTICLE C. Accreditation Process

SECTION 1 Accreditation Process

(a) To obtain a certificate of accreditation (certificate), a laboratory shall meet the following requirements:

(1) Submit an application, pursuant to Section 2;

(2) Except for interim and reciprocal certificates, complete an on-site assessment, pursuant to Article Q for ELAP accreditation;

(3) Achieve Acceptable Results in the required proficiency testing studies (PT studies) pursuant to Article Q for ELAP accreditation; and

(4) Pay the required fees pursuant to Article X.

(b) The period of the certificate shall be based on the anniversary of the initial certificate of accreditation and shall be as follows:

(1) For an ELAP certificate, two years;

(2) For an amended ELAP certificate, the time remaining on the certificate from the date it was amended.

(c) To renew a certificate, at least ninety days prior to its expiration date, a laboratory shall submit a renewal application pursuant to Section 2.

SECTION 2 Application for Accreditation.

(a) To apply for an initial, renewed, or amended ELAP certificate, a laboratory shall submit an application to ELAP that includes the following:

(1) Details on the laboratory's type, location, contact information and ownership;

(2) Qualifications of personnel, addressing the requirements in Article F including, Laboratory Director, Supervisors, and Analytical Specialist(s);

(3) FoA(s) and/or UoA(s) for which accreditation is being requested;

(4) A list of all California State regulatory agencies and data users with unique measurement quality objectives.

(5) Quality assurance manual pursuant to Article I for ELAP accreditation

(6) Fees, pursuant to Article X

(7) Signature of the Laboratory Owner, owner's agent, or officer, and date signed.

(b) To remove one or more UoAs or FoAs from its certificate:

(1) In between renewals, the laboratory shall submit a written request to ELAP and receive an amended certificate.

(2) At the time of renewal, the laboratory shall indicate the requested changes on its renewal application.

Article B — Purposes of Laboratory Accreditation

(a) This chapter was promulgated for the following purposes:

(1) The purpose of this chapter is to protect public health, safety, welfare and the environment by ensuring the accuracy, precision, representativeness, comparability, completeness, sensitivity, and reliability of data generated by environmental laboratories by establishing an accreditation program for environmental laboratories which report results to California state regulatory agencies.
(2) To link the data quality needs of the data users of the California state regulatory agencies to the laboratories that analyze sample through measurement quality objectives
(3) To establish an accreditation program for laboratories performing analyses for California state regulatory agencies;
(A) State Water Resources Control Board – Division of Drinking Water
(B) State Water Resources Control Board – Division of Water Quality / Regional Water Quality Control Boards
(C) Department of Toxic Substances Control
(D) Department of Food and Agriculture
(E) Department of Public Health
(F) Department of Fish and Wildlife
(4) To confine a laboratory's scope of accreditation to the Units of Accreditation for which the laboratory is conducting compliance monitoring for the above agencies;
(5) To establish the procedures to be followed by accredited environmental laboratories, and by laboratories seeking to become accredited environmental laboratories;
(6) To require that accreditation be contingent upon continued compliance with the standards of performance set forth in this chapter; and
(7) To establish the enforcement procedures that the ELAP shall follow to ensure that a certified environmental laboratory is in compliance with this chapter.

(b) Compliance with this chapter will assist a laboratory in meeting the data quality objectives of California state regulatory agencies with regard to accuracy, precision, completeness, comparability, and representativeness. The laboratory shall produce data with known quality assurance and quality control procedures, and in accordance with the Units of Accreditation for which it is accredited.

Article D — Quality Management Systems

(a) All laboratories seeking certification in any Unit of Accreditation as identified in Section 64823 within Field(s) of Accreditation 101 through 129, as listed in Health and Safety Code, Section 1017, are conducting analytical activities for environmental regulatory agencies of the State of California for compliance purposes.

(b) This Article establishes the requirements for laboratories seeking accredited under this chapter for personnel, facilities, equipment, standard operating procedures, records, standards, quality assurance, quality control, method selection, sample handling, corrective action, notification, and documentation requirements for laboratories to meet the measurement quality objectives of those environmental regulatory agencies of the State of California.

(c) Laboratories shall conduct their analytical activities under a quality system that incorporates the provisions of this section. The quality system must incorporate the measurement quality objectives of the appropriate data user from California state regulatory agency.

(1) Laboratories accredited in Fields of Accreditation 101 – 106 and 129 shall use measurement quality objectives used by the data users from the State Water Resources Control Board - Division of Drinking Water Programs.
(2) Laboratories accredited in Fields of Accreditation 107 – 113 shall use measurement quality objectives used by the data users from the State Water Resources Control Board - Division of Water Quality or the Regional Water Quality Control Boards or Department of Fish and Wildlife.
(3) Laboratories accredited in Fields of Accreditation 114 – 121 shall use measurement quality objectives used by the data users from the Department of Toxic Substance Control.
(4) Laboratories accredited in Fields of Accreditation 124 – 125 shall use measurement quality objectives used by data users from the Department of Food and Agriculture.
(5) Laboratories accredited in Fields of Accreditation 126 shall use measurement quality objectives used by the Department of Public Health.

(d) Measurement quality objectives may vary with different projects and programs from different data users in different California state regulatory agencies may be found in Quality Assurance Project Plans, Sampling and Analysis Plans, or other similar documents.

(e) If no measurement quality objectives are available, laboratories shall use the measurement quality objectives identified in Article E.

(f) The laboratory's quality management system shall be described in a Quality Management System Manual which will include all elements required in this chapter.

(g) At least one individual, however named, within a laboratory's organization or under the laboratory's employment shall be identified to the program and in the Quality Management System Manual as responsible for establishing, implementing, assessing, and revising, as needed, a laboratory's quality system. This individual may perform other activities.

Article E Measurement Quality Objectives

(a) As identified in Article D of this chapter accredited laboratories are required to incorporate the measurement quality objectives of the data users in California state regulatory agency to which the results are to be reported. However not all data users and California state regulatory agencies have data quality objectives for every sample submitted for analysis. This Article establishes the measurement quality objectives for laboratories to use when the California state regulatory agency or data user does not provide them.

(b) Laboratories will use the appropriate quality control procedures identified in the approved methods identified in unit of accreditation for which the laboratory is accredited and which the data user has requested.

(c) Those units of accreditation which identify methods that do not have their own quality control requirements shall use the following measurement quality objectives.

(1) Negative Controls shall be processed along with and under the same conditions, including all sample preparation steps, as the associated samples in a preparation batch. The purpose of negative controls is to identify contamination.

(A) Method Blanks are not appropriate or required for analysis of pH, alkalinity, conductivity, disinfectant residuals, color, odor, radiochemistry methods, and bio-assay methods.

(B) Method Blanks shall be processed at a frequency of at least one per preparation batch.

(C) Whenever a method blank contains analytes of interest above the detection limit of an analysis, the laboratory shall evaluate the nature of the interference and its effect on each sample in a preparation batch.

(D) A sample in a batch shall be reanalyzed or qualified if the concentration of an analyte of interest in the associated method blank exceeds the highest of any of the following values:

(i) For FOAs 102 – 105 the Detection Limit for Reporting or Minimum Reporting Level where they exist and the Method Detection Limit where they do not.

(ii) five percent (5%) of the Maximum Contaminant Level or Action Level.

(iii) For FOAs 107 – 111 the Minimum Level as identified in the State Implementation Plan or

(iv) five percent (5%) of the lowest criterion in the California Toxics Rule

(iii) For FOAs 114-117, ten percent of the measured concentration of any sample in the batch.

(E) For FOAs 101, 106, and 127 negative controls consist of sterility checks and negative control cultures. These procedures are described in Standard Methods 9020 and 9050 22nd Edition.

(2) Positive Controls shall be processed along with and under the same conditions, including all sample preparation steps, as the associated samples in a preparation batch. The purpose of positive controls is to identify contamination or loss of analyte.

(A) For FOAs 102 – 105, For FOAs 107 – 111, and FOAs 114-117 Laboratory Fortified Blanks shall be processed along with and under the same conditions, including all sample preparation steps, as the associated samples in a preparation batch as positive controls.

(B) Laboratory Fortified Blanks are not appropriate or required for analysis of pH, alkalinity, conductivity, disinfectant residuals, color, or odor.

(C) Laboratory Fortified Blanks shall be processed at a frequency of at least one per preparation batch.

(D) The recovery of analytes should be between 50% and 150%.

(E) For FOAs 101, 106, and 127 positive controls consist of positive control cultures. These procedures are described in Standard Methods 9020 and 9050 22nd Edition.

Article F Laboratory Personnel

(a) The laboratory shall have management and analytical staff with education, training or experience that allows them to comply with the requirements of this chapter and the measurement quality objectives of the particular data user or California state regulatory agency to which they are reporting results.

(b) Each laboratory shall designate a laboratory director. Except as provided in Subsections (c) and/or (d), the laboratory director shall have as a minimum:

(1) A baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or chemical engineering, natural or physical science; and

(2) Three years of experience in the analysis of chemical, biological, or microbiological samples, prior to being designated laboratory director, subject to the following allowances:

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

(B) A doctorate in chemistry, biochemistry, environmental, sanitary or chemical engineering, biology, microbiology, natural or physical science may be substituted for two years of the required experience.

(c) Except as provided in Subsections (d) and/or (e), prior to being designated a laboratory supervisor an analytical specialist, a person shall have as a minimum a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or chemical engineering, natural or physical science; and, if working for the laboratory, be under the supervision of a laboratory director or analytical specialist; and have:

(1) A certification of completion for a course taught by the manufacturer of the sophisticated laboratory instrument which is being used or supervised by the analytical specialist; or

(2) Six months experience operating a sophisticated laboratory instrument to analyze water, wastewater, solid waste, hazardous waste or other environmental samples, or food.

(d) In lieu of meeting the requirements specified in Subsections (a) or (b), a laboratory director or analytical specialist(s) employed by a laboratory owned by a public drinking water or wastewater utility shall have an Analyst/Water Quality Analyst Certificate from the California Water Environment Association (CWEA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA), pursuant to Table 64814, as follows:

(1) A laboratory director shall have, or obtain within one year of assuming the position, the highest certificate grade required for the performance of any FoA for which the laboratory is accredited.

(2) An analytical specialist shall have, or obtain within one year of assuming the position, the certificate grade required for the FoA(s) and UoAs for which the analytical specialist conducts, analyses, or supervises others conducting analyses for the laboratory.

Table 64814
Minimum Personnel Certification

Fields of Accreditation (FoAs)	*Minimum Certificate Grade*	*UoAs Allowed*
101, 108	I	All
102, 109	I	Alkalinity, Hardness, Total Filterable Residue, Conductivity, Chloride
109	II	Acidity, BOD, COD, Chlorine Residual, DO, pH, Turbidity, Residues
102, 109	III	All
103, 110	III	All, except those using ICP-MS
104, 111	III	All, except those using GC-MS or LC-MS

(e) The following shall be exempt from meeting Subsections (a), (b) and (c):

(1) A laboratory director, laboratory supervisor, or analytical specialist who was employed by an environmental testing laboratory at the time that the laboratory was accredited, provided that the accreditation date was on or before December 31, 1994.; and

(2) A director of a public health laboratory, pursuant to Health and Safety Code Sections 101150 and 101160.

(f) A laboratory director, or his/her designee, shall be responsible for:

(1) All analytical and operational activities of the laboratory; and

(2) The accuracy and quality of all data reported by the laboratory.

(g) A laboratory director shall assume the position of, or shall designate another person as, the analytical specialist responsible for the use of each sophisticated laboratory instrument in the laboratory.

(h) If a laboratory director leaves and is not replaced within 15 days by a person meeting the laboratory director requirements in this section, a person or persons with lesser qualifications may serve as a temporary director for a period not to exceed ninety days, provided that the laboratory notifies ELAP, describing the qualifications of the temporary director and receives written approval from ELAP. Additional extensions of no more than ninety days beyond the original 90-day period may be granted by ELAP; provided the laboratory can document that its good-faith efforts to fill the position with a qualified director were unsuccessful for reasons beyond its control.

(i) The laboratory director shall ensure that when analytical staff are to begin using a new method, they must be trained and then conduct an initial demonstration of capability.

(1) When the method that the laboratory is accredited for contain protocols for demonstrating initial capability personnel performing analyses using these methods for units of accreditation that the laboratory is accredited for shall perform the protocols and shall meet any associated evaluation criteria and document results.

(2) When the method that the laboratory is accredited for does not contain protocols for demonstrating initial capability, personnel performing analyses using this method for units of accreditation that the laboratory is accredited for, the laboratory shall require that the analyst perform the protocols similar to those of methods with protocols. These may include:

(A) Method blanks with results shall be consistent with requirements in Article E

(B) Certified Reference Materials with a recovery within +/-25% of the target value

(C) Laboratory Fortified Blanks with a recovery within +/-25% of the target value

(D) Matrix Spike Samples with a recovery within +/-25% of the target value

(E) The laboratory may propose alternative protocol to the program which achieve the same objective.

(3)The laboratory director shall ensure that documentation that each person performing a given test on compliance samples has satisfied the demonstration of capability criteria established by the laboratory is retained.

(4) The laboratory director shall ensure that standard operating procedures consistent with Article K are produced and represent current laboratory practice

(5) The laboratory director shall ensure that a quality management system consistent with Article D are produced and represent current laboratory practice.

(6) The laboratory director shall ensure that a quality management system consistent is accurately summarized and described in the quality assurance manual consistent with Article I

(5) The laboratory director and laboratory supervisor shall ensure that the analytical staff are familiar with standard operating procedures and are actually implementing them

(6) The laboratory director and laboratory supervisor shall ensure that the analytical specialist are properly trained on the specialized equipment that they assigned and are using the appropriate standard operating procedures.

Article G Laboratory Facilities and Equipment

A laboratory shall be arranged and operated so that:

(a) Utilities are maintained to allow the laboratory equipment to function and produce analyses for each unit of accreditation for which the laboratory is accredited and meeting for the measurement quality objectives for the data users and California state regulatory agency to which the results are to be reported to;

(b) Ventilation and environmental control are maintained to ensure that analytical results do not exceed quality control limits as specified in the approved test methods or in the laboratory's quality assurance manual consistent with Article I and meeting for the measurement quality objectives for the California state regulatory agency to which the results are to be reported to;

(c) The potential for sample contamination is minimized; and

(d) Analytical equipment conforms to analytical method requirements and allows compliance with the appropriate measurement quality objectives.

(e) All support equipment including but not limited to refrigerators, freezers, ovens, autoclaves, scales, mechanical and automatic volumetric dispensing devices, including pipettes, micro−pipettes, burettes and automatic dilutors and dispensers and thermometers shall be kept in working order by submitting it to routine and preventive maintenance. Standard Operating Procedures consistent with Article F shall be developed for operation and maintenance of support equipment. Records of maintenance shall be kept and made available for review consistent with Article L.

(f) All analytical instruments shall be properly operated and maintained.

(1) All analytical instruments shall be operated by personnel trained in their use as described in Article F. Standard Operating Procedures for the use and maintenance of equipment shall be prepare in accordance with Article K and shall be available to instrument operators.

(2) All instruments shall be properly maintained, inspected and cleaned according the SOP. Records of operation and maintenance activities shall be maintained and made available for review.

(3) Analytical instruments have been shown to be defective or outside of performance specifications identified in the SOP shall be taken out of service and either retired or brought back into specifications.

(4) When analytical instruments leave the direct control of the laboratory for maintenance or for any other reason, the laboratory shall ensure that the functional and calibration status of those analytical instruments are checked or demonstrated to be satisfactory before the instruments are returned to service.

Article H Required Test Methods

(a) Any laboratory requesting accreditation from the ELAP for Units of Accreditation in Fields of Accreditation 101 through 106 and/or 128 as identified in Article J, shall employ those methods identified in H&SC 100852 or as identified by the Division of Drinking Water for regulatory compliance purposes. If a Public Water System has a permit issued by the Division of Drinking Water which requires that Public Water System to use a test method for a specific analyte that had once been listed in the Code of Federal Regulation Title 40 Part 141 but is no longer so listed, a laboratory may seek accreditation for that test method and analyte combination but may only use that combination for samples from that Public Water System. If the permit is updated by the Division of Drinking Water and that requirement to use that method analyte combination is removed, the accreditation for the laboratory shall be revoked.

(b) Any laboratory requesting ELAP accreditation from the State Board / ELAP for Units of Accreditation in Fields of Accreditation 107 through 113 as identified in Article J, shall employ those methods identified in H&SC 100852 or as identified by the State Water Resource Control Board or a Regional Water Quality Control Board or the Department of Fish and Wildlife for regulatory compliance purposes. If a National Pollutant Discharge Elimination System (NPDES) permittee or a Waste Discharge Requirement (WDR) holder or other permit issued by the State Water Resource Control Board or a Regional Water Quality Control Board or the Department of Fish and Wildlife which requires that permittee to use a test method for a specific analyte that had once been listed in the Code of Federal Regulation Title 40 Part 136 but is no longer so listed, a laboratory may seek accreditation for that test method and analyte combination but may only use that combination for samples from that permittee. If the permit is updated by the SWRCB or RWQCB and that requirement to use that method analyte combination is removed, the accreditation for the laboratory shall be revoked.

(c) Any laboratory requesting ELAP accreditation from the State Board / ELAP for Units of Accreditation in Fields of Accreditation 114 through 121 as identified in Article J, shall employ those methods identified in 22 CCR § 66261.24 or as identified by the Department of Toxic Substance Control for regulatory compliance purposes.

(d) Any laboratory requesting accreditation from ELAP for Units of Accreditation in Fields of Accreditation 122 through 125 as identified in Article J, shall employ those methods identified in X or as identified by the Department of Food and Agriculture for regulatory compliance purposes.

(e) Any laboratory requesting accreditation from the ELAP for Units of Accreditation in Fields of Accreditation 126 as identified in Article J, shall employ those methods identified by the Department of Public Health for regulatory compliance purposes.

Article I Quality Assurance Manual

(a) To obtain and maintain ELAP accreditation, each laboratory shall establish, have available for review by ELAP, and implement a quality management system consistent with Article D for all UoA for which it seeks, or is maintaining, accreditation which is summarized and described in a quality assurance manual:

(b) The quality manual shall have a format, however conceived, that addresses the content elements specified in this section. Content elements may be presented in narrative, tabular, schematic or graphical form. The manual shall be a document in hard copy or electronic format traceable to the laboratory.

(c)The quality assurance manual shall address all quality assurance and quality control practices to be employed by the laboratory and shall at least, include the quality assurance and quality control requirements specified in the test methods in the UOAs for which the laboratory holds, or seeks, certification. The quality manual shall include, address or refer to, at a minimum, the following elements:

(1) A description of the Quality Management System consistent with Article D, including.

(A) A list of all FoAs and UoAs consistent with Articles H and J.

(B) A list of all data users from California state regulatory agencies to which the laboratory submits results consistent with the information in the application for accreditation in Article C.

(C) A list of all measurement quality objectives consistent with Article E

(D) A list of all SOPs consistent with Article K

(E) A list of all standards consistent with Article M

(2) Organization and management structure of the laboratory.

(3) Procedures for retention, control and maintenance of documents used in or associated with analyses consistent with Article L.

(4) Procedures for achieving traceability of standards, reagents and reference materials used to derive any results or measurements consistent with Article M.

(5) Procedures for handling samples and documenting chain of custody consistent with Article N.

(6) Lists of major analytical instruments and support equipment consistent with Article G.

(7) Description of the facilities consistent with Article G.

(8) Procedures for evaluating quality control samples, such as method blanks, laboratory fortified blanks, laboratory control samples, matrix fortified samples and replicates consistent with Articles D and E.

(9) Procedures for initiating, following up on and documenting corrective action addressing quality assurance and quality control failures, discrepancies or nonconformance consistent with Article O.

(10) Procedures for reviewing analytical data and reporting analytical results consistent with Article P.

(d) The Laboratory Director shall review, and amend if necessary, the quality management system, and quality program manual, standard operating procedures at least annually. The Laboratory Director shall also review and amend the quality assurance program and manual whenever there are changes in methods or laboratory equipment employed, in the laboratory structure or physical arrangements, or changes in the laboratory organization.

Article J Fields of Accreditation

Pursuant to Article C of this Chapter, a laboratory seeking accreditation shall specify the individual units of accreditation (UoAs) within the Fields of Accreditation (FoAs) in Table 1

Table 1

Fields of Accreditation

FOA	State Regulatory Agency	FOA Name
101	SWRCB – Division of Drinking Water	Microbiology
102	SWRCB – Division of Drinking Water	General Physical and Inorganic Tests
103	SWRCB – Division of Drinking Water	Spectroscopy and Ion Chromatography
104	SWRCB – Division of Drinking Water	Volatile Organic Compounds
105	SWRCB – Division of Drinking Water	Semi-Volatile Organic Compounds
106	SWRCB – Division of Drinking Water	Radiochemical Techniques
107	SWRCB – Division of Water Quality	Microbiology
108	SWRCB – Division of Water Quality	General Physical and Inorganic Tests
109	SWRCB – Division of Water Quality	Spectroscopy and Ion Chromatography
110	SWRCB – Division of Water Quality	Volatile Organic Compounds
111	SWRCB – Division of Water Quality	Semi-Volatile Organic Compounds
112	SWRCB – Division of Water Quality	Radiochemical Techniques
113	SWRCB – Division of Water Quality	Whole Effluent Toxicity
114	Department of Toxic Substances Control	Spectroscopy and Ion Chromatography
115	Department of Toxic Substances Control	Waste Extraction Test
116	Department of Toxic Substances Control	Volatile Organic Compounds
117	Department of Toxic Substances Control	Semi-Volatile Organic Compounds
118	Department of Toxic Substances Control	Radiochemical Techniques
119	Department of Toxic Substances Control	Whole Effluent Toxicity
120	Department of Toxic Substances Control	Physical Properties of Hazardous Waste

121	Department of Toxic Substances Control	Bulk Asbestos Analysis of Hazardous Waste
122	Reserved	
123	Department of Food and Agriculture	Inorganic Chemistry
124	Department of Food and Agriculture	Pesticide Residues by GC-MS
125	Department of Food and Agriculture	Pesticide Residues by GC
126	Reserved	
127	Department of Public Health	Shellfish Sanitation
128	Reserved	
129	SWRCB – Division of Drinking Water	Cryptosporidium

Article K Standard Operating Procedures

(a) Laboratories shall maintain written standard operating procedures that document or reference activities needed to maintain their quality management systems and that enable performing or reproducing an analysis in its entirety as performed at the laboratory.

(b) Standard operating procedures shall, where available, incorporate the measurement quality objectives of the data users of the California state regulatory agency to which results are routinely reported. Otherwise the quality control procedures found in methods identified in the UoAs for which the laboratory has or is seeking accreditation or found in Article E if the standard operating procedure is for a test method.

(c) Standard operating procedures may be documents written by laboratory personnel or may consist entirely of copies of published documents, manuals or procedures if the laboratory follows the chosen source exactly.

(d) Standard operating procedures may consist in part of copies of published documents, manuals or procedures if:

(1) Modifications to the published source are described in writing in additional documents.

(2) Clarifications, changes or choices are completely described in additional documents, when published sources offer multiple options, ambiguous directives or insufficient detail to perform or reproduce an analysis.

(e) Standard operating procedures shall indicate their dates of issue or revision.

(f) There shall be standard operating procedures for test methods performed for programs covered by this chapter.

(g) The standard operating procedures for test methods may consist of published or referenced test methods, or standard operating procedures written by the laboratory as allowed in this section.

(h) The essential elements standard operating procedures for test methods may be presented in narrative, tabular, schematic or graphical form. The analytical methods manual shall be an identifiable document in hard copy or electronic format traceable to the laboratory.

(i) When the analytical methods manual consists of standard operating procedures written by the laboratory, each standard operating procedure shall include, address or refer to, at a minimum, the following elements:

(1) Identification of the test method consistent with Articles H and I.

(2) Applicable analytes consistent with the UOAs listed on the laboratories certificate of accreditation.

(3) Applicable matrices.

(4) Method sensitivity.

(5) Potential interferences.

(6) Equipment and analytical instruments consistent with Article G and the test methods in the UOAs listed on the laboratories certificate of accreditation.

(7) Consumable supplies, reagents and standards identified in the UOAs listed on the laboratories certificate of accreditation.

(8) Sample preservation, storage and hold time.

(9) Quality control samples and frequency of their analysis.

(10) Calibration and standardization.

(11) Procedure for analysis.

(12) Data assessment and acceptance criteria for quality control measures.

(k) When a procedure or test method is used to produce results to be reported to different data users with different measurement quality objectives, a separate standard operating procedure will be prepared for each different user.

(l) Standard operating procedures, whether they describe test methods or not, shall have a standard format in the following order.

(1) Name of the laboratory

(2) Title describing what standard operating procedure encompasses.

(3) Summary of the procedure

(4) Data user of the California state regulatory program to which the results are being submitted

(5) Measurement Quality Objective to be met

(6) Equipment and Supplies

(7) Reagents and Standards

(8) Sample Collection, Preservation, and Storage

(9) Quality Control /Quality Assurance

(10) Calibration and Standardization

(11) Procedure

(12) Data Analysis

Article L Records and Documents

(c) The laboratory shall establish procedures to control and manage all records and documents that form part of its quality system and that are required to demonstrate compliance with this chapter.

(d) The procedures shall be written and consistent with Article K and be part of the Quality Assurance Manual described in Article I.

(e) Each laboratory shall maintain comprehensive records of all laboratory activities, including original observations, calculations and derived data, calibration records and copies of test reports for a minimum of five (5) years

(f) The department may require in writing that records be retained for a longer period than that specified in paragraph (c) if ELAP or a data user from a California state regulatory agency has initiated legal action involving test results or the certification or registration status of the laboratory.

(g) The laboratory shall identify to ELAP a responsible party for retaining documents and records for the required period in the event the laboratory changes ownership or ceases to be accredited.

(h) Records and documents shall be handled and stored in a manner that ensures their permanence and security for the required retention period, and that facilitates their retrieval to demonstrate compliance with this chapter.

(i) Records and documents shall be legible and their entries shall be safeguarded against obliteration, erasures, overwriting, and corruption.

(1) Handwritten records shall be recorded in black or blue ink.

(2) Records and documents that are stored only on electronic media shall be supported by the hardware and software necessary for their retrieval and reproduction into hard copy.

(3) Corrections or other alterations made to entries in records or documents may not obscure the original entry, must be dated and initialed.

(4) The laboratory shall have procedures to prevent unauthorized access or amendments to records and documents.

(j) Administrative records that laboratories shall maintain include:

(1) Certificates of certification or registration issued by ELAP.

(2) Records of personnel qualifications, experience and training when personnel are required to possess or maintain specific Records of demonstration of capability for each analyst required to perform the demonstrations consistent with Article F

(3) Copies of or access to other standards and documents necessary for the laboratory to operate or to maintain compliance with this chapter.

Article M Standards

(k) The laboratory shall ensure that results of analyses can be linked to all the standards and reagents used to derive results. Standards and reagents used in analyses shall conform to the purity specifications contained in approved methods identified in the units of accreditation for which the laboratory is accredited. When approved methods do not specify the purity of the standards and reagents to be used, the laboratory shall choose standards and reagents of sufficient purity to ensure the results consistent with measurement quality objective identified in Article E.

(l) The laboratory shall certify the accuracy of all reference materials used to calibrate or verify the calibration of analytical support equipment. Reference materials shall be calibrated by a body independent of that in charge of analytical operations that can provide traceability to primary standards maintained by National Institute of Standards and Technology.

(m) When reference materials traceable to NIST are not produced, manufactured or commercially available, the laboratory shall use materials of a quality that will ensure the accuracy of the calibrated or verified support equipment for its intended use and consistent with the measurement quality objectives in Article E.

(n) The laboratory may not use standards and reagents beyond the expiration dates identified by the manufacturer, unless the laboratory can verify their reliability in a defensible manner.

(o) The laboratory shall document the identity, source and purity of all standards and reagents used in tests methods performed. The laboratory shall retain records of certificates of analysis or purity, when the records are provided by the supplier, and are necessary to establish the identity, source or purity of standards and reagents.

(p) Original containers of standards and reagents shall be labeled with a receipt and an expiration date.

(q) The laboratory shall document the lot number, manufacturer, date of receipt and the date of expiration of stock standards and reagents separately from their containers to ensure this information will be retained when the containers are discarded.

(r) The laboratory shall maintain records that detail the preparation of intermediate and working standards and reagents consistent with Article L. These records shall link the intermediate and working standards and reagents to their respective originating stocks or neat compounds and shall indicate their date of preparation, expiration and the identity of the preparer.

(s) The laboratory shall retain records and certificates that trace reference materials used to calibrate or verify analytical support equipment to the source of the corresponding reference materials.

(t) The laboratory shall retain records demonstrating that the accuracy of the reference materials has been certified or verified, at the required frequencies, by a body outside of that in charge of analytical operations.

Article N Sample Handling and Chain of Custody

(u) The laboratory shall have and follow a written policy that clearly outlines the conditions under which samples will be accepted or rejected for analysis, or under which associated reported results will be qualified. The policy shall be in the format of a standard operating procedure consistent with Article K and be part of the quality assurance manual as described in Article I. The policy will be provide procedures to ensure that the measurement quality objectives of the data user from a California state regulatory agency for which the samples are being analyzed are met or if no such MQOs exist, the measurement quality objectives of Article E are met.

(v) The policy shall describe how samples received by a laboratory for analysis shall:

(1) Be assigned a unique identification code. This code may be as simple as a location and a date or equivalent so long as it is unique.
(2) The unique identification code shall be placed on a sample container as a durable label.
(3) The unique identification code shall be used as a link to associate samples with their complete history, including treatment and analysis, while in the laboratory's possession.
(4) Chain−of−custody documentation shall be required for samples collected for compliance with this chapter.

(w) The policy shall include the sample preservation procedures and holding times required by state and federal regulations and the measurement quality objectives of the state regulatory agency. If the sample preservation procedures and holding times are not required by state or federal regulations, laboratories shall follow the sample preservation procedures and holding times established in the analytical method identified in the UOA that they are accredited for and are using for the samples being processed.
(1) Laboratories analyzing samples for UOAs found in FOA 101 – 106, 127, and 129 shall be compliant with requirements found in the Code of Federal Regulations Title 40 Section 141
(2) Laboratories analyzing samples for UOAs found in FOA 107 – 113 shall be compliant with requirements found in the Code of Federal Regulations Title 40 Section 136
(3) Laboratories analyzing samples for UOAs found in FOA 114 – 113 shall be compliant with requirements found in the California Code of Regulation Title 22 Division 4.5 Chapter 11
(4) Laboratories accredited in Fields of Accreditation 124 – 125 shall use measurement quality objective used by the Department of Food and Agriculture.

(x) The laboratory shall retain records supplied by the collector in a fashion consistent with Article L to allow the laboratory and ELAP on site assessors to evaluate collection procedures against the laboratory's sample acceptance policy.

(y) When the laboratory provides containers and preservatives for sample collection, including glass bottles, plastic bottles, and bulk sampling containers such as "carboys", the laboratory shall have standard operating procedures in place which address concerns that the containers are adequately

cleaned and not contributing to contamination of samples, do not contain analytes of interest at levels which will affect sample determinations and that the preservatives used are sufficiently pure to maintain the validity of reported results. Containers supplied by the laboratory for sample collection shall allow collecting a sufficient amount of sample to perform all required or requested determinations at the required or desired sensitivity.

(z) The laboratory shall document the receipt and condition of all samples in chronological hard copy or electronic records as well as the history of the sample from collection to analysis. Chain of custody records shall be part of the sample handling policy and practice. The records may be maintained in any format that retains the following information:

(1) The identity of the client or entity submitting samples, or the project associated with the received samples.
(2) The dates of sample collection and laboratory receipt.
(3) The unique sample identification code assigned by the laboratory.
(4) Documentation of sample preservation status and other sample conditions on receipt.
(5) An unequivocal link between the sample identification code assigned by the laboratory and the field collection identification code assigned by the collector.
(6) The reference to requested test methods, when the collector or sample originator specifies them.
(7) Any comments resulting from the inspection undertaken to determine whether samples meet the policy identified above.

(aa) The laboratory shall have procedures and appropriate facilities which will:

(1) Avoid deterioration, contamination, loss or damage of samples during storage.
(2) Samples shall be stored separately from all standards, reagents, food and other potentially contaminating sources.
(3) Samples shall be stored in areas that prevent or minimize cross−contamination.
(4) Sample extracts, digestates, leachates or concentrates, resulting from any initial preparatory step, shall be stored as specified in this subsection.

Article O Corrective Actions

(1) The laboratory shall take corrective action when:
(a) Departures from established policies and procedures in the quality management system consistent with Article D and codified in the Quality Assurance Manual in Article I are identified or become apparent.
(b) Measurement quality objectives consistent with Article E, including measurement quality objectives required by data users from California state regulatory agencies, the individual methods identified in the UoAs for which the laboratory is accredited, or the Article E itself.
(c) Quality control samples and procedures, including proficiency testing samples, fail established acceptance limits or evaluation criteria.
(2) The corrective action shall identify the source of the problem, correct the problem, and have a mechanism to verify the action has had the desired effect.
(3) The laboratory shall document corrective action taken to address the nonconformance and any other changes resulting from corrective action investigations. Changes taken to address failures of quality control samples to meet established acceptance criteria shall be those that resolve or address the failure in an expeditious manner before affected results are released or reported by a laboratory.
(4) The laboratory shall monitor the effectiveness of implemented corrective action changes and take additional corrective action when initial and or subsequent corrective action fails to resolve the nonconformance.

Article P Notification and Reporting

(bb) Laboratories certified for FoAs 101, 102, 103, 104, 105 and/or 106 shall conform to the following reporting and notification requirements.

(1) Laboratories reporting bacterial quality results as required by Title 22, California Code of Regulations, Section 64423.1 shall submit a bacterial monitoring report including information required in Title 22, California Code of Regulations, Sections 64423.1(c)(2) and (c)(3) directly to the Department.

(2) The laboratory shall notify a water supplier's designated contact person as soon as possible, but within 24 hours, and record the method and time of notification or attempted notification, whenever any of the following occur:
(A) The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli) is confirmed.

(B) A bacterial sample is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b).

(C) A nitrate sample exceeds the MCL.

(3) If the laboratory is unable to make direct contact with the supplier's designated contact person within 24 hours, pursuant to subparagraphs (2)(A) or (C), the laboratory shall immediately notify the Department and provide a written record of the time and method of attempted contacts.

(4) All analytical results conducted pursuant to Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring, shall be reported directly to the Department electronically using the Electronic Deliverable Format as defined in The Electronic Deliverable Format [EDF] Version 1.2i Guidelines & Restrictions dated April 2001 and Data Dictionary dated April 2001, by the 10th day of the month following the month in which the analyses were completed.

(5) Whenever a laboratory is requested by a water supplier, pursuant to Title 22, California Code of Regulations, Section 64425(a)(2), to submit evidence invalidating a sample due to laboratory error, the laboratory shall provide the supplier with information which shall include:

(A) A letter from the Laboratory Director to the water supplier agreeing to the invalidation request by reason of laboratory accident or error;

(B) Complete sample identification, laboratory sample log number (if used), date and time of collection, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question;

(C) Complete description of the error alleged to have invalidated the result(s);

(D) Copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and

(E) Any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question.

(b) Laboratories certified for FoAs 122 and 123 shall verify the identity and quantity of a pesticide residue before reporting the results.

(c) In any arrangements between laboratories involving the transfer of samples, or portions of samples, the laboratory issuing the report of analyses shall include the original of any report(s) (or copy of the original) prepared by all other laboratories

Article Q On-Site Assessment

(a) Each laboratory shall be subject to an on-site assessment to obtain its initial certificate and every two years thereafter by ELAP to verify the information submitted with its ELAP certificate application pursuant to Article C, including compliance with requirements in:

(1) Methods used for each UoA for which the laboratory seeks accreditation consistent with Article H;

(2) Quality Management Systems consistent with Article D

(3) Measurement quality objectives consistent those listed in the application described in Article C and with Article E

(4) Personnel Requirements consistent with Article F

(5) Quality Assurance Manual consistent with Article I

(6) Standard Operating Procedures consistent with Article K

(7) Record keeping and retention consistent with Article L

(8) Standards and traceability consistent with Article M

(9) Sample handling procedures consistent with Article N

(10) Corrective action policy and practice consistent with Article O

(11) Notification and Reporting practice consistent with Article P

(b) Other on-site assessments.

(1) If ELAP identified a deficiency on a previous on-site assessment, the agency may conduct a follow-up on-site assessment.

(2) ELAP may conduct an on-site assessment when a laboratory applies to modify its scope of certification, when a transfer of owner occurs that affects personnel, equipment, or the laboratory facilities, or when a laboratory applies for an exemption or a variance. Any other change occurring in a laboratory's operations that might reasonably be expected to alter or impair analytical capability and quality may trigger an on-site assessment.

(c) ELAP may conduct, at its discretion, either announced or unannounced on-site assessments. Advance notice of an assessment shall not be necessary.

(d) On-site Assessment process

(1) On-site assessors shall arrive at the laboratory during established working hours. The laboratory manager (or, if unavailable, the laboratory manager's designee) shall be located as soon as possible after the assessment personnel arrive on the premises.

(2) A laboratory's refusal to admit the on-site assessors for an on-site assessment shall result in an automatic failure of the laboratory to receive certification or loss of an existing certification by the laboratory, unless there are extenuating circumstances that are accepted and documented by ELAP staff.

(3) An opening conference shall be conducted and shall outline to goals of the on-site assessment, the items to be assessed on-site, records, personnel, equipment, facilities, documents that need to be examined.

(4) On-site assessors may examine any records, equipment, facilities, documents that need to be examined that are part of the UOAs that the laboratory is seeking accreditation for and identified in the application submitted consistent with Article C.

(5) On-site assessors may interview any personnel working in the facility that is identified in the application submitted under Article C or the Quality Assurance Manual identified in Article I or who may have a significant role in the quality of laboratory results.

(6) On-site assessors may ask laboratory personnel to demonstrate how procedures and test methods are actually performed or examine procedures and test method in operation at the time of the on-site assessment. This may include conducting analytical tests, operating support equipment, sampling handling, record keeping, or any other activity described in this Chapter.

(7) A closing conference shall be conducted and shall outline the findings of the on-site assessment. Any deficiencies or deviations for the standards listed in this chapter shall be identified.

(8) The on-site assessors will prepare a letter following the closing conference summarizing the on-site assessment and all deficiencies and a schedule for rectification by the laboratory.

(9) The laboratory may appeal the decision of the on-site assessors to the program within 30 days of receiving the deficiency letter.

(e) Deficiencies deviations from specific requirements found in the methods listed in the UOAs that the laboratory is accredited for found in Article H, or any Article in this Chapter, California Health and Safety Code 100825 – 100920.

TNI STANDARD & WORK PLAN TIMELINE

recommended by ELTAC TNI Subcommittee

RECAP OF NEED FOR TNI STANDARD

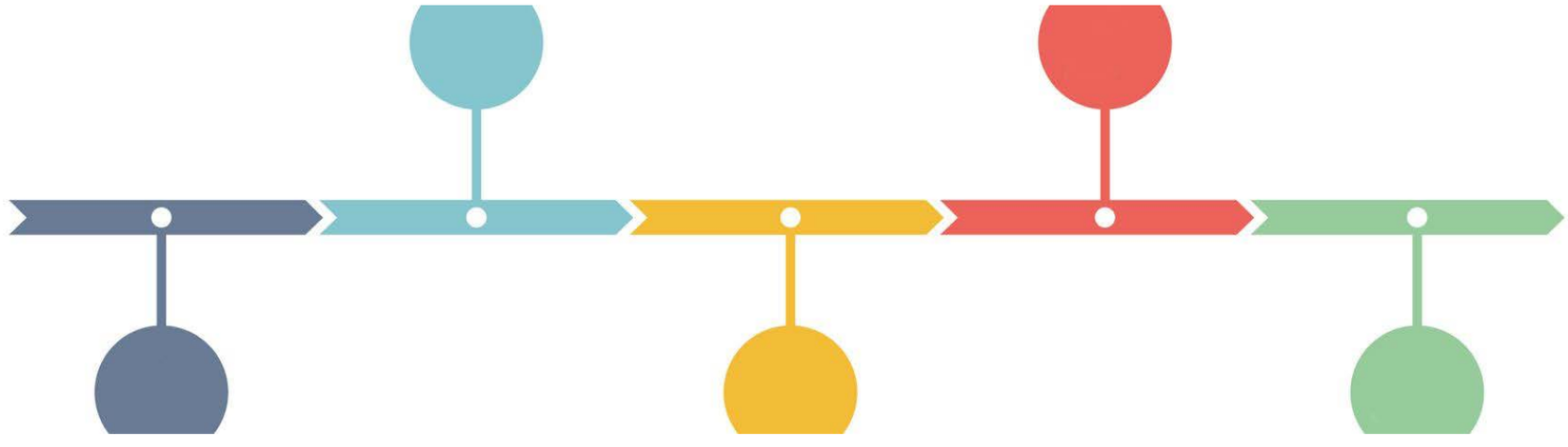
- Comprehensive
  - Widely recognized: employs ISO17025, reciprocity in 23 States, 12 State AB's, recognized in 35 out of 50 States.
  - Consensus Based: Culmination of more than 20 years of work by laboratory & regulatory professionals
  - Addresses PTs & ABs
  - Scalable for small labs & Applicable to specialty labs and multiple regulatory programs
- Practical
  - Well established & continuously improved
  - Resources available, including training & templates
- Economical
  - Ready to use now
  - Recreating the wheel = Years + $$$$$$$$

RECOMMENDED VERSION OF TNI: 2016

- 2003 Standard
  - Not a viable option; outdated
- 2009 Standard
  - Problems with language and some modules
- 2016 Standard - Recommendation
  - ELTAC members in attendance at NEMC meeting agreed 2016 Standard is best of all TNI revisions available for adoption
  - Provides some key clarifications, easier to implement in smaller labs
- 2016 Standard has been approved and published; Does not require TNI adoption for use
  - Copies of the 2016 Standard have been provided to ELTAC members for their review, at no cost
  - TNI's Jerry Parr will provide ELTAC with summary of changes between 2009 and 2016 Standards

PROPOSED TIMELINE FOR IMPLEMENTATION

- Proposed timeline for implementation of the Standard will involve several different but interrelated timelines:
  - SWRCB decision regarding Standard selection
  - Legal rule making process
  - Training for ELAP personnel
  - Training for labs
  - Lab implementation



PROPOSED TIMELINE FOR IMPLEMENTATION

ELTAC RECOMMENDATIONS to ELAP:

- TNI training & conformity assessments for labs implemented over 3 year period
  - Starts January 2017 (training)
  - Includes training and orientation for labs on a need/want basis
  - Progresses to a first round of TNI Standard lab assessments in 2018-2020
    - Full implementation no later than Dec. 31, 2020
- Implementation should include provisions for interim accreditation of nonconforming labs during initial 3 year period

PROPOSED TIMELINE FOR IMPLEMENTATION

ELTAC RECOMMENDATIONS:

- ELAP attitude toward initial assessments should be cooperative and educational, i.e. compliance assistance
  - Primary mission should be training labs on how to comply with the Standard
- After first round(s) of TNI Standard assessments, labs will be expected to:
  - Create corrective actions with time frames
  - Schedule for resolution
- Once full implementation begins, repeat findings from assessment to assessment will then result in escalated actions

PROPOSED IMPLEMENTATION STRATEGIES

- TNI Standard 2016 should be adopted by California ELAP

QUESTIONS?

In Support of California Adoption of the TNI Standard

Allison Mackenzie

Babcock Laboratories, Inc.

Prepared for the May 11th, 2016

Environmental Laboratory Technical Advisory Committee (ELTAC) meeting

In Support of California Adoption of the TNI Standard

> "ELAP does not have a relevant accreditation standard…" and "…these deficiencies have cost the program credibility among key constituencies" (Phelps, Adelson, Arms, Miller, & Speis, 2015).

These were some of the stark conclusions of a panel of five laboratory accreditation experts from across the United States after their external examination of the existing California Environmental Laboratory Accreditation Program (CA ELAP). Their conclusion was that not only does California need a robust accreditation standard, but adoption in a timely fashion is of critical importance as hundreds of labs across the state and the country test and report thousands of pieces of analytical data—data that is vital to the protection of the public health and preservation of the environment—to California agencies daily. This paper will explore the key reasons why CA ELAP should adopt The NELAC Institute (TNI) Standard. Simply stated, the TNI Standard is the most comprehensive, practical, and economically viable option available to CA ELAP.

To begin, it is important to understand the basic purpose of accreditation. According to the website of the California State Water Resources Control Board (SWRCB), "ELAP-accredited laboratories have demonstrated capability to analyze environmental samples using approved methods" (ELAP, 2016). The purpose of a quality systems based laboratory standard is to ensure the competency of a laboratory to produce data of known and documented quality. All labs—public and private— produce data for decision making purposes affecting public health and safety and therefore must be held to the same standard, regardless of lab size. Labs perform compliance testing that is vital to the future of environmental sustainability and human health (Morgan, 2015; See also Appendix B). It is precisely because State agencies use this analytical data to monitor and make decisions regarding the environment and public health that ELAP "provides evaluation and accreditation on environmental testing laboratories to ensure the quality of analytical data [produced]" (ELAP, 2016). With ELAP's purpose defined, we can assume that CA ELAP agrees with Parr's (2010) following statement on data quality:

> Data of known and documented quality is critical for end users of environmental measurement data and government agencies to make accurate, reliable and cost-effective decisions to protect the public health and the environment.

Focusing an accreditation system on methods alone is insufficient to ensure quality and consistency. As Parr (2010; See also Appendix C) continues to explain:

> An important factor in improving the quality of environmental data and ensuring that the data are adequate for the intended purpose, is a consistent, stringent, comprehensive and yet practical accreditation program to ensure the competency of all environmental testing laboratories and related sampling and measurement organizations in the United States.

With this understanding of the basic purpose of accreditation under CA ELAP and the need for a quality system based laboratory standard to ensure data quality, this paper proposes that CA ELAP should adopt the TNI Standard because it is the most comprehensive, practical, and economically viable option available to CA ELAP.

Comprehensive

Sitting on the edge of the Pacific Rim and boasting the world's 8th largest economy, California is a global leader in agriculture, education, industry, manufacturing and technology (Sisney, Garosi, 2015). Interstate and international commerce depend on mutual recognition of standards and in fact, California's trade and commerce extend across all fifty states and into countries around the world.

The TNI Standard employs the International Organization for Standardization (ISO) 17025, a quality systems document recognized nationally and internationally for the conformity assessment of testing laboratories. ISO standards, including ISO 17025, are used around the globe and are requisite in many nations, including the European Union (EU) countries and in Asia, (ISO, 2014).

With ISO 17025 as the foundation, the TNI laboratory standard adds requirements, specifications, and clarifications unique to the environmental field and necessary to assure a consistent approach to quality and establish the foundation for data comparability between labs. At the present time, the TNI Standard is recognized in over twenty five (25) states across the United States and has full reciprocity in twenty three (23) states. Twelve (12) states are qualified as TNI Assessment Bodies (AB) and TNI has been adopted by several states as the only acceptable accreditation standard across all regulatory programs, (Morgan, 2015; See also Appendix B). Founded in 1998 as the National Laboratory Accreditation Council and the National Laboratory Accreditation Program (NELAC & NELAP), the TNI Standard is well established and widely recognized (Parr, 2010; See also Appendix C).

Perhaps the most important feature of the TNI Standard is that it is a consensus-based standard which has been developed over twenty years with input and comment from hundreds of laboratory and regulatory professionals at the federal, state, and local levels. Countless hours of time have been devoted by experts with proficiency in all areas of environmental testing—from microbiology and chemistry to whole effluent toxicity and radiological testing—to create the TNI Standard. Hundreds of professionals gather twice each year at TNI conferences to discuss, clarify, recommend, and ultimately adopt improvements to the Standard with input having been derived from multiple committees working throughout the year. Collaboration and technical knowledge is the power of TNI, resulting in recognition of the TNI Standard as an American National Standard by the American National Standards Institute (ANSI).

Founded in 1918, ANSI's mission is "To enhance both the global competitiveness of U. S. business and the U. S. quality of life by promoting…consensus standards and conformity assessment systems" (ANSI, 2016). In addition to creating guidelines and standards that impact

energy, agriculture, construction, etc., a key activity of ANSI is to evaluate the competence of organizations that determine conformity assessment. ANSI recognition of TNI and the Standard adds credibility and further wide-spread recognition.

TNI is a comprehensive standard because it includes more than one aspect of accreditation. TNI has established standards for laboratory Performance Testing (PT) and for the providers of PTs. It outlines the requirements necessary for conformity in production, distribution, and evaluation of PTs and the generation and interpretation of PT results. Additionally, TNI addresses the quality systems necessary for an organization or program that provides accreditation under the Standard —the conformity of the AB. The AB's must also adopt quality systems and practices to maintain consistency and demonstrate competence, and to ensure objectivity in assessment.

The TNI Standard has also shown scalability and applicability to a wide variety of laboratories. Large laboratories with more than 75 staff, specialty laboratories such as whole effluent toxicity and microbiology laboratories, and small laboratories with only one or two employees have all successfully implemented and benefited from the TNI Standard (Morgan, 2009). TNI and the lab professionals engaged in the continuous evaluation and improvement of the Standard have demonstrated a commitment to quality and sensitivity to the limited resources of small labs. In fact, many of the resources available through TNI, the working committees, and at the annual meetings are a direct reflection of this commitment. These resources include templates for Quality Assurance Manuals and Standard Operating Procedures (SOPs) and training webinars on implementation.

Practical

Adoption of the TNI Standard in California is the most practical option offering the quickest and most efficient implementation. The Standard is already well established and would not require the resources that would be necessary to create a California laboratory accreditation standard from scratch. At the onset, it took more than ten years to complete and adopt the first TNI Standard and more than five years is spent just to update the existing Standard.

In Wisconsin, a state that opted to take elements of existing standards and customize them, the process of creating and adopting a standard took six years (Sotomayor, 2015; See also Appendix D). Even using the regulatory framework developed more than six years ago in California as a starting point, agreement and consensus would take time and create delays. Given the constraints of the Bagley-Keene Act—and the strongly held opinions of members of ELTAC, the regulated community, and the regulatory agencies—collaboration would be both contentious and costly.

Adoption of the TNI Standard would enable ELAP and environmental laboratory managers to spend valuable time learning and applying the Standard and refining their existing laboratory systems and processes to meet the new criteria. Training and orientation of laboratory personnel could also begin sooner rather than waiting for new program development, approval and implementation. Additionally, the drafting, review and adoption of new regulations can begin in a more time efficient manner.

Data suggests TNI Standard adoption and implementation would improve data quality and defensibility across numerous regulatory programs: drinking water, recycled water, wastewater, and solid waste. According to a 2009 NELAP survey with 553 respondents from 42 states and six countries, 85% of the labs surveyed believed that implementation of NELAP had improved the quality and defensibility of the data they produced. 294 of the respondents were labs with 10 or fewer staff members and 17.5% (97) were small labs with less than three employees. Further, 476 out of 553 labs felt that NELAP improves employee quality awareness (Morgan, 2009). Implementing a standard that benefits both the data consumers and data producers is exceptionally practical.

Accreditation consistency is enhanced by the TNI Standard because ABs and labs must follow the same quality systems based program. Not only are the expectations of the accredited labs more clearly defined, but the AB must also meet clearly defined expectations. Therefore, in addition to serving the needs of State agencies by ensuring data quality and defensibility, the Standard also serves the needs of labs by ensuring the AB follows a specific set of rules and it offers a means of reconciling differences of perception through a formal standard interpretation request process.

Economical

Development of a customized California laboratory accreditation standard would be costly and fiscally irresponsible. According to conservative estimates, each year that the ELTAC and ELAP spend working to create a standard will cost the state of California, public agencies, and commercial laboratories somewhere between $200,000 and $500,000 (Appendix A). Even three years spent to accomplish the initiative could have a potential price tag of $1.5 Million. Arguably, that money is better invested in implementation and training instead of recreating the proverbial wheel.

A common misconception is that TNI places an undue financial burden on labs based on size. As previously discussed, there has been considerable effort made to streamline TNI requirements and to minimize the cost of implementation to small laboratories. All laboratories should be capable of the same level of quality, documentation, and technical ability. Indeed, all laboratory data—especially data used for regulatory compliance—must be of known quality and integrity. **Size of population served should not have a bearing on the quality and reliability of the lab or the lab's test results.** Organizations and agencies unwilling or incapable of investing the time to meet a minimum level of regulatory conformity and quality should not be generating data critical to protection of the public health and the environment.

Finally, the TNI Standard provides the State of California and the laboratory community with resources that they would otherwise lack. The power of TNI rests in collaboration with environmental professionals across the United States, with direct access through TNI to the top experts in the environmental field and at regulatory agencies, and with the myriad resources developed by those professionals over the course of the existence of the national laboratory

accreditation efforts. Without a doubt, the TNI Standard is the most economically viable option that is fiscally responsible to the water rate payer and to the California taxpayer.

In conclusion, if the intention of CA ELAP is to best serve its stakeholders—laboratories, State agencies, regulators, and the general public—adopting the TNI Standard is the answer. The TNI Standard is comprehensive in scope, service, and expertise. Its ISO 17025 and consensus-based foundation give the Standard wide-spread recognition, support, and applicability. The Standard is well-established and has proven benefits, making it the most practical choice in terms of manageable and effective implementation. Furthermore, adopting the TNI Standard is the most cost-effective solution for the State, as it can invest in implementation and training rather than the development of a new, untested program. In addition, the Standard will help ensure all labs operate at the appropriate level of quality—a level that is consistent with the quality of protection to which the public and environment are entitled. In short, the Standard is the best option for California which is why CA ELAP should adopt the TNI Standard.

References

ANSI (2016). ANSI Mission. Retrieved from http://www.ansi.org/about_ansi/overview.

ELAP, 2016. California State Water Resources Control Board website information on the Division of Drinking Water Environmental Laboratory Accreditation Program. Retrieved from http://www.waterboards.ca.gov/drinking_water/certlic/labs/index.shtml.

ISO (2014). Using and referencing ISO and IEC standards to support public policy. Retrieved from http://www.iso.org/sites/policy/documents.

Morgan, J. (2009). NELAP survey conducted Nov. 7th to Dec. 20th, 2008. Powerpoint presentation, 2009 National Environmental Monitoring Conference, San Antonio, TX.

Morgan, J. (2015). ACIL Laboratory Accreditation Perspective. Powerpoint presentation, Expert Review Panel Meeting, March, 2015, Costa Mesa, CA. Retrieved from http://sccwrp.org/elap.

Parr, J. (2010). History and future of laboratory accreditation. Presented at WEFTEC in 2008 and updated in 2010.

Phelps, L., Adelson, J., Arms, S., Miller, M., Speis, D. (2015). Expert Review Panel Final Report, October, 2015, Costa Mesa, CA. Retrieved from http://sccwrp.org/elap.

Sisney, J., Garosi, J. (2015). 2014 GDP: California Ranks 7th or 8th in the world. Retrieved from http://www.lao.ca.gov/LAOEconTax/Article/Detail/90.

Sotomayor, A. (2015). Hybrid accreditation standards: Wisconsin's laboratory accreditation. Powerpoint presentation, Expert Review Panel meeting, August, 2015, Sacramento, CA.

Appendix A

Potential Financial Burden of ELAP-created or Modified Accreditation Standard

A 4-hour-long Environmental Laboratory Advisory Committee meeting held monthly to discuss and craft an accreditation standard for California will cost approximately $230,000 per year. This estimate can rapidly escalate and easily double if meetings are held more frequently, or ELTAC members devote more than 10 hours a month to development of a standard.

ELAP time: 19 hours x 12 months x $72/hour = $16,416

ELTAC time: 18 committee members x 10 hours x 12 months x $100/hour = $216,000

These estimates do not include facilities costs, IT costs, or travel costs associated with meetings.

Assumptions

1. Fully burdened cost of ELAP staff as reported by Larsen and Sotelo to the Expert Review Panel in March, 2015 is $72/hour.
2. Estimated staff time to prepare documents and post notifications for committee meetings compliant with Bagley-Keene Act is 3 labor hours per meeting.
3. Estimated staff time for 4 employees to attend a 4 hour committee meeting is 16 labor hours.
4. The average fully burdened cost to the employer of ELTAC members is $100/hour.
5. Estimated ELTAC time to attend monthly meetings is an average of 6 hours per member.
6. Estimated time spent by ELTAC members to research and prepare for monthly meetings is an average of 4 hours per month.

- Salary range for QA Director $105,991 to $167,652 with median of $139,521 based on website: http://www1.salary.com/CA/Anaheim/Quality-Assurance-Director-salary.html
- Benefits based on Rancho California Water District website: http://www.ranchowater.com/index.aspx?NID=138

ACIL LABORATORY ACCREDITATION PERSPECTIVE

Presented by: Judith R. Morgan, MS, REM
ACIL Environmental Sciences Section, Chairman
ESC Lab Sciences
VP, Chief Regulatory Officer
Mt. Juliet, TN

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Appendix B

American Council of Independent Laboratories (ACIL)

- Founded in 1937
- Trade association representing independent, commercial scientific and testing laboratories
- Membership is comprised of professional services firms engaged in:
  - ✓ testing
  - ✓ product certification
  - ✓ consulting
  - ✓ research and development
- Affiliate members are manufacturer's laboratories, consultants, and suppliers to the industry

Appendix B

American Council of Independent Laboratories (ACIL)

- **ACIL exists to support the needs of the Independent Testing Industry**

Independent Testing Firms are defined as:

Commercial entities engaged in the following activities for the public:	
Analysis	Product Certification
Testing	Research & Dev
Inspection	Sampling
Materials engineering	Related other consulting services

A N D

Not affiliated with any institution, company, or trade group that might affect their ability to conduct investigations, render reports, or give professional, objective, and unbiased counsel

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ACIL White Paper - 2012

"Economic Benefits of National Environmental Laboratory Accreditation Using an Alternative Accreditation Process"

- Summarizes the maturity of the National Environmental Laboratory Accreditation Program (NELAP)
- Outlines the need for the use of 3rd Party Accreditation
- Addresses economic benefit to state budgets
- Outlines the process to migrate from traditional certification/accreditation programs to 3rd party based programs

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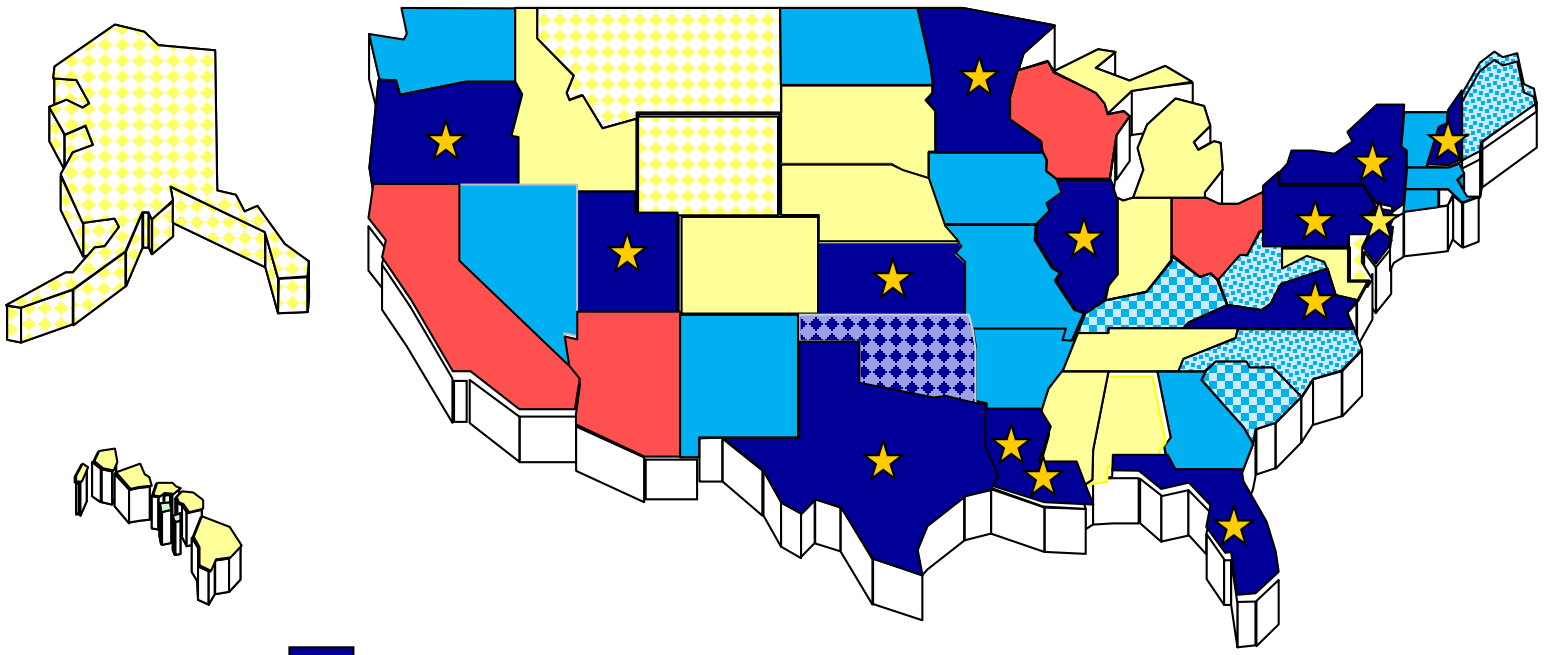
ACIL Representation

Maxwell Report 2014

- Top 30 Environmental Laboratories
  - ✓ Represent 1.02 Billion in Revenue
- ACIL Environmental Laboratory Members
  - ✓ Represent 9 of the Top 12
  - ✓ Total 672M in Revenue from Maxwell Top 30 members
- ACIL Environmental Laboratory Members represent an estimated 750M of the total available environmental market.

Appendix B

The National Program Today



NELAP Accreditation Body (14)

Accept NELAP (Full reciprocity)

Working on NELAP Application

Accept NELAP & Applies State Reqs

Has a State program that incorporates NELAP elements

State program with significant differences (4)

Drinking Water Primacy Only (12)

Drinking Water Primacy + Specialty Area (ie: UST)

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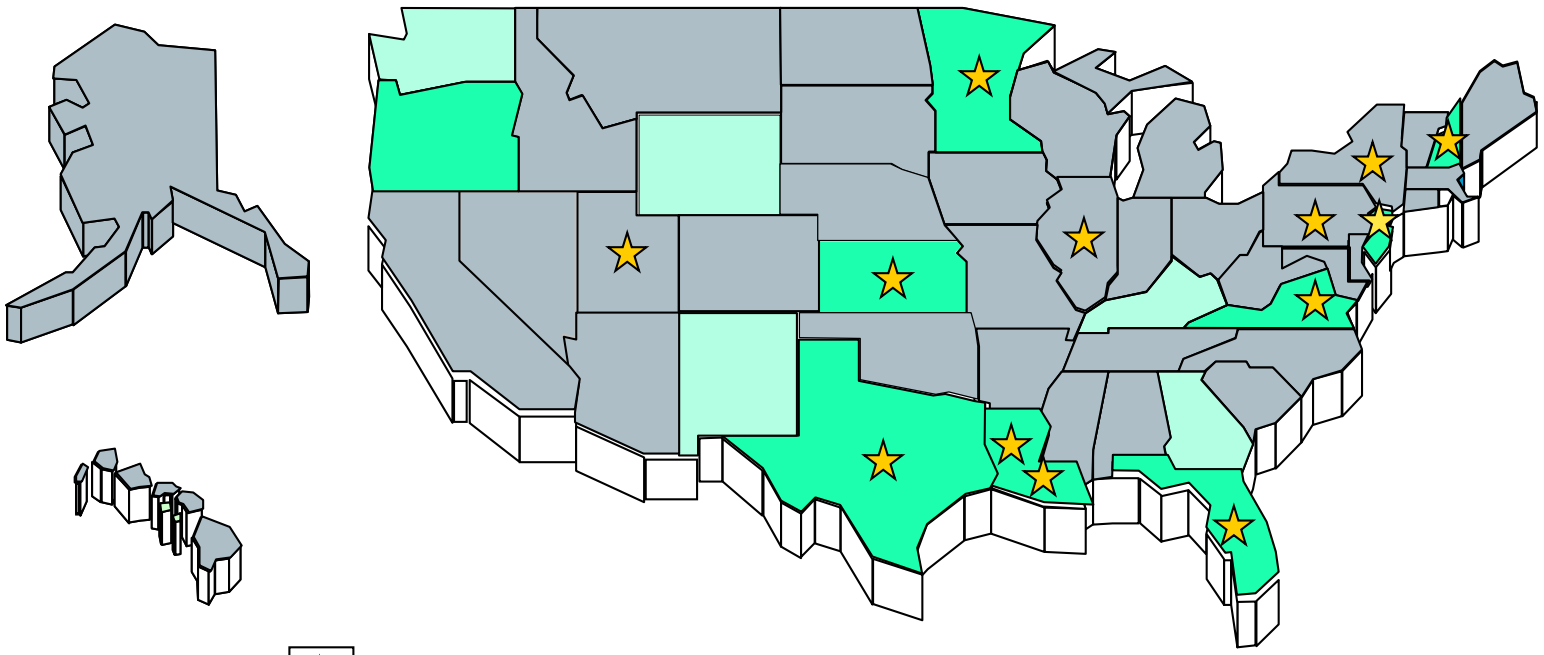
Contract Assessors and 3rd Party Accreditation



NELAP Accreditation Body

States using contract assessors

States accepting 3rd Party Accreditation (General and/or Specialty)

Others using or specifying 3rd Party Accreditation and/or Assessment:

Dept. of Defense, Dept. of Energy, EPA NLLAP, EPA NVLAP, etc.

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ACIL Vision for CA ELAP

1. Realization of Equivalency Among Data Producers

- **All labs**, public and private:
  - ✓ Produce data that determines public health and safety
  - ✓ Must be held to the same standard
  - ✓ Perform compliance testing that is key to the future of environmental sustainability and human health
- **No** defendable **reason** for ELAP to have two programs
- Data defensibility is necessary for all compliance monitoring and is not proportional to size
  - ✓ No different than other professionals: Note that the medical profession does not offer different levels of MD's based on population served.
- Size and revenue are not proportional to quality expectation
  - ✓ **All** laboratories are capable of the same level of quality system and technical ability
  - ✓ Environmental equity and justice, knows no budget or size

Appendix B

ACIL Vision for CA ELAP

2. Accreditation Consistency – National Consensus Based Standard

- Adopt a National Consensus Based Standard (TNI Standard)
- CA rejoin NELAP
  - ✓ CA can actively participate in the development , implementation and adoption of the standard.
  - ✓ Provides peer collaboration and support via the Accreditation Council
- Reform current regulations to adopt a **single program** built on a national consensus based standard
  - ✓ TNI is accredited by ANSI and the TNI Standard incorporates multiple ISO standards
- TNI Standard (ISO 17025 Based)
  - ✓ Requires the same foundational quality system regardless of lab type or size.
  - ✓ Defensibility is achieved via adherence to the same requirements for quality, technical, personnel, ethics/data integrity, and documentation
- **Ultimate goal** is to provide data of known and documented quality that is consistent across **ALL** providers, public and private.

Appendix B

WHY the TNI Standard…

- ANSI Accredited
- Incorporates ISO 17025 as the foundation for quality systems
- Most experienced and expansive "brain trust" of individuals participate in the development:
  - ✓ Many more participants and resources than any single agency has
  - ✓ Known experts with specific disciplines, from public & private sectors, including multiple non-NELAP states, collaborate together
- Polices & Processes in place for: Organization, standard development, balance, stakeholder representation, acceptance, and implementation
- Formal Standard Interpretation Request (SIR) Process:
  - ✓ Aids in ensuring consistent interpretation and implementation of the standard
  - ✓ AC must agree on interpretation
  - ✓ Interpretations are incorporated into future standard revisions
  - ✓ Available to entire membership and community
- Requires consistency for method validation, addition of non-traditional analytes, data integrity, data qualification and many other processes not addressed by every individual state program.

Appendix B

ACIL Vision for CA ELAP

3. Accreditation Consistency – Accreditor Options

- Require program conformance to ISO 17011
- Accept 3rd party accreditation via existing Accreditation Bodies (AB) conforming to ISO 17011
- **All ABs need oversight** to maintain consistency and guarantee improvement
- ABs with no oversight **cannot objectively** identify, monitor and correct their own insufficiencies
  - ✓ TNI ELSS Volume 2 requires a review of each Accreditation Body to ensure uniform conformance to the standard and assess documentation, procedures, qualifications and training
- Utilize TNI's Non Governmental Accreditation Body (NGAB) program to be implemented this year (2015)
  - ✓ TNI ELSS Volume 2 adds value above and beyond pure 17011
  - ✓ The program ensures that all NGABs comply with the TNI Standard
- Utilize known and qualified contract assessors to augment the program (like Florida). This provides access to additional qualified personnel in high volume or unusually busy time periods.
- Laboratories want the **option to choose** a suitable and equivalent path for their needs:
  - ✓ For accreditation
  - ✓ That best fits their needs and requirements for laboratory conformity assessment

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ACIL Vision for CA ELAP

4. Establish Recognition/Reciprocity with Other Programs ….. (states, national entities or private accreditation services)

- Existing programs, currently conforming to the TNI Standard, are **consistently** implemented, enforced, and assessed.

- Existing Reciprocities/recognitions:
  - ✓ 14 NELAP AB's – Full bi-directional recognition
  - ✓ WA – Full recognition of NELAP and A2LA
  - ✓ GA - Full recognition of NELAP and A2LA, ACLASS, AIHA, CALA, NSF, QAI
  - ✓ 29 Others – Full recognition of NELAP
  - ✓ 9 "DW Only" Primacy states will accept NELAP in lieu of home state

NOTE:

- 45 States reference NELAP, in full or part, in their regulations
- DOD incorporates NELAP combined with additional program specific requirements. Accreditation is granted by approved 3rd party accreditors conforming to ISO 17011.

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ACIL Vision for CA ELAP

5. Personnel Consistency

- **Professionalism** and technical knowledge are requirements.
- Adopt personnel requirements that include **training** that is **consistent** with requirements of ANSI, TNI and/or other relevant consensus organizations
- TNI Environmental Laboratory Sector Standard (ELSS) provides qualification requirements for:
  - ✓ Accreditors and Assessors (TNI ELSS V2M1 & V2M3)
  - ✓ Laboratory Personnel (TNI EL V1M2)
- Utilize the available national resources via TNI Educational and Training network
- National standard compliance reaches beyond the program constraints and limited program implementation of the EPA DW Certification Manual (which is insufficient for NPDES, RCRA, and other regulatory programs).

Appendix B

ACIL Vision for CA ELAP

6. Personnel Qualifications

- Assessors must have:
  - ✓ Actual experience in a testing laboratory
  - ✓ Education in a scientific discipline
  - ✓ The knowledge, experience, and personality to mentor and suggest improvements
  - ✓ Successful auditing experience
  - ✓ Necessary resources to provide assistance
  - ✓ Solid understanding of applicable standards, methods, quality and technology
  - ✓ Desire to stay current on new technology and methods in order to ensure proper implementation and documentation
  - ✓ Credentials that prove their expertise

Appendix B

ACIL Vision for CA ELAP

7. Fees

- Offer Separate licensing and accreditation options
- Fees should be commensurate with type of accreditation:
  - ✓ Licensing (reduced cost) – "Full reciprocity = less resources"
    - ☆ ELAP labor is limited to review of reciprocal accreditation documents
    - ☆ PT review, Corrective Actions, etc. are the responsibility of the reciprocal/accepted accreditor
  - ✓ Full accreditation via ELAP – ELAP provides all services for accreditation, which requires increased resources thus a higher cost
- Should use above suggested options to:
  - ✓ Save taxpayer monies
  - ✓ Ensure consistency of requirements across CA and neighboring state borders
  - ✓ Move the program to a position of relevance to today's labs and data users

Appendix B

ACIL Vision for CA ELAP

7. Fees - Example

In 2012 CA NELAP fees were a multiple of ELAP fees:

A fully accredited reciprocal out-of-state commercial lab

NELAP = $17,200 vs ELAP $5400

Both are reciprocal recognitions and are **document review only**, since the primary accreditor is responsible for accreditation details and documents

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ACIL Vision for CA ELAP

8. Proficiency Testing Program

- **Ensure evaluation consistency:** Mandate the use of ISO* approved providers participating in the national consensus based standards process.
- **Provide real time review of PT results**: Require true corrective action, suspension or other actions where necessary.
- **Develop a thorough process for PT review:** Define actions related to unacceptable PTs and enforce in a timely manner
- **Reciprocal/recognized accreditors maintain PT tracking** for their laboratories. No need to duplicate effort.
  - ✓ reduce cost and save time/labor for CA
- **Consider contracting PT review to a 3rd Party –** Save time, resources, and improve accuracy and efficiency

** ISO Guide 34:2009(E) General requirements for the competence of reference material producers.*
ISO 17043:2010(E) General requirements for proficiency testing

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9. Provide Program Services to Labs and Data Users

- Create metrics that reflect accountability measures for timeliness and service. Be transparent regarding operations.
- Keep community updated and provide assistance for regulatory rule changes (fed and state): i.e. Method Update Rule (MUR)
- Provide valuable services and communication in a timely manner to the accredited community
- Provide outreach, quality assurance functions, and assistance to improve the laboratory community
- Provide access to knowledgeable personnel who are available to assist with questions or issues and can provide consistent feedback
- Include up to date program news and FAQs on the ELAP website
- ELAP should help data users (public/private) understand the basic requirements needed to produce data of known and documented quality

Appendix B

Top Priorities

1. Mandate a national consensus based standard (i.e. TNI)
2. Apply the standard to all laboratories
3. Utilize 3rd party resources to remove the current backlog and close gap between current programs and national standard
   a) ISO 17011 Accreditation Bodies (NELAP ABs, NGABs)
   b) Contract assessors
4. Reorganize the program and personnel to support the implementation and maintenance of the national standard
5. Allow for a licensing or full accreditation option with appropriate fees for each
6. Current draft regulations introduce language and acronyms outside of industry standard. Recommend re-writing and simplifying the regulations to reference a national standard and provide support operations accordingly

Appendix B

Conclusions

- All environmental labs produce data that determines current and future public health and safety
- **All labs**, public and private, must be held to the same standard across the entire industry. Labs want a level playing field.
- Complete data defensibility is necessary and is not proportional to laboratory size
- CA needs a single program built on a national consensus based standard (ie: TNI standard) and should rejoin NELAP
- All accreditations should be performed by ABs conforming to ISO 17011
- Labs want a choice for accreditation.
- Options should exist for accreditation and fees:
  - ✓ NELAP – Full service via state or contract assessment, where state evaluates and monitors all requirements, including PTs, Corrective Actions, etc.
  - ✓ NGAB – Licensing by CA via ISO 17011 AB, where accreditor evaluates and monitors all requirements, including PTs, Corrective Actions, etc.

Appendix B

Conclusions

- Establish reciprocity or recognition with other programs conforming to a national consensus based standard
- Adopt personnel requirements that are consistent with requirements of ANSI, TNI and/or other relevant consensus organizations
- Require personnel to be experienced and credentialed
- Mandate the use of ISO accredited providers for Proficiency Testing
- Provide timely, value added, services to the lab community that will promote improvement and consistency while advancing the knowledge base of the laboratory

Appendix B

Thank you for your time!

Questions?

Judy Morgan
jmorgan@esclabsciences.com

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Appendix C

HISTORY AND FUTURE OF LABORATORY ACCREDITATION

Jerry L. Parr
The NELAC Institute
jerry.parr@nelac-institute.org

ABSTRACT

In 1978, the US Environmental Protection Agency (EPA) initiated a laboratory certification program for laboratories involved in analyzing drinking water and delegated the authority for operation of the program to state agencies. Over the ensuing years, many states expanded this program to include other environmental media. As a result of efforts that began in 1987, a National Environmental Laboratory Accreditation Program (NELAP) has been created and is now managed by The NELAC Institute (TNI). This article summarize the activities leading up to the formation of TNI, describe in detail the core programs being performed by the new organization and provide information about the future of national laboratory accreditation.

INTRODUCTION

Laboratory accreditation serves multiple purposes for different constituents. In general, NELAP accreditation attests to the competency of a laboratory for conducting environmental measurements.

- For the public, NELAP accreditation promotes confidence that environmental data used to make policy decisions to protect public health and the environment are generated by laboratories with demonstrated competence.
- For data users, NELAP accreditation serves a consumer protection purpose. It provides assurance that the laboratory has been evaluated and has met accepted standards of competency established by and within the profession.
- For the profession, NELAP accreditation advances the field by promoting accepted standards of practice and advocating rigorous adherence to these standards.
- For government agencies, NELAP accreditation provides a basis to determine whether environmental monitoring data are adequate for their intended use.
- For the laboratory, NELAP accreditation provides ongoing internal and external evaluations, demonstrates a commitment to continuous improvement, provides an effective mechanism for accountability, and enhances its reputation.

THE BEGINNING

Almost all environmental compliance, regulatory and clean-up decisions are made based on measurement information. Data of known and documented quality is critical for end users of environmental measurement data and government agencies to make accurate, reliable and cost-effective decisions to protect the public health and the environment. An important factor in improving the quality of environmental data and ensuring that the data are adequate for the

intended purpose, is a consistent, stringent, comprehensive and yet practical accreditation program to ensure the competency of all environmental testing laboratories and related sampling and measurement organizations in the United States.

EPA, with the states as its implementation partners, maintains requirements for the certification of drinking water laboratories as well as outlining accreditation requirements for laboratories that analyze lead in paint and asbestos. Many states independently established accreditation programs covering the analysis of waste waters, solid and hazardous wastes, and air samples. In the 1980's, the commercial laboratory community began to advocate for a single national accreditation program to consolidate the multiple state programs that contained divergent accreditation requirements. A national program would provide the foundation for ensuring the capability and competence of laboratories to foster the generation of data of known and documented quality. Over twenty years ago, EPA recognized the problem of uncoordinated, inconsistent and redundant state and federal laboratory accreditation programs. In a 1988 Report to Congress on the comparability of laboratory test procedures, the EPA recommended that it explore the feasibility of establishing a uniform, national laboratory accreditation program

In 1990, EPA's Environmental Monitoring Management Council (EMMC) established an ad-hoc panel to respond to the concerns from laboratories and regulators about the diverse number of state accrediting programs with different, sometimes conflicting requirements. This group was to consider the feasibility and advisability of a national environmental laboratory accreditation program. The workgroup concluded that a national program was a viable option, and recommended that EPA consult with representatives of all stakeholders, by establishing a federal advisory committee.

The Committee on National Accreditation of Environmental Laboratories (CNAEL) was chartered in 1991 under the Federal Advisory Committee Act (FACA) and its members represented the stakeholder community (federal, state accrediting programs, commercial laboratories, etc.). CNAEL was to explore the possibilities of a national program and provide recommendations to EPA concerning the alternatives for a national program as well as the implementation and administration of such a program. In its final report to EMMC in 1992, CNAEL recommended that a self-supporting national program for laboratory accreditation be established and provided recommended models and structure for the organization that would implement the program. CNAEL recommended the program consist of performance evaluation testing, combined with a laboratory process and quality assurance certification program, which would include onsite audits.

THE EARLY YEARS

In response to the CNAEL recommendations, EPA, state and federal representatives formed the State/EPA Focus Group in 1993. The participants in these meetings represented EPA program offices, state regulatory agencies, states with differing types of accrediting programs, and federal agencies that had a need to perform environmental testing. This group developed a proposed

framework, modeled after the National Conference on Weights and Measures and prepared a draft Constitution, Bylaws and Standards, which were published in the Federal Register in December 1994.
On February 16, 1995, state and federal officials voted to approve an interim Constitution and Bylaws – thus establishing the National Environmental Laboratory Accreditation Conference (NELAC), a standards setting organization. The major objective of NELAC was to develop accreditation standards and adopt them so that the standards could be used to support a National Environmental Laboratory Accreditation Program (NELAP). These standards were developed by a set of standing committees, who were each responsible for a chapter of the NELAC standards.

In 1999, NELAP was established with 11 states receiving recognition as NELAP accreditation bodies. The goal of NELAP is to foster cooperation among the current accreditation activities of different states and other governmental agencies and to unify the state and federal agency standards. Each of the recognized accreditation bodies must implement the NELAC standards, and must accept the accreditation of laboratories accredited by other NELAP accreditation bodies. There are currently 13 state agencies that are recognized NELAP accreditation bodies.

NELAC was structured as an association of co-regulators: EPA, the states, and other federal agencies. Stakeholder groups such as commercial laboratories, municipalities, and trade groups were encouraged to attend meetings and participate on the NELAC committees. A vote to approve standards was limited to representatives from the state and federal agencies. If a private-sector organization felt the need to provide recommendations, such consensus could only be solicited through a committee chartered under the Federal Advisory Committee Act (FACA). In 1997, the Environmental Laboratory Advisory Board (ELAB) was established under the FACA to provide consensus advice on various issues, including recommendations on the NELAC standards.

NELAC was established as a way for the national laboratory accreditation effort to begin. The NELAC operations developed and adopted standards for laboratory accreditation. In addition in 2002, the initial standard for field activities was passed. This 2002 NELAC standard was the first to recognize the need for accreditation of field sampling and measurement organizations. However, not having the authority of an act of Congress to establish an accreditation program, NELAC relied on the voluntary participation of states to implement the program. States that decide to become part of the program are expected to use one set of requirements, the “NELAC Standards.”

EPA had always intended for the program to be self-sufficient. EPA followed the recommendations of CNAEL in retaining oversight of the program, but expected a graduation into autonomy. It is clear that without EPA’s leadership and monetary support NELAC would not have progressed beyond the conceptual stage, but lacking an anchoring Federal statute, NELAC could not presume continued funding from EPA or the Agency’s perpetual management of the program.

THE TRANSITION

Two significant events occurred in the late 1990's that required changes to the original NELAC structure:

- The National Technology Transfer and Advancement Act (NTTAA) became law in March 1996. The NTTAA outlined requirements Federal agencies must implement relative to the use of private sector standards and conformity assessment practices. Federal agencies were directed to adopt private sector standards, wherever possible, in lieu of creating proprietary, non-consensus standards.
- A revised OMB Circular A-119 was issued in February 1998. This circular established policies on Federal use and development of voluntary consensus standards and on conformity assessment activities. Voluntary standards were defined as standards that were developed by a voluntary consensus standard body (VCSB). OMB Circular A-119 further defined the attributes and functions of a VCSB, which included, among other requirements, balanced interests in the standards development and approval process.

Clearly, NELAC, in its original structure, did not meet the definition of a voluntary consensus organization. Therefore, in 2002, NELAC amended its Constitution and By-Laws to make the conference a standards adoption body only. NELAC established itself as an organization that could receive and consider standards that have been developed by standards development organizations that use a consensus process as defined in OMB A-Circular 119. The last NELAC standard was published in 2003 and implemented in 2005.

While there are many recognized voluntary consensus standard bodies (ASTM International, American Industrial Hygiene Association (AIHA), etc.), no one group came forward to develop standards specifically designed for accreditation of environmental laboratories and field activities. In 2002, a new voluntary consensus standard organization, the Institute for National Environmental Laboratory Accreditation (INELA) was formed with a mission of developing standards for NELAC and other organizations to use.

INELA was incorporated as a non-profit member organization. The membership was entitled to vote on all standards and could voluntarily participate on any committee. INELA formed expert committees that functioned like the standing committees of NELAC, but with balanced representation from all stakeholder groups. Using the NELAC standards as a template, these expert committees began the process of developing consensus standards. The first INELA standard was accepted by member vote in September 2004, but was not adopted by the organization as it did not represent any significant change over the 2003 NELAC standard. In May, 2005, INELA began the process of reorganizing the 2004 standard so that a single volume would contain all the requirements for accrediting a targeted program such as environmental laboratories, field operations, taxonomy, etc.

THE RESTRUCTURING EFFORTS

The EPA Office of Research and Development (ORD) began providing financial and staffing support from the early meetings of the State-EPA Focus Groups. The ORD funding support allowed the National Environmental Laboratory Accreditation Conference (NELAC) and the National Environmental Laboratory Accreditation Program (NELAP) to begin operations and provided direct support through August 2006. At the Interim meeting in 2000, EPA reminded the NELAC community of the recommendation in the Committee on National Accreditation of Environmental Laboratories (CNAEL) document dealing with self-sufficiency. In 2005, Lara Phelps, the NELAC Executive Director announced that a series of cooperative agreements would provide support for facilitating NELAC's transition to self sufficiency. These were awarded to several groups for various tasks deemed necessary to support the future program. As a step toward self sufficiency, Ms Phelps resigned from her role as NELAC and NELAP Executive Director in August, 2006, but continued as the project manager for the self-sufficiency effort.

The National Forensic Science Technology Center (NFSTC) was selected as the primary organization to assist the NELAC board in determining the structure and format of a future organization. The NELAC board selected a team of individuals, the Self Sufficiency Task Group (SSTG) to provide recommendations on a plan for self-sufficiency, and a transition strategy to ensure the continuation of the NELAC and NELAP activities until the transition was complete. The SSTG solicited input from the NELAC community during the January 2006 NELAC meeting. The suggestions from this meeting were used to develop a draft vision, mission and purpose for the new organization, and to identify key characteristics that the new organization should possess. In addition, the SSTG used the input from the meetings to develop a strategy for transition into a new organization, and identified immediate, interim and final goals.
The SSTG also considered current standard setting organizations and solicited offers from professional organizations who might be interested in assisting with the NELAC self-sufficiency efforts. INELA was one several organizations that responded to this solicitation. Of the responses, INELA best fit the characteristics and criteria defined by the SSTG.

After an informal meeting between the INELA Board of Directors and representatives of the SSTG in April, 2006, the SSTG drafted a non-binding Memorandum of Understanding (MOU) for consideration and approval by both the INELA and NELAC Boards of Directors. In June 2006, both boards approved the MOU and selected five members from each organization to form a joint Partnership Planning Team (PPT) to explore the potential combination of the two organizations. The PPT developed a proposed model for the new organization and presented this to the stakeholder community at the NELAC meeting in Kansas on August 14 and 15, 2006.

THE PLAN FOR TRANSITION TO SELF-SUFFFICIENCY

The presentation in August 2006 covered the proposed mission, values, organization, governance and structure of a transformed organization that would build on the attributes of both NELAC and INELA.

The underlying assumptions the PPT provided for moving towards a combination were:

- Combining the operations of NELAC and INELA would result in a stronger organization.
- Combining operations would allow NELAC to achieve self-sufficiency quicker.
- Combining operations would be less disruptive to the stakeholder community.

The core values identified by the PPT as necessary in the transformed organization were:

- An organization that is inclusive and responsive to the needs of all stakeholders
- An organization based upon integrity and honesty
- A quality based organization that encompasses both a belief that the program is worthwhile and that quality is the underlying value for everything that is done.

The PPT recommended that the corporate structure of the organization be that of an incorporated 501(c)3, not-for-profit member organization managed by a board of directors.

At the end of the NELAC meeting, a vote was held by the government officials in attendance that overwhelmingly confirmed that the NELAC Board of Directors should continue to work with INELA on pursuing options for working together. The INELA membership in attendance at the meeting unanimously endorsed this direction as well. Based on the outcome of the NELAC meeting, the PPT continued its work with the goal of having the transformed organization operational by the next meeting of these groups in January 2007.

The PPT met by teleconference on a weekly basis and had a three-day meeting in late September, 2006, to complete their task of developing recommendations. Concurrently with this effort, the NELAC board formed a task group to develop recommendations about the governance and structure of the accreditation programs. These efforts were completed in October, 2006 at which time recommendations were sent to the NELAC and INELA boards for their consideration and were published on both the NELAC and INELA websites in a special report titled *Recommendations for Combining NELAC and INELA Operations*. A meeting of the INELA and NELAC Boards of Directors and Committee chairs occurred on November 6, 2006, to consider the recommendations.

FORMATION OF THE NELAC INSTITUTE

On November 6, 2006 a giant step towards achieving the long-term goal of the environmental laboratory and monitoring communities to have a national accreditation program was realized. After years of an evolving program under the auspices of the NELAC and INELA, the respective Board of Director's took actions necessary to form The NELAC Institute (TNI).

The actions taken on November 6th to form TNI were the result of years of hard work to create a national program through NELAC, years of hard work by INELA to create a consensus process for the development of accreditation standards, and months of intense exploration by a Partnership Planning Team (PPT) representing both entities that culminated in this new

organization. As reflected in the new name, The NELAC Institute (TNI) has combined the heritage of NELAC with the consensus process of INELA into one organization.

The NELAC Institute (TNI) is a 501(c)3 non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community. The organization is managed by a Board of Directors and is governed by organizational Bylaws. Members of the organization include individuals from laboratories, data users, federal and state agencies and anyone interested in promoting environmental data of known and documented quality.

More information about TNI is available at www.nelac-institute.org.

TNI's PROGRAMS

The NELAC Institute operates the following major programs:

- Consensus Standards Development,
- Laboratory Accreditation System,
- National Environmental Laboratory Accreditation,
- National Environmental Field Activities Accreditation
- Proficiency Testing, and
- Technical Assistance.

Consensus Standards Development Program (CSDP)

The purpose of the Consensus Standards Development Program (CSDP) is to develop consensus standards for the accreditation of environmental laboratories. Accreditation standards are developed by Expert Committees using a consensus process that includes the elements of openness, balance, due process, and consensus as established by Circular A-119 published by the US Office of Management and Budget. Standards have been developed that are widely applicable, and will therefore promote a uniform national program of environmental laboratory accreditation. These standards are modular, allowing their assembly into a series of volumes, each specifically designed for a stakeholder group (Laboratories; Accreditation Bodies; Proficiency Test Providers; Proficiency Test Provider Oversight Bodies; and Field Sampling and Measurement Organizations). The standards that have been developed by this program are summarized in Table 1.

Table 1. TNI Accreditation Standards

Environmental Laboratory Sector

Appendix C

Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis
Module 1 - Proficiency Testing
Module 2 - Quality Systems: General Requirements
Module 3 - Asbestos Testing
Module 4 - Chemical Testing
Module 5 - Microbiological Testing
Module 6 - Radiochemical Testing
Module 7 - Toxicity Testing
Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories
Module 1 - General Requirements
Module 2 - Proficiency Testing
Module 3 – On-site Assessment
Volume 3: General Requirements for Environmental Proficiency Test Providers
Volume 4: General Requirements for an Accreditor of Environmental Proficiency Test Providers
Field Sampling and Measurement Organization (FSMO) Sector
Volume 1: General Requirements for Field Sampling and Measurement Organizations
Volume 2: General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement

It is important to note that the TNI laboratory accreditation standard differs from the EPA certification program in one very significant manner. The TNI standard is based on ISO/IEC

17025, an international standard that contains both technical and management requirements. The TNI standards also address the policy defined by EPA to adopt quality systems during sample collection and testing operations. (See ANSI/ASQ E-4 2004)

National Environmental Laboratory Accreditation Program (NELAP)

The National Environmental Laboratory Accreditation Program (NELAP) was established as a means to improve the quality and consistency of environmental data throughout the United States. Although NELAP is a national program; state governmental agencies serve as Accreditation Bodies. States, which apply to NELAP to become an accreditation body, may select to operate an accreditation program which covers all of the EPA regulatory programs or as few as one. For example, many states may select to only accredit laboratories for chemistry and microbiology under the drinking water program. Other states may select to operate a comprehensive program, which includes all types of analyses for all types of media (i.e., hazardous waste, waste water, drinking water, air, soil, etc.) under the five EPA regulatory programs [i.e., Clean Air Act (CAA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Clean Water Act (CWA), Resource Conservation and Recovery Act (RCRA), and Safe Drinking Water Act (SDWA)]. There is no requirement that a state incorporate any particular portion of the possible scope into its program. The scope of accreditation, the type of laboratory included under the state's program, including the regulatory or voluntary nature of the program itself, the assessment of fees, and the use of third party assessors are all options of the state.

A NELAP Accreditation Body will accept by recognition, the accreditation status of a laboratory issued by another NELAP Accreditation Body (this is called secondary accreditation). Each Accreditation Body must adopt and adhere to this principle as a condition of membership in NELAP. In accepting the accreditation status of a laboratory through recognition, the Accreditation Body assumes accreditation responsibilities as a secondary accreditation body. A laboratory seeking accreditation must apply to its home state Accreditation Body for accreditation. However, if the Accreditation Body does not offer accreditation for testing in conformance with a particular field of accreditation (matrix-method/technology-analyte/analyte group), laboratories may obtain primary accreditation for that particular field of accreditation from any other NELAP Accreditation Body.

National Environmental Field Activities Program

The National Environmental Field Activities Program (NEFAP) is an accreditation program for field sampling and measurement organizations (FSMOs). TNI has published the accreditation standard for organizations that perform measurements in the field and collect samples. The standard is a management system standard.

The TNI Standard addresses the industry need for ensuring that field data and sample information must be of a known and documented quality. The data from environmental

laboratories is only as good as the sample collected and presented for measurement. Many professionals in the environmental industry have often wondered why the sample collection and field testing do not require an independent review of these operations. Field test data used in making environmental decisions must be produced by organizations with a management system that is comparable to the fixed laboratory testing accreditation requirements.

The requirement for accreditation of field activities is extremely limited in regulatory programs or is does not exist in any government program. Therefore this is a voluntary program that is managed through the oversight of TNI to ensure consistency of implementation. The implementation of this standard by ABs and FSMOs will demonstrate that these organizations are interested in independent assessment of their organization to produce information and data that is appropriate for the intended use by their clients.

The TNI standard for FSMOs is modeled after ISO/IEC 17025:2005 "General Requirements for the Competence of Testing and Calibration Laboratories". TNI Standard Volume 1 is the FSMO Competency standard which is the same international standard for fixed laboratories. TNI Standard Volume II is the FSMO accreditation body (AB) requirements to accredit FSMOs. The AB standard is based on ISO/IEC 17011:2004 "Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies".

Proficiency Testing Program

Proficiency Testing (PT) is defined as a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. The TNI PT program consists of:

- A PT Expert Committee that establishes the requirement for proficiency testing.
- A PT Program Executive Committee who manages the implementation of the program.
- A PT Provider Accreditor that accredits organizations as PT Providers.
- Private and public sector PT Providers that manufacture and provide PT samples and evaluate the results.

The TNI PT Expert Committee has developed standards for laboratory proficiency testing and proficiency testing samples, including: criteria for selection of the providers of the samples; protocols for the use of proficiency test samples and data in the accreditation of laboratories; and criteria for Proficiency Test Provider Accreditors (PTPAs).

The PT Executive Committee maintains a national PT program that contains the following elements:

- Fields of Proficiency Testing (analytes, concentrations, matrices and acceptance limits) appropriate for the scope of environmental monitoring performed in the United States
- Oversight of organizations that provide PT samples to laboratories to ensure these organizations are competent to do so.

Technical Assistance Program

The purpose of the Technical Assistance Program is to provide assistance to stakeholders, particularly those seeking accreditation and those who accredit. The program develops tools, training, and other resources to enable stakeholders to efficiently participate, adopt, implement and comply with the TNI standards. Specifically, this program:

- Develops tools and templates to assist laboratories and accreditation bodies with implementing accreditation programs.
- Ensures that training programs relevant to the needs of the stakeholder community are provided.
- Ensures that laboratory assessors have a forum to discuss common issues.
- Develops a mentoring program to assist both laboratories and accreditation bodies with implementing accreditation programs.
- Provides a voice and solution strategies for small organizations.

THE FUTURE

Lessons from history provide insight into key practices offering stability and growth to the new organization.

- TNI has achieved short-term financial stability, primarily through cooperative agreements with EPA and membership dues, but also through sound fiscal practices such as maintaining a small staff and virtual office with low administrative overhead.
- There is very strong stakeholder support for the work TNI is doing with more than 90% of its stakeholders believing in the programs being offered.
- Dedicated volunteers with a passion for this effort, committee structure and balance, and the expertise and experience of the organization's membership are all proven assets.
- Significant progress has been made towards implementing a new accreditation standard.
- Committees to operate the TNI programs are well established and viable.
- TNI has been accredited by the American National Standards Institute as a consensus standards organization.
- An infrastructure has been established to allow TNI to expand the program into non-traditional areas of monitoring such as field sampling and measurements, stack emission testing, and taxonomy.

Implementation of the New TNI Standards

The 2003 NELAC Standard has been used by NELAP-recognized Accreditation Bodies (ABs) since 2005, and as such, is very familiar to the ABs as well as the accredited laboratory community and other stakeholders. However, the 2003 NELAC standard contains language about the operation of an organization that no longer exists, contains administrative detail that does not pertain to the operation of an accreditation program, contains obsolete language from an obsolete version of ISO 17025, is very hard to read and understand by laboratories that have not

been accredited, and is not recognized by the EPA as a consensus standard. The 2003 NELAC Standard is widely perceived as one of the barriers to increasing the participation of both laboratories and states in the program.

The 2009 TNI standards, which have been in development since 2003, were developed to respond to criticisms of the 2003 NELAC standard. The TNI standards were developed by a true consensus process, use the current version of ISO 17025, have incorporated ISO 17011, are organized to make it easier for a laboratory to understand the requirements, and have improved some of technical weaknesses in the 2003 NELAC standard.

National Accreditation

TNI's vision is that every organization that generates environmental monitoring data will be accredited to a consensus standard. For this vision to become a reality, a number of actions need to occur.

- TNI needs to reach out to EPA program offices and state agencies to understand their needs and concerns and then take action to address these needs and concerns.
- TNI needs to reach out to those laboratories that believe the program to be too onerous and find ways to alleviate their concerns.

To address these concerns, TNI's Advocacy Committee has taken on the task of reaching out to other organizations to understand their needs and concerns on national accreditation and bring those needs and concerns back to TNI for action. Specifically, the Advocacy committee has initiated efforts to meet with EPA program offices (e.g., Air, Solid Waste, Wastewater), other federal agencies, state agencies, and other data users to understand their needs for reliable environmental data and work to ensure the TNI program meets the needs of all data users, and to meet with trade associations representing laboratories to understand their perspectives on laboratory accreditation and work to ensure the TNI program addresses their concerns.

Small Laboratories

Many small laboratories perceive the 2003 NELAC standard has too onerous. TNI believes many of these concerns can be solved with the outreach effort that has begun, but TNI also believes more can be done to help small laboratories. TNI has already accomplished some actions to help small laboratories:

- a Quality Manual template has been developed
- templates for technical and administrative Standard Operating Procedures have been developed,
- laboratory "mentoring sessions" are now a integral component of every TNI meeting,
- several training courses and workshops to help small laboratories have been held, and
- the position of Small Laboratory Advocate within TNI has been created.

As a result of these actions, many small laboratories, including many 1 and 2 person laboratories have become accredited over the last few years. TNI believes much more can be done, including:

- developing more tools and guidance,
- offering web-based training,
- ensuring that all requirements in the standard are essential for data quality, and
- improving the consistency of laboratory assessments.

Presented at WEFTEC in October, 2008, updated in 2010.

For more Information about TNI, contact TNI at:

PO Box 2439
Weatherford, TX 76086
817-598-1624
www.nelac-institute.org

Hybrid Accreditation Standards: Wisconsin's Laboratory Accreditation

Alfredo Sotomayor
Laboratory Manager
Central Laboratory

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PARTNERS FOR A CLEANER ENVIRONMENT

Disclaimer

The views and opinions expressed in and during this presentation are solely the author's and do not represent the official positions of the Laboratory Certification and Registration Program of the Wisconsin Department of Natural Resources or the Milwaukee Metropolitan Sewerage District.

Consult these links for official information:

http://dnr.wi.gov/regulations/labcert/

http://www.mmsd.com/

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Program Profile

* Chemistry and Whole Effluent Toxicity
* SDWA, NPDES, RCRA, CERCLA
* Commercial, Municipal, Public Health, Industrial
* In and Out of State
* Fee Supported
* Registration for Non-Commercials
* Certification for Commercials

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Hybrid Program

* Certification vs. registration
* NELAP elements vs. state requirements
* Drinking water vs. all other matrices
* Attempt to merge the best of several systems
* Follows already established tradition

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NELAP Technical Advisory Committee (TAC)

* In 1998 recommended becoming a NELAP AA
* Two-tiered system:
  * Commercials NELAP
  * Others covered by State program
* Needed a change in the Statute
* Required legislative sponsorship

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Green Bay Packers Rule

- Had a strong sponsor in House of Representatives.
- However, Senate leader focused on funding alternatives for GBP stadium renovation.
  - Would not consider any rule changes until GBP stadium renovation satisfied party's concern.
- Stadium renovation funding mechanism approved.
- WI NELAP statute changed approved by House, not considered by Senate.
  - Rule change died in session.

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Aftermath

* Agency got cold feet.
  * Commercials objected to two-tiered system.
  * Municipals did not want to be part of NELAP.
  * Both groups essentially lobbied against a NELAP compromise.
* No sponsor in next legislative session.
* No substantial internal or external support to become a NELAP AA (AB).

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Other Reasons for 1998 Outcome

* Wisconsin's Program predated NELAP by more than a decade.
* Lack of local control over the accreditation standard.
* Perceived by some as a costly alternative that did not add significant value to what already was in place.
* Suspicion from the not-for-profit sector that commercials would take over.
* Commercials insistence on a single accreditation tier.

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Regroup

* Realization that NR 149 needed change.
  * The Code had not undergone a major revision since it was created in 1986.
* Formed NR 149 Rule Advisory Committee to:
  * Use the NELAC Standards as the basis for NR 149 revision.
  * Take what was best and sensible from the NELAC Standards.
  * Retain some Wisconsin-specific provisions.

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The Product

* Extensive compromising and negotiation.
* Process took approximately six years.
* Revised NR 149 published in April 2008.
* Revision became effective September 2008.
* Process for revising the 2008 version has started.
  * New rule process would take at least three years to complete.

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NELAP Items that Made It

* Tiers of Accreditation
  * Technology – Matrix – Analyte
  * Method – Matrix – Analyte
* Quality Systems Approach
* Majority of the provisions of the Quality Systems Standard

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NELAP Items that Did NOT Make It

* Two PTs per year
  * NR 149 requires one PT in combination with either three quality control standards or a second source verification program.
* Internal audits
* Annual management system reviews
* Personnel qualifications
* Unannounced assessments
* Five-years for records retention

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Items Unique to NR 149

* Extensive and “particular” calibration section for analytical instruments.
* Exclusion of PTs for AA flame analysis and colorimetric procedures.
  * Must analyze three quality control standards evenly spaced in a year.
* Program does not accept solid PT sample results.

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Observations

* NELAP has raised the bar.
* Systems approach has worked.
* Documentation has improved dramatically.
* Laboratories certified under NR 149 have been able to transition to NELAP relatively easily.

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On the Other Hand…

* Have lost all reciprocal agreements previously in place with non-NELAP states.
* Easy for out-of-state laboratories to miss Wisconsin specific requirements.
* Remain in partial isolation.
* Have not lessened assessment load.

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My Laboratory

* Certified for chemistry by WDNR under NR 149.
* Certified for microbiology by WDATCP under ATCP 77.
* Accredited to 2009 TNI Standards by Florida.
* Not that difficult to maintain certifications and accreditations.
  * Similar to complying with special client requirements.
* NELAP accreditation improves credibility of results.
  * Needed or useful to market Milorganite®

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Editorials

* Have uniformity as a principal goal.
* Shun preferences that buy you little and that are obstacles to uniformity.
* If you must have a two-tiered program, make demarcation clear and provide incentives that favor joining NELAP.
* Avoid incorporating provisions in statute.
* Try to incorporate as much as possible by reference.

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And…

* Know that adopting a standard in whole has advantages:
  * Do not have to argue over selection.
  * Do not have to re-invent content.
  * Gives reason to justify all requirements.

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Contact

Alfredo Sotomayor

Laboratory Manager

Milwaukee Metropolitan Sewerage District

414-277-6369

ASotomayor@mmsd.com

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MEMORANDUM

To: Lara Autry, US EPA

From: Raymond G. Merrill, Eastern Research Group, Inc.

Date: December 15, 2008

Subject: Draft 2008 Crosswalk between the OW Certification Manual and the TNI Environmental Laboratory Sector Accreditation Standard

The text and tables that follow are a comparison of EPA Office of Water's Fifth Edition (January 2005) Manual for the Certification of Laboratories Analyzing Drinking Water and the 2008 NELAC Institute (TNI) Standards for accreditation of environmental laboratories. As an addition to the review, ERG also provides input on whether TNI standards conform to the International Standards Organization (ISO) requirements in related areas. This review and comparison updates the previous comparison completed by Versar Inc. in May of 2006. We've summarized the major differences in the two programs below and we've also provided detailed tables describing the similarities and differences. If you have any questions or comments please feel free to contact me.

Comparison of TNI and OW Laboratory Assessment Standards

The following tables present a comparison between the EPA Office of Water Fifth Edition (January 2005) Manual for the Certification of Laboratories Analyzing Drinking Water (OW CM) including Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-F-08-006, June 2008) and the 2008 TNI Standards (December 2007).

Review and keywords searches were performed on the TNI Standards and the Supplement to the OW CM primarily. The previous comparison of OW CM certification standards performed by Versar was used to capture some of the original OW CM requirements that were not changed with the publication of the June 2008 supplement.

Tables are formatted with six columns identifying the:

- assessment subject,
- TNI citation,
- TNI Citation conformance to ISO 17025,
- OW CM citation,
- similarities and
- differences

"Not Found" as noted in the tables indicates that a requirement or topic in one assessment standard was not located in the comparison standard. If the TNI reference was found to be ISO/IEC 17011 or ISO/IEC 17025 compliant, this was noted in the appropriate column of the table.

The purpose of this comparison is to define the technical differences between the two programs. In doing so, the differences between the two programs can be evaluated by Environmental Laboratory Advisory Board (ELAB) to formulate advice to EPA on future improvements to laboratory compliance or accreditation programs. This effort will in turn provide information needed to improve the National

Program for laboratory accreditation and promote a single onsite inspection and assessment process rather than the current certification process requiring independent multiple states assessment.

With the recent update to the TNI Standards and the Supplement to the OW CM, the two standards moved toward the goal of a unified process for certification or accreditation. The recent Supplement to the OW CM refers to TNI. Also the TNI standard update includes some SWDA-based requirements from the drinking water program.

The organization of the contents of the OW CM and TNI Standard differ. Chapters in the OW CM include an Introduction (I), Responsibilities (II), Implementation (III), Critical Elements of Chemistry (IV), Critical Elements of Microbiology (V), and Critical Elements of Radiochemistry (VI). The updated TNI standard consists of 4 Volumes, two of which contain a number of Modules.

The TNI volumes cover laboratory assessment requirements for more than drinking water laboratory assessment (e.g., solid waste, air) The first volume the of the TNI standard entitled "Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis," contains Module 1 (Proficiency Testing), Module 2 (Quality Systems General Requirements), Module 3 (Quality Systems for Asbestos Testing), Module 4 (Quality Systems for Chemical Testing), Module 5 (Quality Systems for Microbiological Testing), Module 6 (Quality Systems for Radiochemical Testing), and Module 7 (Quality Systems for Toxicity Testing). Volume 2, General Requirements for Accreditation Bodies Accrediting Environmental Laboratories, contains Module 1 (General Requirements), Module 2 (Proficiency Testing), and Module 3 (On-Site Assessment). Volume 3 is General Requirements for Environmental Proficiency Test Providers. Volume 4 is General Requirements for an Accreditor of Environmental Proficiency Test Providers.

Both standards are valid approaches to assess laboratories and improve quality programs in laboratories analyzing environmental samples. The OW CM is more focused on drinking water programs and requires a laboratory to adhere to the quality control defined by the method and to prepare a quality plan that reflects that control. No attempt has been made to summarize the quality requirements in OW methods or to compare the method specific requirements with the TNI standard. Therefore, some of the differences noted in the two standards may be accounted for in the OW methods.

TNI requires a quality system and a quality manual (however named) that documents the system. The TNI standard requires laboratories to meet requirements in the contract they sign with their client(s). If specific quality requirements are not listed in the contract then the quality requirements in the methods coupled with the laboratory's Quality Plan have primary authority for setting specific quality requirements during sample analysis. OW CM certification are restricted to meeting the quality requirements in prescribed methods for drinking water in contrast to TNI which has greater scope and is geared toward the needs of individual clients and their data quality requirements. Therefore, differences between the OW CM and TNI standards related to specific QC requirements listed in the methods are of less importance than the broader program requirements for each group.

TNI standard tends to require more documentation and detail on QA/QC requirements since there is no standard set of methods to reference. TNI accreditation evaluates laboratories on their quality program responding to client or contract agreements and the methods referenced in the contract agreements. OW CM evaluates laboratories on the performance of reference methods which contain the body of QC details required by the program.

The education and experience required for the personnel who perform methods evaluated by either of the two assessment approaches (manuals) a significant different. The OW CM provides more detail on individual positions and education/experience levels in the method sections. Other than the technical

manager, TNI does not provide education or experience requirements for laboratory personnel. TNI focuses on documentation of qualifications for analysis and demonstration of proficiency by the laboratory analysts rather than formal education and degrees.

Documentation required from a certified or accredited laboratory is a topic where the two manuals have significant differences. The TNI requires much more documentation than the OW CM. Differences include the TNI requirement for a comprehensive Quality Manual for laboratory operation and responsibility for program management. The OW requirement for a Quality Plan is much more like a project specific project plan. While the OW requirement can include all that the TNI standard requires, the OW CM does not list in detail the requirements for either the Quality Plan or method SOPs.

TNI does not address several important topics to the drinking water program covered by OW such as Principal State Laboratories, Interim Certification, reciprocity, and numerous method specific technical details.

The two approaches also differ in several non-technical areas. OW CM does not discuss subcontracting, management reviews, internal audits, data integrity training, electronic transmission of results, preventative action, and client confidentiality, TNI includes specific requirements for each of these topics.

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
Document Titles			Manual for the Certification of Laboratories Analyzing Drinking Water and Supplement 1 to EPA 815-R-05-004		
Evaluation of Certification Program***	Environmental Laboratory Sector TNI Standards Adopted December 22, 2007 Management and Technical Requirements for Laboratories Performing Environmental Analysis		III.1	Similar sections, different programmatic roles. The Office of Water Certification Manual (OW CM) and the NELAC Institute (TNI) Standard both describe the roles, the responsibilities, and the structures of their respective programs.	Differences in the standards reflect the differences between the overall programs. TNI Standard outlines aspects of its program in greater detail than OW CM.
Requirements for Certification of Laboratories	EL-V1M1-2008 Section 4.0, EL-V2M2-2008 Sections 5.1.1, 5.2.1, 5.2.3, EL-V2M3-ISO-2008 Section 5.1		III.2	Both require Proficiency Test (PT) samples, Programs differ on the initial and ongoing requirements.	OW CM requires passing a PT for each analyte/each method once a year. The National Environmental Laboratory Accreditation Conference Institute (TNI) standard, handles PTs in much more detail. TNI has differing requirements for initial (2 successful PTs for each matrix, technology/method, and analyte), continuing (2 successful PTs per

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
					year for each matrix, technology/method, and analyte), and experimental PTs (2 PTs for each matrix, technology/method, and analyte).
Requirements for Certification of Laboratories	EL-V1M1-2008 Section 4.0, EL-V2M2-2008 Sections 5.1.1, 5.2.1, 5.2.3, EL-V2M3-ISO-2008 Section 5.1		III.2	Both programs require onsite assessment.	Programs differ regarding on-site audit frequency; OW CM requires once every three years with questionnaires given on other years, TNI requires onsite assessment once every two years.
Individual(s) Responsible for the Certification Program	EL-V1M1-2008 Section 3.1, EL-V2M1-ISO-2008 Section 3.2	ISO/IEC 17011	III.3	Each program has officers or authorities empowered to certify or accredit laboratory programs.	The program structures also differ slightly by definition and duties of authorities within the program. OW CM has Certification Authority (CA), Certification Program Manager (CPM), and Certification Officers (CO) that may represent the state and regional personal. TNI Standard has Accreditation Bodies whose authority is generally derived from regulatory authority acceptance of the accreditation process.
On-Site Laboratory Audit Team	EL-V2M3-ISO-2008 Sections 4.2.3, 4.2.4, 4.2.5		III.4.1	Both programs require appropriate education/training.	OW CM requires that auditors have a Bachelor's degree or equivalent education/experience in the field they certify. OW CM requires that the CO complete the appropriate EPA laboratory training course. OW CM has no requirement for

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
					supervised assessments. TNI states an assessor shall hold at least a Bachelor's degree in a scientific discipline or have commensurate experience acquired by having performed verified assessments of environmental laboratories, and have completed and attained a passing score on the written examination of courses approved by the employing accreditation body on assessing quality systems and all technical disciplines comprising a technology or combination of method and technology that the assessor will assess. Also states that an assessor needs to have participated in one or two on-site assessments under the supervision of a qualified assessor before performing an unsupervised assessment.
Third Party Auditors	EL-V2M1-ISO-2008 Sections 3.1, 7.4.2	ISO/IEC 17011	III.3, III.4.2, Appendix D	Both standards state the Accreditation Body (AB) may use a third-party assessor if outside expertise is required, so long as the body verifies the third party is free of conflict of interest and competent to perform the assessment.	Appendix D of the OW CM manual discusses EPA's policy on third party auditors and potential for conflict of interest. TNI takes full responsibility for all subcontracted assessments and assess the potential for conflict of interest.

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
Plans for Certification of Laboratories and Certification Process	EL-V2M1-ISO-2008 Sections 4.6, 7.7.2	ISO/IEC 17011	III.5, III.7	OW CM's CPM and TNI 's AB have similar responsibilities for planning assessments.	The TNI standard has pre-specified procedures for certification. These procedures are detailed for the laboratory in Volume 1 and Volume 2. OW CM refers to CPM as the individual responsible for developing and recording certification plans, schedules, etc. A similar comparison can be made to a TNI Assessment Board (certifying, auditing, and auditing record keeping elements), who establishes the plans and procedures for on-site assessments. The OW CM process is less prescriptive, using terms like should and may. The OW program allows the CPM to make program decisions based on the audit assessment.

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
Principal State Laboratories (Laboratories that have available facilities capable of performing analytical measurements for all federally mandated contaminants specified in the State Primary Drinking Water Regulations)	Not Found		III.6	No	TNI omission.
Terminology: Certified vs. Accredited	EL-V1M1-ISO-2008 Section 4.0		III.8.1	Both programs address laboratory assessment.	TNI uses the term accredited, OW CM uses the term certified. TNI stipulates differences between the accreditation process of initial and continuing accreditation. Participation in the TNI process is voluntary.
Provisionally Certified	EL-V2M1-ISO-2008 Section 3.0, EL-V1M1-ISO-2008.1 Section 3.0	ISO/IEC 17011	III.8.2	Both programs address performance and nonperformance issues in laboratories.	TNI uses the term suspension- the laboratory can not perform analysis for which field it is suspended. OW CM allows the laboratory to conduct the analysis if the client is aware of its certification status, unless the evaluation team believes that the laboratory can perform the analysis within acceptable limits. TNI provides additional causes for suspension (i.e. failure to maintain a quality system); OW CM lists the

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
					cause as being deficiencies either in PT studies or on-site visits. TNI-The status can be reversed if compliance is demonstrated to the primary AA. TNI also mentions the right to due process.
Not Certified	EL-V2M1-2008.1 Sections 7.5.6.1, 7.9, EL-V2M2-2008.1 Section 10.0		III.8.3	Both programs state that deficiencies prevent laboratories from becoming certified.	OW CM states that a laboratory is not certified if it has deficiencies and cannot produce valid data. TNI includes an outline of deficiencies that prevent a laboratory from becoming accredited. It also categorizes these deficiencies in three categories: suspended, withdrawn, or reduced accreditation. TNI mentions due process. Due process in reference to certification status is not discussed in OW CM, but in other sections is does states that the laboratory has the right to be heard by EPA.
Interim Certification	Not Found		III.8.4	No	OW CM states that an on-site audit should be made as soon as possible but not later than 3 years after an interim certification is granted.
Drinking Water Laboratories	EL-V1M6-2008 Section 1.5.2.2 (MDL)		III.9	Both programs require methods that meet the client's requirements.	OW CM-Laboratories that analyze drinking-water samples for Safe Drinking Water Act (SDWA) compliance monitoring shall use methods whose detection limits

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
					meet the requirements of 40 CFR 141. Although TNI does not have specific subsections or sections dealing with this exact subject matter, TNI does stipulate that laboratories must meet federal agency requirements, and the requirements of the methods they use, which would include the Safe Drinking Water Act.
Laboratory Quality Assurance Plan	EL-V1M2-2008 Sections 4.2.2, 5.9		III.11	OW CM recommends a quality plan, TNI requires a quality plan.	OW CM-laboratory must adhere to the quality control required by the methods and should prepare a quality plan, while TNI requires a quality system and quality manual (however named). OW CM does not require that QA Plan format include an identifier, page number, etc. OW CM does not state that the QA Plan contain information on review of new work requests, a policy for deviations from documented procedures or method specifications. OW CM does not state that major equipment or electronic signatures be included in the QA Plan. Nor does it state that procedures for dealing with complaints or protecting confidentiality be included.
Laboratory	EL-V1M2-ISO-2008	ISO/IEC	III.11.1	Programs are similar for	Other than the Technical Manager,

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
organization and responsibility	Section 4.1, 4.2, 5.2	17025		technical management and QA management.	TNI does not specify positions or type/amount of education, experience, and/or training needed, only "appropriate". Waiver of academic training is also not discussed in the TNI standards. OW CM does not indicate whether the person responsible for preparing a document may or may not review the report for final release. OW CM describes the internal audit process through a certification program. OW CM does not specifically state that laboratory personnel can conduct internal audits to check compliance with certification or accreditation standards.
Methodology	EL-V1M2-ISO-2008 Section 5.4		III.13.2	Both programs require methods that meet client requirements.	OW CM requires Federal Reference Methods listed in specific sections of IV, V, I (and specified in 40 CFR part 141). TNI states that methods published in international, regional, or national standards shall preferably be used, but that the laboratory use methods which meet client requirements.
On-Site Evaluation	EL-V2M3-ISO-2008 Sections 5.0, 6.0	ISO/IEC 17011, most of Section 6.0 is	III.13.3	Both programs require onsite assessment.	OW CM suggests that an on-site assessment be conducted once every three years and sooner if the laboratory previously did not do

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
		ISO/IEC 17011			well during an audit or has had a major change. For TNI , the interval between the surveillance on-site assessments should not exceed 2 years, with the first surveillance on-site assessment carried out no later than 12 months from the date of initial accreditation.
Notification of Certifying Authority (CA) of Major Changes	Not Found		III.13.4	No	TNI does not require accrediting authority be notified that major changes have occurred. TNI requires changes be documented in the appropriate laboratory documents.
PT Criteria	EL-V2M1-ISO-2008 Section 7.0	Most of TNI Standard Section 7.0 is ISO/IEC 17011	III.14.1, 14.2	Both programs require PT sample analysis as a means to evaluate laboratory conformance to the standard.	TNI requires the laboratory to conduct two PT studies for each field of proficiency testing per year for "matrix-technology/method-analyte/analyte group". OW CM requires PT samples to be analyzed at least annually for "regulated contaminants for which they wish to be certified, by each method for which they wish to be certified (OW CM I Introduction)".
Certification or Accreditation Status Review	EL-V2M1-ISO-2008 Section 7.0		III.14.1, 14.2	Both programs use PT performance as a means to downgrade certification or accreditation status.	OW CM states that a laboratory should be downgraded to provisionally certified, whereas, TNI may suspend a laboratory for failure to comply with PT analysis

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
					requirements. An OW CM laboratory may continue to do work but have to note suspension in writing on any report. A TNI accredited laboratory can not continue as a certified laboratory after failure to comply and suspension. Both TNI Standards and OW CM specify their own procedures and criteria for downgrading/revoking certification status. TNI and OW CM both require analysis of PTs and penalize for falsification; but TNI provides more detail. TNI mentions due process, OW CM states that EPA or the state provide technical assistance to help identify and resolve the problem. TNI discusses other aspects like personnel requirements that may cause suspension, OW CM does not.
Criteria/ Procedures for Revocation	EL-V2M1-2008.1 Sections 7.5.6.1, 7.9.1, 7.9.4.2, EL-V2M2-2008.1 Section 10.0		III.14.3, 14.4	Both programs have procedures for revocation of certificates.	OW CM states that a laboratory is not certified if it has deficiencies and cannot produce valid data. TNI lists the deficiencies that lead to revocation. TNI mentions due process. Due process in reference to certification status is not discussed in OW CM, but in other sections is does state that the

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
					laboratory has the right to heard by EPA.
Upgrading or Reinstatement of Certification	EL-V1M1-2008.1 Section 8.0, EL-V2M1-2008.1 Section 7.9.5		III.14.5	Both standards require the facility to pass accreditation status before upgrading or reinstatement can be done.	OW CM requires a written request from the laboratory seeking upgrading or reinstatement of certification. TNI-requires the laboratory to meet the requirements for continued accreditation to be reinstated after suspension, . Under TNI, to reinstate accreditation after revocation, the laboratory must meet the requirements for initial accreditation.
Record Keeping	EL-V1M2-ISO-2008 Section 4.13	ISO/IEC 17025	III.15	Both programs address records maintenance.	OW CM states that records should be maintained for a minimum of 6 years and TNI states a minimum of 5 years. OW CM addresses that the record keeping procedures should be documented in the QA Plan. TNI requires that a laboratory establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. TNI includes records of subcontractors, disposal of records, legibility, and storage environment, preventing unauthorized access, archiving files, naming files, or overwriting/obliterating old files,

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
Implementation					
					electronic data storage, whereas OW CM does not.
Reciprocity	Not Found		III.16	No	Although TNI does support reciprocity between states and regions, no statement was found in the standard regarding reciprocity.
Alternate Test Procedures (ATPs)	EL-V1M4-ISO-2008 Section 1.5.3.d		III.18	Non-standard methods must be validated for certification in both programs.	The OW CM requires new methods or modified methods be approved by the EPA via written submission. TNI only requires that the new/modified method be validated through laboratory analysis and documented for their review. TNI offers Tier I, Tier II, and Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) as a possible approval process.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
PT Studies, and Use of Accreditation					
Analysis of PT samples and use of own laboratory PT results	EL-V1M1-2008.1 Section 5.1		III.13.1, III.14.3, IV.7.2.1, V.7.2, VI.7.2	Both TNI and OW CM state that the PT sample shall be analyzed in the same manner as routine samples.	OW CM also states that the laboratory should be able to provide documentation that the person analyzing the samples is a laboratory employee who routinely analyzes drinking water compliance

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
PT Studies, and Use of Accreditation					
					samples. TNI lists actions that should not be taken with PT samples, such as subcontracting, analyzing PT samples for other labs to gain accreditation, obtaining results from PT providers, or discussing PT results with other labs. OW CM does not discuss these issues.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Organization					
Legal responsibility	EL-V1M2-ISO-2008 Section 4.1.1, EL-V2M1-ISO-2008 Section 4.1		IV.8.1, V.8.1, VI.8.1	No	The OW CM does not discuss the legal responsibility of the accreditation body. TNI states that the accredited laboratory or organization can be held legally responsible. It also discusses the legal responsibility of the AB.
Activities carried out according to a defined standard	EL-V1M2-ISO-2008 Section 4.1.2		II	Both programs require activities performed to the standards.	OW CM states that the EPA encourages the States to base certification of drinking water laboratories either upon criteria contained in the manual or upon state-developed equivalents that are at least as stringent as the manual. TNI states that laboratories should carry out activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.
Instrument testing & calibration.	EL-V1M2-ISO-2008 Section 4.1.2		III.11.6 (calib.), III.11.2 (client objective)	Both programs have requirements for calibration.	TNI requires laboratories to perform testing in such a way to meet the needs of the client and regulatory authorities or organizations. OW CM states that the QA Plan should include processes to identify clients' data quality objectives (DQOs). OW CM presents QC such as calibrations as method-specified.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Organization					
					TNI requires laboratories to perform calibration in such a way to meet the needs of the client and regulatory authorities or organizations.
Quality system	All of EL-V1M2-ISO-2008, EL-V2M1-ISO-2008 Section 5.7.4	Most of the V1M2 (if not all) is ISO/IEC 17025	III.2, III.11, IV.7, V.7, VI.7	With the Supplement to OW CM, both standards require a quality system to be implemented.	TNI requires that the effectiveness of the required quality system be reviewed in the annual internal audit.
Management system that covers other facilities (temp. or mobile)	EL-V1M2-ISO-2008 Section 4.1.3	ISO/IEC 17025	III.11.4	Both standards require the management system to cover temporary facilities of all types.	OW CM does not discuss management of mobile or field activities, however it does describe the similar concept of field work throughout the standard. TNI -The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.
Conflict of interest (between data quality/compliance with other topics)	EL-V1M2-ISO-2008 Section 4.1.4, EL-V2M1-ISO-2008 Section 7.4	ISO/IEC 17025,ISO/IEC 17011	Appendix D	Both standards emphasize the importance in preventing conflicts of interest between the laboratory and the accrediting body.	TNI-The accreditation body, shall identify, analyze and document the relationships with related bodies to determine the potential for conflict of interest, whether they arise from within the accreditation body or from the activities of the related bodies. Where conflicts are identified, appropriate action shall be taken. OW CM- Conflict of Interest is found in Appendix D addressing sensitivity to potential conflict of interest, but no real discussion of conflict of interest.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Organization					
Personnel with authority and resources to carry out work and see deviations from quality system	EL-V1M2-ISO-2008 Sections 4.1.5.a, 4.1.5.b, 4.1.5.h	ISO/IEC 17025	III.10.2 and III.10.3	Programs are similar although worded differently.	TNI discusses that the laboratory must have technical management who have the authority and resources to carry out work and see departures from the management system and initiate preventive actions. OW CM states the QA Manager should be independent from lab management and have access to senior management.
Protect client confidentiality and storage of data	EL-V1M2-ISO-2008 Sections 4.1.5.c, 4.7.1, 5.4.7.2	ISO/IEC 17025	IV.8.2, V.8.2, VI.8.2	No	OW CM does not discuss client confidentiality, but does discuss reporting stored results to clients before removal. TNI discusses protecting confidential information, both discuss records retention.
Ensure internal and external pressure does not affect personnel	EL-V1M2-ISO-2008 Section 4.1.5.b	ISO/IEC 17025	Not Found	No	TNI-(4.1.5.b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work; OW CM does not discuss the issue of internal and external pressure that would impede on competence, integrity, or impartiality.
Organization (lab and larger entity) structure and job specification of personnel	EL-V1M2-ISO-2008 Sections 4.1.5.e, 4.1.5.f, EL-V1M2-ISO-2008 Section 4.0	ISO/IEC 17025	III.11.1	Both standards mandate that the laboratory structure and personnel job specifications should be outlined in the Management Plan (TNI) or Quality Assurance Plan (OW CM.)	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Organization					
Adequate supervision, supervision by personnel who are familiar with test. Technical managers document personnel qualifications?	EL-V1M2-ISO-2008 Sections 4.1.5.g, 4.1.5.h	ISO/IEC 17025	III.10.2, IV.1.1, V.1.1, VI.1.1	Both programs have specifications for personnel performing analysis. Neither standard indicates whether or not a technical manager documents personnel qualifications.	OW CM supervisors and personnel working at a specific type of lab (chemist, micro., and radio.) have their specifications of education etc. listed under appropriate section. TNI standard 5.2.6.1 for technical managers requires a BS with 24 credit hours in chemistry and 2 years in analysis, a year experience or masters/doctorate. OW CM does not have credit hour requirements in chemistry or analysis. TNI technical managers of limited laboratories (covering only one field) have an associate's degree in specific type with 16 hours college credit hours and 2 years in analysis in appropriate field.
QA manager who is independent but has access to upper management	EL-V1M2-ISO-2008 Sections 4.1.5.i, 4.1.7.1	ISO/IEC 17025	III.10.1-3, III.11	Both standards ask that quality assurance managers have direct access to upper management and be independent from the management.	OW CM does not indicate whether or not the QA manager has functions independent from laboratory operations for which they have QA oversight. It does state that the QA manager should be independent from the laboratory management, if possible. The OW CM plan does not state that the QA manager is responsible for conducting internal audits or for corrective actions (section III.11 indicates that the QA plan should state who that person is). TNI does not specify that the QA manager needs to have a bachelors degree

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Organization					
					and a year of experience in quality assurance. OW CM supervisors and personnel working at a specific type of lab (chemist, micro., and radio.) have their specifications of education etc. listed under appropriate sections. The OW CM document does not elaborate on the specific requirements of the QA manager position. TNI states that the technical director may also be the QA manager; (the QA manager has functions independent from laboratory operations for which they have QA oversight (4.1.7.1.b)).
Appoint deputies for key managerial personnel like the technical director and quality manager	EL-V1M2-ISO-2008 Section 4.1.5.j	ISO/IEC 17025	Not Found	No	TNI requires the laboratory to appoint deputies for key managerial personnel (NOTE: Individuals may have more than one function and it may be impractical to appoint deputies for every function). OW CM plan does not discuss appointing deputies for key management staff.
PT Testing	EL-V1M1-2008.1, EL-V2M2-ISO-2008		III.13.1, III.14, IV.7.2.1, V.7.2, VI.7.4	Both require PT testing and obtaining PT samples from acceptable certification suppliers.	TNI -Volume 1, Module 1 provides the requirements for laboratory participation in the TNI Proficiency Testing (PT) program. To obtain initial accreditation, the laboratory shall successfully analyze two unique TNI compliant PT samples (FoPT) for each field of accreditation being sought. The

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Organization					
					laboratory must obtain PT samples from a PTOB/PTPA approved PT provider. The results from the PT studies must be returned to the PT provider for analysis. The accrediting authority (AA) should have access to the results of the PT testing. OW CM-sites a CFR for maintaining certification status through proficiency testing. Drinking water labs must satisfactorily analyze a PT sample at least annually for chemical contaminants. The lab must obtain PT samples from a supplier acceptable to the appropriate certification authority (CA).

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Quality System					
Quality Assurance	EL-V1M2-ISO-2008 Section 5.9, individual technical modules	ISO/IEC 17025	III.11, IV.4.5, V.7, VI.7	Both include specific QA in individual method sections.	In general, OW CM specifies that laboratories should maintain a Quality Assurance Plan and lists the topics for inclusion in the plan. QA is discussed throughout the TNI document with requirements for a quality management plan for the laboratory operation. (Section EL-V1M2-ISO-2008 Section 5.9) as a technical requirement of

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Quality System					
					accreditation.
Laboratory documentation to ensure quality	EL-V1M2-ISO-2008 Sections 1.1, 4.2.2	ISO/IEC 17025	III.11, IV.7, V.7, VI.7	Quality documentation is required: OW CM's QA Plan, TNI 's QA Manual	OW CM states that laboratories must adhere to the method required QC and document these activities in a QA Plan. TNI states the laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). OW CM suggests a QA Plan, whereas TNI requires a QA Manual.
Objectives included in QA plan	EL-V1M2-ISO-2008 Sections 4.2.2, 4.2.8.3.g, 4.2.8.3.h	ISO/IEC 17025	III.11, IV.7, V.7, VI.7	No	TNI standard indicates that a quality policy statement should be issued under the authority of top management. OW CM QA Plan does not include the laboratory's objectives but requires project data quality objectives per EPA QA/R-5.
Quality manual inclusions	EL-V1M2-ISO-2008 Sections 4.2.2, 4.2.5, 4.2.6, 4.2.8.3, 4.2.8.4	ISO/IEC 17025	III.11, IV.7, V.7, VI.7	Both list the required inclusions.	The OW CM does not have specific title page and table of contents instructions, TNI does. OW CM does not state that the quality manual should state the structure of QA plan. OW CM does not state that the QA manual should provide a reference of exceptions from the manual for managers to follow. TNI requires exceptions to be referenced or documented: 4.2.8.4.m).
Manual should include responsibilities of the QA manager.	EL-V1M2-ISO-2008 Sections 4.2.6, 4.2.8.2	ISO/IEC 17025	III.11.1 and III.10, IV.7, V.7, VI.7	Both include responsibilities of the QA manager.	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Quality System					
List schedules of internal and external system and data quality audits and interlaboratory comparisons	EL-V1M2-ISO-2008 Sections 4.0 (interlab comp), 4.1.7.1.f, 4.11.5, 4.14, 4.2.8.4.c	ISO/IEC 17025	III.11.10	Both programs have requirements for internal QA checks.	OW CM states that the QA Plan should list schedules of internal and external system and data quality audits and interlaboratory comparisons (may reference SOP). TNI states the quality manual shall contain or reference verification practices, which may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes (4.2.8.4.c)

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Document Control					
Control of all documents in the quality system	EL-V1M2-ISO-2008 Section 4.3	ISO/IEC 17025	III.11 (intro)	Yes	
Revision status of QA manual	EL-V1M2-ISO-2008 Sections 4.2, 4.3.2.1, EL-V2M1-ISO-2008 Section 5.7.4	ISO/IEC 17025	III.11 for QA plan and III.11.3 for procedures	Both programs require review and update of the QA manual/plan.	The OW CM manual requires annual review of both the QA plan and all SOPs. TNI requires an annual review of the quality manual during the internal audit. TNI also requires identifying the current revision, which OW CM does not address.
Specification of outdated/function/ availability of QA manual	EL-V1M2-ISO-2008 Section 4.3.2.2	ISO/IEC 17025	III.11, IV.7.1.1, V.7.1.1, VI.7.1.1	No	OW CM does not have a requirement that deals with handling invalid manuals once revisions are conducted. Section

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Document Control					
					III.11 simply states that it is the responsibility of the QA manager to conduct periodic revisions of the manual and make sure appropriate information is always included. TNI has defined procedures for handling obsolete documents.
Identification of QA Manual documents and ID type text	EL-V1M2-ISO-2008 Sections 4.3.2.3, 4.3.3.2	ISO/IEC 17025	III.11	No	The OW CM manual does not specifically state that QA manuals should include an identifier, page number, etc as required in EPA QA/R-5. OW CM requires the date of last revisions of SOPs. TNI recommends QA Plan document format with identifier, page number, revision, etc.
Review of documents (who and do they have references)	EL-V1M2-ISO-2008 Sections 4.1.7.1, 4.3.2, 4.3.3.1	ISO/IEC 17025	III.11.1	No	TNI-Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval (4.3.3.1).
Altered text highlighted and hand amendments, process for changing electronic documents	EL-V1M2-ISO-2008 Sections 4.3.3.2, 4.3.3.3, 4.3.3.4	ISO/IEC 17025	III.11.5, III.11.13, IV.8.2, IV.8.6, V.8.2, VI.8.2, VI.8.6	No	OW CM has control of electronic data throughout, however does not address altered text in electronic documents or QA documents. TNI requires the altered or new text to be identifiable in the document or the appropriate attachments (4.3.3.2). As well as, procedures to describe how changes in documents

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Document Control					
					maintained in computerized systems are made and controlled (4.3.3.4).

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Review of Requests, Tenders and Contracts					
Reviews	EL-V1M2-ISO-2008 Section 4.4	ISO/IEC 17025	Not Found	No	CM OW does not address review of contracts. TNI discusses it in detail.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Subcontracting					
Subcontracting	EL-V1M2-ISO-2008 Section 4.5, EL-V2M1-ISO-2008 Section 7.4, EL-V2M3-ISO-2008 Section 6.2	ISO/IEC 17025, ISO/IEC 17011	Not Found	No	OW CM does not discuss the issue of subcontracting.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Purchasing Services and Supplies					
Procedures for purchasing, reception, and storage of	EL-V1M2-ISO-2008 Section 4.6, EL-V1M2-ISO-2008	ISO/IEC 17025	VI.7	No	In the radiochemistry method of the OW CM, it is stated that the QA program should encompass the

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Purchasing Services and Supplies					
reagents and standards	Section 5.6.4.2				purchase of supplies. This is the only mention of a purchasing procedure in the OW CM. TNI requires a laboratory policy/procedure for the selection and purchasing of services and supplies.
Chain-of-Custody Procedures	EL-V1M2-ISO-2008 Sections 5.8.7.4, 5.8.7.5, 5.8.8, EL-V1M3-2008 Section 1.7.8.1	ISO/IEC 17025	III.12, Appendix A	Both discuss chain-of-custody procedures.	OW CM gives a detailed example of the chain-of-custody procedure in Appendix A. TNI also contains a detailed requirement for COC.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Service to Client					
Laboratory service to client and confidentiality	EL-V1M2-ISO-2008 4.7, EL-V2M1-ISO-2008 4.4	ISO/IEC 17025, ISO/IEC 17011	III.11.2	No	OW CM has "Process used to identify clients' Data Quality Objectives" listed as a QAP inclusion, but provides no details on the confidentiality or laboratory response to client complaints. TNI requires a laboratory to cooperate with the client, monitor their performance in relation to the work performed for that client, and provide confidentiality.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Control of Nonconforming Environmental Testing and/or Calibration Work					
Policy and procedure for nonconformity with own procedures	EL-V1M2-ISO-2008 Sections 4.9, 4.11, EL-V2M1-ISO-2008 Sections 5.5, 5.6	ISO/IEC 17025, ISO/IEC 17011	Not Found	No	TNI requires laboratories to have a policy/procedure to implement in the event of work that does not conform to testing procedures. OW CM does not require such a policy.
Action required for nonconformance	EL-V1M2-ISO-2008 Section 4.11, EL-V2M1-ISO-2008 Section 5.5	ISO/IEC 17025, ISO/IEC 17011	Not Found	No	TNI requires laboratories to have a policy/procedure to implement corrective actions when work does not conform to testing procedures. OW CM does require a corrective action procedure in the laboratory QAP, but does not mention nonconformance.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Preventive Action					
Preventive action	EL-V1M2-ISO-2008 Section 4.12, EL-V2M1-ISO-2008 Section 5.6	ISO/IEC 17025, ISO/IEC 17011	Not Found	No	TNI requires laboratories to have a procedure to identify potential sources of nonconformity. OW CM does not require such a policy.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Control of Records					
Record system	EL-V1M1-2008.1 5.3, EL-V1M2-ISO-2008 4.13,	ISO/IEC 17025 except Sect. 5.3	III.11.13, III.15, IV.8.2, V.8.2, VI.8.2,	Both include a list of required records. Both have a similar minimum length of	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Control of Records					
	5.8.7(records are mentioned throughout Vol1)		IV.8.1, V.8.1, VI.8.1	record storage, OW CM: 6 years, TNI: 5 years.	
Data access and disposal procedures and other criteria	EL-V1M2-ISO-2008 Section 4.13	ISO/IEC 17025	III.5, III.11.12, III.15, IV.8, V.8, VI.8, III.11.13	No	OW CM does not describe disposal of records, legibility, and storage environment or procedures for preventing unauthorized access. OW CM does not have a set format for archiving files, naming files, or overwriting/obliterating old files. TNI discusses control of records in detail.
History of records	EL-V1M2-ISO-2008 Sections 4.13.3.a, 4.13.3.f	ISO/IEC 17025	Not Found	No	TNI requires laboratories to establish a record keeping system shall allow the history of the sample to be readily available.
Raw data	EL-V1M2-ISO-2008 Section 4.13.3.f.i	ISO/IEC 17025	IV.8.4, V.8.4, VI.8.4, IV.8.2, V.8.2, VI.8.2	Both programs discuss raw data management.	
Mistakes and alterations	EL-V1M2-ISO-2008 Section 4.13.2.3	ISO/IEC 17025	IV.8.3, V.8.3, VI.8.3, IV.8.2, V.8.2, VI.8.2	Yes	All records of analyses must be available for inspection by accrediting authorities. OW CM manual does not have this requirement.
Security of records	EL-V1M2-ISO-2008 Sections 4.13.3.f.xv, 4.13.3.e, 4.13.1.2, 4.13.1.3, 4.13.1.4	ISO/IEC 17025	IV.2, IV.8.2, V.8.2, VI.2.1, VI.8.2, III.11.8, III.11.13	Both require a suitable environment and security of electronic data.	OW CM provides general guidance for security and maintenance of data. TNI has specific requirements for confidentiality, security of data such as indexing of records and disposal procedures.
Samples	EL-V1M2-ISO-2008 Section 4.13.3	ISO/IEC 17025	III.11.4, III.11.5,	Both require similar sample/data documentation,	OW CM discusses required records throughout the manual, but not as a

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Control of Records					
			III.12, Appendix A, IV.6, V.6, VI.6, IV.8.3, V.8.3, VI.8.3	but TNI provides more detail.	list of required records. TNI requires sample/data documents that allow the history of the sample to be readily understood and list what is to be included.
Retention of raw data, final reports, SOPs, PT	EL-V1M2-ISO-2008 Section 4.13.3.f	ISO/IEC 17025	III.11.8, III.11.13, III.15, Introduction	Yes	
Sampling, analytical and administrative records	EL-V1M2-ISO-2008 Section 4.13.3.f	ISO/IEC 17025	IV.8.4, V.8.4, VI.8.4, IV.8.3, V.8.3, VI.8.3, III.10.1, III.11.1, III.12	Similar, but TNI requires more detailed sample/data records.	TNI requires more records including all manual calculations and a log of signatures for personnel authorized to sign laboratory records or deliverables. OW CM does not discuss required records at the same level of detail.
Reconstruction of Data	EL-V1M2-ISO-2008 Section 4.13.3.f	ISO/IEC 17025	IV.8.5	Both require adequate information be available to allow the auditor to reconstruct the final results for compliance samples and PT samples.	
Internal audits	EL-V1M2-ISO-2008 Section 4.14	ISO/IEC 17025	Not Found	No	According to TNI, the laboratory shall periodically conduct internal audits of its activities.
Steps taken after audit finds errors or deficiency	EL-V1M2-ISO-2008 Sections 4.14.2, 4.14.3, 4.14.4	ISO/IEC 17025	Not Found	No	TNI requires that in the event of audit findings, the laboratory shall take timely corrective action, record the findings and corrective actions, and follow-up.

Subject	TNI Standard Reference	TNI Reference	OW/DWLCP Reference	Similarities	Differences

		conform to ISO?			
Management Reviews					
Management Reviews	EL-V1M2-ISO-2008 Section 4.15, EL-V2M1-ISO-2008 Section 5.8	ISO/IEC 17025, ISO/IEC 17011	Not Found	No	OW CM does not discuss reviews that are conducted by quality assurance managers. TNI requires a management review of the QA/QC program in a laboratory.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Data Integrity					
Data integrity and follow-up of audits	EL-V1M2-ISO-2008 Sections 4.2.8.1, 4.2.8.1, 4.16	ISO/IEC 17025	Not Found	No	TNI requires the laboratory to establish and maintain a documented data integrity system Laboratories maintain SOPs that accurately reflect current laboratory activities, such as assessing data integrity.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Personnel					
Personnel	EL-V1M2-ISO-2008 Section 5.2	ISO/IEC 17025	III.10, III.11.1, IV.1, V.1, VI.1, 4.1.1.1	Similar Programs	TNI does not specify positions (NOT including technical directors, Sect. 5.2.6.1) or type/amount of education, experience, and/or training needed, only "appropriate". Waiver of academic training is also not discussed in the TNI standards.
Contracted Personnel	EL-V1M2-ISO-2008 Section 5.2.3	ISO/IEC 17025	V.1.1	Vague	TNI-The laboratory shall use personnel who are employed by, or under contract to, the laboratory.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Personnel					
					Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system. OW CM only discusses contracted personnel for the supervisor/consultant position in the critical elements for microbiology chapter.
Personnel Job Descriptions	EL-V1M2-ISO-2008 Section 5.2.4	ISO/IEC 17025	III.11.1	Similar Requirements	
Personnel Records	EL-V1M2-ISO-2008 Section 5.2.5	ISO/IEC 17025	III.10.2, III.11.1, IV.1, V.1, VI.1, IV.8.4.6	Similar Requirements	
Up to Date Training	Individual technical modules Section 1.6.3		VI.1.5, IV.7.2.9	Similar requirements of ongoing demonstration of competence in the chemistry and radiochemistry sections.	OW CM only mentions ongoing demonstrations of proficiency for analysts and technicians in the critical elements for chemistry and radiochemistry chapter. TNI addresses ongoing demonstrations of proficiency in individual technical modules.
Activity Documentation	EL-V1M2-ISO-2008 Section 4.1.4	ISO/IEC 17025	III.11.7, IV.8, V.8, VI.8	Similar in regard to documenting the method and QC procedures used.	TNI-If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Personnel					
					to identify potential conflicts of interest.
Data Integrity Training	EL-V1M2-ISO-2008 Section 5.2.7	ISO/IEC 17025	Not Found	No	OW CM does not discuss data integrity training.
Laboratory Analyst and Technician	Individual technical modules Section 1.6		IV.1.2 and IV.1.3	No	OW CM specifies required education and experience for the laboratory analyst and technician, in addition to specialized training for the operation of analytical instrumentation. Additional requirements apply for the analysis of compliance samples. TNI-The analyst (s) shall demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. TNI does not discuss educational or experience requirements for the laboratory analyst and technician.
Sampling Personnel	EL-V1M2-ISO-2008 Sections 4.13.2.1, 5.2, 5.2.5	ISO/IEC 17025	IV.1.4	Yes	OW CM requires that personnel who collect samples should be trained in the proper collection technique for all types of samples which they collect. Their technique should be reviewed by experienced sampling or laboratory personnel. TNI-The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Personnel					
					particular types of equipment. The laboratory shall maintain records of the relevant authorization (s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.
Waiver of Academic Training Requirement	EL-V1M2-2008 Section 5.2.6.2		IV.1.5	Similar with some exceptions	Similar, but TNI does not have a "Waiver". OW CM-The certification officer may waive the need for specified academic training, on a case-by-case basis, for highly experienced analysts. TNI -A person who does not meet the technical manager education credential requirements, but meets the listed requisites can be a technical manager.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Accommodations and Environmental Conditions					
Facilities and Control of Environmental Conditions	EL-V1M2-ISO-2008 Section 5.3	ISO/IEC 17025	IV.2, V.2, VI.2, III.11.4, III.11.11, III.11.12	Both require measures to prevent cross contamination.	TNI is not as specific as the OW CM in the standards for measures to prevent cross contamination. TNI does not describe the specific environment of the laboratory (i.e. cleanliness, instrument location, area for sample preparation, safety, and cleaning of glass wear).
Preventive maintenance procedures and schedules	EL-V1M2-ISO-2008 Sections 5.5.3, 5.5.5.g, 5.5.6, EL-V1M5-2008 Section 1.7.3.7.b.ii	ISO/IEC 17025	III.11.11	Yes	OW CM mentions that the preventative maintenance procedures and schedules should be addressed in the QA plan. TNI mentions that the laboratory shall have procedures for use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.
Laboratory Safety	EL-V1M2-ISO-2008 Section 4.2.8.5.f.viii	ISO/IEC 17025	IV.4.4, V.4, VI.4.4	Similar	OW suggests that laboratory personnel apply general and customary safety practices as a part of good laboratory practices. Each laboratory is encouraged to have a safety plan as part of their SOP. Where safety practices are required in an approved method, they must be followed. For radiochemistry, OW CM requires certain protective equipment. TNI just states that safety shall be included or referenced in each test method.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Environmental Test and Calibration Methods and Method Validation					
Environmental Test and Calibration Methods and Method Validation	EL-V1M2-ISO-2008 Sections 5.4, 5.5	ISO/IEC 17025	III.11.4, III.11.5, III.11.6, III.11.7, III.11.8, III.11.9, IV.3, V.3, VI.3, IV.5.1, VI.7.1	Yes	OW CM discusses use of EPA-approved methods, whereas TNI discusses client-specified and laboratory-approved methods. TNI discusses that deviation from environmental test and calibration methods should occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. OW CM does not.
SOPs with dates of last revision	EL-V1M2-ISO-2008 Sections 4.2.8.5.c, 5.4.1	ISO/IEC 17025	III.11.3	Both require annual review, signatures, and dated revisions.	TNI requires archive of SOPs so previous data can be paired with SOP requirements in force at the time of analysis.
Methods manual	EL-V1M2-ISO-2008 Section 5.9.3, EL-V1M2-ISO-2008 Section 5.4.1, EL-V1M7-2008 Section 1.7.1.1.d(tox)		III.11, IV.5.1	Both require manuals to be available, and have provisions for using non-standard methods.	TNI specifies the items to be included or referenced for each test method. The quality control protocols specified by the laboratory's SOP shall be followed (see Section 4.2.8.5 in this Standard). The laboratory shall ensure that the essential standards outlined in the individual Technical Modules or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent, the QC in the mandated method or regulations is to be followed. OW CM states that laboratories should

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Environmental Test and Calibration Methods and Method Validation					
					prepare a written description of its QA activities.
Methods for clients	EL-V1M2-ISO-2008 Section 5.4.2	ISO/IEC 17025	III.11.2	No	OW CM has "Process used to identify clients' Data Quality Objectives" listed as a QAP inclusion, but provides no details on the topic. TNI discusses that the laboratory shall use methods that meet the needs of the customer.
Standards and Methods	EL-V1M2-ISO-2008 Sections 5.4.1, 5.4.2, 5.4.3, 5.4.4, 5.4.5	ISO/IEC 17025 except 5.4.4 and 5.4.5	IV.5, V.5, VI.5, IV.8.2, V.8.2, VI.8.2	Yes	OW CM does not discuss if laboratories must use the latest valid edition of a standard.
Method Confirmation and Demonstration	EL-V1M2-ISO-2008 Section 5.4, Individual technical modules Section 1.5	ISO/IEC 17025 except technical modules	III.11.9, V.5.6.1.4.1, V.5.6.1.4.5	Yes	OW CM does not discuss test method confirmation and validation (TNI 5.4.2, 5.4.5). OW CM specifies certain procedures that require initial and continuing demonstration of method capability and performance. TNI states that all methods should require those demonstrations and includes specific documentation and time requirements. TNI also addresses method validation in the individual technical modules.
Environmental Test and Calibration Methods	EL-V1M2-ISO-2008 Section 5.4	ISO/IEC 17025	Not Found	Similar	OW CM discusses use of EPA-approved methods, whereas TNI discusses client-specified and laboratory-approved methods.
Uncertainty	EL-V1M2-ISO-2008 Sections 4.13.2.1, 5.4.1, 5.4.6	ISO/IEC 17025 except Sect. 5.4.6	VI.7, 8.4.7, 8.5.9	No	OW CM only discusses uncertainty in the critical elements for radiochemistry chapter. TNI-The laboratory shall retain sufficient

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Environmental Test and Calibration Methods and Method Validation					
					information to facilitate, if possible, identification of factors affecting the uncertainty. The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope, including where appropriate, an estimation of the measurement uncertainty.
Calculations and Data	EL-V1M2-ISO-2008 Sections 4.13.2.2, 5.4.7.1, 5.9.3.a.v, individual technical modules	ISO/IEC 17025 except Sect. 5.4.7.1	III.11.3, III.11.8, III.11.9, III.11.13, IV.8.2, IV.8.6, V.8.2, VI.7.6, VI.8.2, VI.8.6	Yes	
Laboratory Software Configuration or Modification Validation	EL-V1M2-ISO-2008 Sections 4.13.3.f.xv, 5.4.7.2, 5.5.5	ISO/IEC 17025 except Sect. 5.4.7.2	III.11.13, IV.8.6, VI.8.6	Yes	
Calibration Curve	EL-V1M2-ISO-2008 Sections 5.5.1, 5.9.3.a.iii, individual technical modules	ISO/IEC 17025	IV.7.2.3	Yes	
Calibration Check	EL-V1M2-ISO-2008 Sections 5.9.3.a.iii, 5.5.10, 5.6.3.3, individual technical modules, EL-V1M4-2008 Section 1.7.2 (chem), EL-V1M5-2008 Section 1.7.2 (microb), EL-V1M6-	ISO/IEC 17025 except Sect. 5.6.3.3 and technical modules	IV.7.2.4	Yes	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Environmental Test and Calibration Methods and Method Validation					
	2008 Section 1.7.1.b(radio)				
Quantitation of Multicomponent Organic Analytes	EL-V1M4-2008 Sections 1.7.2.b, 1.7.3.2.3.b (chem)		IV.7.2.10	Both have provisions for quantitation of multicomponent organic analytes using a representative number of components.	OW CM (chemistry) indicates the analyst's professional judgment should be used and refers to EPA SW 846 for more information. A representative number (5-9) of peaks is suggested. TNI (chemistry) indicates that for continuing calibration and LCS for multi-component analytes, a representative chemical related substance or mixture can be used.
Low Level Quantitation	EL-V1M6-2008 (radiochem)		IV.7.2.12	No	OW CM-Minimum reporting limits (MRL) must be below the MCL. Laboratories should run a Laboratory Fortified Blank (LFB) at their MRL every analysis day and should not report contaminants at levels less than the level at which they routinely analyze their lowest standard. TNI-For low level samples the laboratory may analyze duplicate laboratory control samples or a replicate matrix spike to determine reproducibility within a preparation batch in place of a sample replicate.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences

Equipment					
Laboratory Equipment and Instrumentation	EL-V1M2-ISO-2008 Section 5.5, individual technical modules	ISO/IEC 17025 except technical modules	IV.3, V.3, VI.3	Both standards cover equipment and instrumentation	OW CM does not mention the use of equipment outside of a laboratories permanent control. TNI does not mention specific types of equipment and/or specific maintenance/calibration requirements.
Calibration	EL-V1M2-ISO-2008 Section 5.5	ISO/IEC 17025	IV.3, 4, 5, 6, 7; V.3, 4, 5, 6, 7; VI.3, 4, 5, 6, 7; III.11.6	Yes	Calibration requirements in the TNI standards are divided into two parts (analytical support equipment and instrument calibration). TNI-Instrument calibration requirements presented in the technical modules. Calibration requirements in the OW CM standards are found within the equipment, general laboratory practices, analytical methodology, sample, and quality control sections of each critical elements chapter (Section 3, 4, 5, 6, and 7 of Ch. IV, V, and VI).
Support Equipment	EL-V1M2-ISO-2008 Sections 5.5, 5.5.13.1	ISO/IEC 17025	III.11.9, III.11.11, III.11.12, IV.3, IV.7.1, V.3, V.8.5, VI.3, VI.7	Yes	OW CM specifies that preventive maintenance documents should be kept for five years. TNI does not mention specific types of equipment and/or specific maintenance/calibration requirements. OW CM specifies type of equipment, proper maintenance, and calibration for certain pieces of equipment needed in each critical element chapter.
Specific Device Accuracy	EL-V1M2-ISO-2008 Section 5.5.13.1.e	ISO/IEC 17025	Not Found	No	OW CM does not discuss mechanical volumetric dispensing devices or glass microliter syringes. TNI-Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) must be

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Equipment					
					checked for accuracy on a quarterly basis.
Autoclave	EL-V1M5-2008 Section 1.7.3.7.b.ii		V.3.5	Both require autoclave operation records.	OW CM only mentions the use of an autoclave in the critical elements for microbiology chapter. OW CM does not state that pressure should be recorded for each run of the autoclave. TNI-Records of autoclave operations shall be maintained for every cycle. Records shall include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analyst's initials.
Instrument Calibration	EL-V1M2-ISO-2008 Section 5.5, individual technical modules	ISO/IEC 17025 except technical modules	III.11.3, III.11.9, IV.3, 7; V.3, 7; VI.3, 7, III.13.2	Similar but not identical	TNI standard does not specify detailed procedural steps for calibration, but establishes the essential elements for selection of the appropriate techniques. OW CM does not discuss verification of initial instrument calibrations by a standard obtained from a second manufacturer or lot (TNI 1.7.1.1.d for chem)(1.7.1.a.iv for radio). OW CM does not state if the lower calibration standard should be above the detection limit. TNI-the lowest cal point shall be at or below the LOQ. (1.7.1.1.f for chem)
Zero point and single point calibration standard	EL-V1M1-2008.1 Section 5.2.1.b, EL-V1M4-2008 Section	ISO/IEC 17025 except technical	Not Found	No	OW CM does not discuss instrument technology with validated techniques from

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Equipment					
	1.7.1.1.h (chem)	modules			manufacturers or methods employing standardization with a zero point and a single point calibration standard.
Calibration Results	EL-V1M2-ISO-2008 Sections 5.5.2		III.11.9, III.11.12, IV.3, 7; V.3, 7; VI.3, 7	Yes	
Equipment use and maintenance	EL-V1M2-ISO-2008 Sections 5.5.6, 5.5.7		IV.3, 4, 5, 6, 7; V.3, 4, 5, 6, 7; VI.3, 4, 5, 6, 7; III.11.11, III.11.12	Yes	OW CM states that corrective actions are performed, described, and documented. OW CM does not discuss a "control of nonconforming work" procedure (TNI 5.5.7).
Equipment Records	EL-V1M2-ISO-2008 Sections 5.4.1, 5.5.3, 5.5.4, 5.5.5, 5.5.13.1, EL-V1M5-2008 Section 1.7.3.7.b.ii (microb)	ISO/IEC 17025 except technical modules	III.11.11, V.8.5, VI.7	OW CM's microbiology and radiochemistry sections require equipment records similar to TNI.	OW CM does not specify the exact items needed in records for equipment or labeled on equipment. TNI-The laboratory must have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both.
Continuing instrument calibration verification	EL-V1M2-ISO-2008 Sections 5.9.3.a.iii, 5.5.10, 5.6.3.3, individual technical modules, EL-V1M4-2008 Section 1.7.2 (chem), EL-V1M5-2008 Section 1.7.2 (microb), V1M6 Section 1.7.1.b (radio)	ISO/IEC 17025 except Sect. 5.6.3.3 and technical modules	III.11.6, IV.7.2.4, VI.3.1.2, VI.3.1.5	No	In OW CM continuing instrument calibration verification is discussed in the chemistry and radiochemistry methods of the OW CM. TNI requires a standard from a second manufacturer or lot as continuing calibration verification for chemical testing and radiochemical testing.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Measurement Traceability					
Measurement Traceability	EL-V1M2-ISO-2008 Section 5.6		IV.3, 4, 5, 6, 7; V.3, 4, 5, 6, 7; VI.3, 4, 5, 6, 7	Yes	
Testing Laboratories	EL-V1M2-ISO-2008 Sections 5.4.6, 5.9.3, EL-V1M7-2008 Sections 1.7.1.1(tox),1.7.1.6.q	ISO/IEC 17025 except Sect. 5.4.6 and technical modules	III.11.6, III.11.13, IV.3, 4, 5, 6, 7; V.3, 4, 5, 6, 7; VI.3, 4, 5, 6, 7	Yes	
Reference Standards and Materials	EL-V1M2-ISO-2008 Sections 4.2.8.4, 5.6.3, 5.6.4, 5.9.1, 5.9.3, individual technical modules	ISO/IEC 17025 except Sect. 5.6.3 and technical modules	IV.3, IV.7, V.3, V.7, VI.3, VI.7, III.11.3, III.11.13	Yes	OW CM specifies type of equipment, reference material, and calibration for certain pieces of equipment needed in each critical element chapter. TNI does not mention a specific type of reference standard or material and/or specific calibration requirements, however it states "Where possible, traceability shall be to national or international standards of measurement or to national or international standard reference materials" (TNI 5.6.4.1.b).
Records and Label	EL-V1M2-ISO-2008 Sections 5.6.4.2, 5.8.5, 5.8.6, individual technical modules	ISO/IEC 17025 except Sect. 5.6.4.2 and technical modules	III.11.6, 11.7, 11.9, 11.13	Yes	OW CM does not specify the exact items needed in records or labeled for all standards, reagents, reference materials and media.
Record keeping procedures	EL-V1M1-2008.1 Section 5.3, EL-V1M2-ISO-2008	ISO/IEC 17025 except Sect. 5.3	III.11.13, III.15, IV.8.2, V.8.2, VI.8.2,	Both have lists of inclusions for their individual record keeping procedures. Have	OW CM-records should be maintained for 6 years. A list of inclusions is provided. TNI-records

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Measurement Traceability					
	Sections 4.13, 5.8.7, (records are mentioned throughout Vol1)		IV.8.1, V.8.1, VI.8.1	similar record retentions - OW CM 6 years and TNI 5 years.	should be maintained for 5 years. Provides a list of information necessary for reconstruction of data.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Sampling					
Sampling	EL-V1M2-ISO-2008 Sections 5.4.1, 5.4.2, 5.5.2, 5.7, 5.8.4 Note 2, individual technical modules	ISO/IEC 17025 except technical modules	III.11.4, III.11.5, III.11.9, III.11.13	Yes	
Sample Collector	EL-V1M2-ISO-2008 Sections 4.13.2.1, 5.2.5	ISO/IEC 17025	IV.6.5	No	OW CM makes a general statement about sample collector training requirements. The records must include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results. TNI requires name of collector to be documented
Sample Compositing	Not Found		IV.6.7	No	OW CM–Compositing must be done in the laboratory, and only if the laboratory detection limit is adequate for the number of samples being composited (maximum of five).

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Handling of Samples					
Samples	EL-V1M1-2008.1 Sections 5.0, 5.8, individual technical modules	ISO/IEC 17025 except Sect. 5.0 and technical modules	III.11.4, III.11.5, IV.6, V.6, VI.6	Yes	
Identification	EL-V1M2-ISO-2008 Sections 5.8.2, 5.8.5	ISO/IEC 17025	III.11.4, III.11.5, IV.6, V.6, VI.6, Appendix A	Yes	
Temperature	EL-V1M2-ISO-2008 Sections 5.3.2, 5.8.4, 5.8.9.a.i, individual technical modules	ISO/IEC 17025 except technical modules	IV.6.2, V.6.3	Yes	TNI mentions regulatory or method criteria for temperature, but gives a general guide for sample temperature if none is given. Also has more information in individual technical modules. OW CM is more specific than TNI on shipping and storage temperature.
Neutralization (stabilization)	EL-V1M2-ISO-2008 Sections 5.8.4, 5.8.9.a, EL-V1M5-2008 Sections 1.7.5.b (microb)	ISO/IEC 17025 except technical modules	V.3.15.4	OW CM and TNI specify that sodium thiosulfate should be added to each container to neutralize any residual chlorine.	OW CM and TNI standards specify that sodium thiosulfate should be added to each container to neutralize any residual chlorine, but OW CM does not list minimum concentrations that samples should be neutralized to. TNI instructs laboratory to neutralize at minimum 5 mg/l of chlorine for drinking water and 15 mg/l of chlorine for wastewater samples.
Sample Rejection	EL-V1M2-ISO-2008 Sections 5.8.3, 5.8.7.2.a	ISO/IEC 17025	IV.6.1	No	Only OW CM discusses rejection of samples in the critical elements for chemistry chapter.
Maximum Holding Times	Not Found EL-V1M2-ISO-2008	ISO/IEC 17025 except Sect.	IV.6.3	No	OW CM has a general statement indicating that holding times are to

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Handling of Samples					
	Sections 4.13.3.f.v, 5.10.11.a, EL-V1M7-2008 Section 1.7.1.6.s(tox)	5.10.11.a and technical modules			be followed according to the specific method being used. TNI specifies hold time prescribed by the method and approved by the regulatory agency. TNI does present some hold times, such as: "The maximum holding time of effluents (elapsed time from sample collection to first use in a test) shall not exceed thirty-six (36) hours; samples may be used for renewal up to seventy-two (72) hours after first use except as prescribed by the method and approved by the regulatory agency having authority for program oversight" (EL-V1M7-2008 1.7.1.6.s).
Sample Collection and Transport	EL-V1M2-ISO-2008 Sections 5.4, 5.7, 5.8, individual technical modules	ISO/IEC 17025	IV.6.4	Both OW and TNI make general statements and indicate that sample collection is to be followed as specified in the method being used.	
Chain-of-Custody	EL-V1M2-ISO-2008 Sections 5.8.7.2.b.i, 5.8.7.4, 5.8.7.5, 5.8.8, EL-V1M3-2008 Section 1.7.8.1(asbestos)	ISO/IEC 17025 except technical modules	Appendix A, IV.8, V.8, VI.8	Both discuss chain-of-custody procedures.	TNI is not as specific in the chain-of-custody procedures for handling of samples and does not include examples of chain-of-custody forms in their standards.
Sample Acceptance	EL-V1M2-ISO-2008 Section 5.8.6	ISO/IEC 17025	IV.6.1 V.6, VI.6	OW CM states the laboratory should document its rejection criteria. TNI requires the laboratory to develop an overall sample acceptance	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Handling of Samples					
				policy addressing the items listed in Section 5.8.6.	
Handling/Storage of Samples	EL-V1M2-ISO-2008 Section 5.8		III.11.4, III.11.5, IV.6, V.6, VI.6, Appendix A.D	Yes	
Storage Temperature	EL-V1M2-ISO-2008 Sections 5.8.4, 5.8.9		III.11.5, IV.6.2	Both discuss storing samples at appropriate temperatures.	Temperature requirement is only discussed in the critical elements for chemistry chapter of the OW CM standards. TNI discusses it more broadly, mentions using method specified temperatures for storage.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Assuring the Quality of Environmental Test and Calibration Results					
Quality Control	EL-V1M2-ISO-2008 Sections 5.9.1, 5.9.2, 5.9.3	ISO/IEC 17025	III.11, IV.7, V.7, VI.7	Yes	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Reporting the Results					
Data reduction, validation, reporting and verification	EL-V1M2-ISO-2008 Section 5.10, Individual technical modules		III.11.8	No	OW CM only mentions that the procedure for data reduction, validation, and reporting should be included in the QA Plan.
Sample Report	EL-V1M2-ISO-2008 Sections 5.10.2, 5.10.3	ISO/IEC 17025	III.11.8, IV.6.6, VI.8.5, Appendix A	Both OW CM and TNI identify the minimal requirements of what should be included in sample reports.	OW CM discusses sample report format in the chemistry and radiochemistry methods. TNI encompasses all methods and requires more information for the Sample Report, such as consecutive page numbers, accreditation statements, management signatures etc.
Calibration Reporting Requirements	EL-V1M2-ISO-2008 Sections 5.10.1, 5.10.2, 5.10.4	ISO/IEC 17025 except Sect. 5.10.4	IV.8.4.5, VI.8.4.5	Yes	OW CM does not discuss calibration certificates or specific reporting requirements for calibration. However, OW CM does discuss calibration requirements and specifies type of equipment, reference material, and calibration for certain pieces of equipment needed in each critical element chapter. OW CM's critical elements of chemistry and radiochemistry chapters state that calibration and standards information must be reported in the analytical records. TNI specifies the actual items and circumstances that should be reported for calibration.
Subcontractor Reports	EL-V1M2-ISO-2008 Section 5.10.6		Not Found	No	OW CM does not discuss reporting requirements for work performed by contractors. TNI-When the test

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Reporting the Results					
					report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically. When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.
Electronic Transmission of Results	EL-V1M2-ISO-2008 Sections 5.4.7, 5.10.7		Not Found	No	OW CM does not discuss requirements in the case of transmission of environmental test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means. TNI-In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the standard requires conformance to the International Standards Organization requirement (see also 5.4.7).
Understandable Format	EL-V1M2-ISO-2008 Section 5.10.8		III.11.13, IV.8, V.8, VI.8, Appendix A	Yes	TNI-The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.
Amendment to Test Reports and Calibration Certificates	EL-V1M2-ISO-2008 Section 5.10.9		Not Found	No	OW CM standards do not discuss requirements for amendments to test reports or calibration certificates.
Action in Response to	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.9	No	TNI does not specify the

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Reporting the Results					
Noncompliant Laboratory Results	Section 5.10.3.1.b				notification of water authority.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Demonstration of Capability					
Initial Demonstration of Capability (DOC)	Individual technical module Section 1.6.2		IV.7.2.9, IV.8.4.6, V.5.6.1.4, III.11.9, IV.7.2.11	No	OW CM does require an Initial Demonstration of Capability be performed, but does not indicate when it is necessary. TNI-An initial DOC shall be conducted prior to using any test method, and at any time there is a change in instrument type, personnel or test method or any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period.
Specifics of sample preparation and reporting	Individual technical module Sections 1.6.2.2, 1.6.3		IV.7.2.9, IV.8.4.6, V.5.6.1.4	No, program specific differences exist.	OW CM does not indicate that the samples used are from outside sources. For biological testing, TNI does not specifically state that the DOC test consists of ten reagent water samples spiked with enumerated sewage or equivalent at 1-2 PFU per sample for each coliphage type used or for each coliphage type analyzed, three field samples are spiked with 1-2 PFU, however it does give guidelines to prepare DOC samples. TNI

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Demonstration of Capability					
					provides non-specific requirements for initial and on-going DOC in each test module. OW CM does not indicate the steps that need to be taken if the initial DOC fails. TNI does.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Essential Quality Control Requirements: Chemical Testing					
Availability of QC Information	EL-V1M2-ISO-2008 Section 4.13.3.c	ISO/IEC 17025	IV.7.1.2	All quality control information should be readily available for inspection by auditors.	
Balances and Weights	EL-V1M2-ISO-2008 Section 5.5.13.1	ISO/IEC 17025	IV.7.1.3	Should be appropriate for the application to be used; balances should be calibrated at least annually. TNI requires that support equipment be calibrated or verified at least annually.	
Color Standards	Not Found		IV.7.1.4	No	TNI has no specific information about color standards.
Temperature Measuring Devices	EL-V1M2-ISO-2008 Section 5.5.13.1, EL-V1M5-2008 Section 1.7.3.7.b.i	ISO/IEC 17025	IV.7.1.5	Both require calibration or calibration verification.	OW CM has more detail and additional (more frequent calibration) requirements for digital thermometers, thermocouples, and infrared detection devices. TNI requires that support equipment be calibrated or verified at least annually.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Essential Quality Control Requirements: Chemical Testing					
Traceability of Calibration	EL-V1M2-ISO-2008 Section 5.6.3	ISO/IEC 17025	IV.7.1.6	Both require calibrations of all measurement devices be traceable to national standards whenever applicable.	
Negative Control Purpose	EL-V1M4-2008 Section 1.7.3.1		IV.7.2.5	Both require a blank.	OW CM-blank should be analyzed as required by the method. TNI requires one method blank analysis at a minimum per preparation batch.
Laboratory Control Samples	EL-V1M4-2008 Section 1.7.3.2		IV.7.2.2	Both require a Laboratory Control Samples (LCS).	OW CM at least one LCS should be analyzed per quarter and LFBs as required by the method. TNI requires one LCS analysis at a minimum per preparation batch.
Matrix Spikes	EL-V1M4-2008 Section 1.7.3.3		IV.7.2.7	Both require a Matrix Spike (MS).	Both OW CM and TNI mention that the test method specifies the frequency of MS analysis, however OW CM does not mention Matrix Spike Duplicates (MSDs).
Detection Limits	EL-V1M4-2008 Section 1.5.2		IV.7.2.9, 7.2.11	Yes	OW CM is much more specific than TNI in stating the procedures and requirements for determining detection limits.
Quality Control Samples	EL-V1M4-2008 Section 1.7.3		IV.7.2.2	Yes	OW CM specifies frequency and procedures for detection limit studies of quality control samples.
Analytical Test	EL-V1M4-2008 Section 1.4 (Method Selection)		Not Found	No	OW CM does not discuss the involvement of the analytical method process or the matrix of interest. TNI-If there is not a regulatory requirement for the parameter/method combination, the

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Essential Quality Control Requirements: Chemical Testing					
					parameter/method combination need not be validated under 1.5.1.b as a non-standard method if it can be analyzed by another similar standard method of the same matrix and technology.
Detection Documentation	EL-V1M4-2008 Section 1.5.2		IV.8	Yes	
Data Reduction Documentation	EL-V1M4-2008 Section 1.7.3.4		IV.7, 8	Yes	OW CM specifies the process and method of documentation. TNI specifies that the procedures for data reduction shall be documented.
Quality of Standards and Reagents	EL-V1M4-2008 Section 1.7.3.5		IV.4.1.1, 4.2.1, 4.3.1	Both specify the reagents must meet the method requirements.	TNI specifies that the quality of water sources shall be monitored, documented, and shall meet method specified requirements.
Verification of Titrants	EL-V1M4-2008 Section 1.7.3.5.c		Not Found	No	OW CM does not discuss the verification of concentrations of titrants, TNI does.
Selectivity	EL-V1M4-2008 Section 1.7.3.6		Not Found	No	TNI lists requirements for selectivity, OW CM does not.
Glassware preparation	Not Found		IV.4.2.2, IV.4.2.3	No	OW CM refers glassware cleaning requirements to those specified in the methods (summaries provided). TNI does not discuss glassware preparation in this technical module.
Analytical Methods - Analyses approved by the State	EL-V1M4-2008 Section 1.4		IV.5.2	No	TNI states "When a laboratory is required to analyze a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a standard method".

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Essential Quality Control Requirements: Chemical Testing					
Sample Collection, Handling, and Preservation	EL-V1M2-2008 Sections 5.7, 5.8, EL-V1M4-2008 Section 1.7.5		IV.6.7	Yes	OW CM was more specific in the requirements.
Quality Control	EL-V1M4-2008 Section 1.7.3		Entire Section of IV.7 (except 7.1.1 to 7.1.3, 7.2.5, 7.2.9, and 7.2.11)	Yes	OW CM was more specific in the requirements.
Action Response to Noncompliant Laboratory Results	Not Found		Entire Section of V.9	No	The listed OW CM sections on action regarding QC failure or noncompliant lab results are either not found or only briefly discussed in TNI.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Whole Effluent Testing Detailed Method Review					
Toxicity Testing	EL-V1M7-2008		Not Found	No	OW CM does not discuss or contain a section regarding toxicity testing.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Microbiology Testing Detailed Method Review					
Supervisor/consultant and analyst	EL-V1M2-2008 Section 5.2.6.1		V.1.1, V.1.2	TNI and OW CM have similar educational requirements.	TNI and OW CM have similar educational requirements, but TNI requires 16 college credit hours microbiology and biology while

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Microbiology Testing Detailed Method Review					
					OW CM requires one course if the degree is in a field other than microbiology. OW CM also states that the supervisor needs to have two weeks of federal training of drinking water analysis or 80 hours on the job training and a laboratory may have consultants fulfill these duties if documentation showing that the consultant is acceptable to the state is presented during audits. OW CM requires that analysts have at least a high school degree; three months of microbiology testing experience in water, milk, or food media. TNI does not specify media or necessary bench criteria.
Waiver of academic training	EL-V1M2-2008 Section 5.2.6.2		V.1.3	Similar	TNI does not have an experience "Waiver" for academic training. OW CM-The certification officer may waive the need for specified academic training, on a case-by-case basis, for highly experienced analysts. TNI-A person who does not meet the technical manager education credential requirements, but meets the listed requisites can be a technical manager.
Personnel records	EL-V1M5-2008 Section 1.6 (DOC), V1M2-2008 Section 5.2		V.1.4	OW CM and TNI require similar records for personnel.	TNI makes this the responsibility of the management and includes an analyst signature record sheet.
Sterility Checks and Blanks	EL-V1M5-2008 Section 1.7.3.1		V.3, 4, 5, V.5.1.6.4	Yes	TNI does not list control organisms or frequency for testing

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Microbiology Testing Detailed Method Review					
					commercially prepared medium. OW CM has specific requirements.
Filtration	EL-V1M5-2008 Sections 1.7.3.1.b.ii, 1.7.3.1.b.v		V.5.4.1.2, V.5.4.1.3	Both discuss rinsing the filtration funnels.	OW CM states that the funnel may be exposed to UV light at specified wavelength and time. OW CM states to test for growth and all data must be rejected if the control indicates contamination. TNI does not.
Container Sterility	EL-V1M5-2008 Section 1.7.3.1.b.iii		V.4.2	Both specify one check per lot (commercial) or batch (lab-prepared).	TNI does not specify the procedure for confirming container sterility such as amount and type of broth, incubation, etc.
Reagent grade water	EL-V1M5-2008 Section 1.7.3.5.c		V.4.3	Yes	OW CM provides quality requirements. Both have specific parameters with associated frequencies for testing.
Dilution Water Sterility	EL-V1M5-2008 Section 1.7.3.1.b.iv		V.4.4.3	Both specify one check per lot (commercial) or batch (lab-prepared).	TNI does not specify the procedure for confirming container sterility such as amount and type of broth, incubation, etc.
Dilution/rinse Water	Not Found		V.4.4 (except V.4.4.3 above), V.5.3.2.1.1, 4.3.2, 8.2	No	
Plate Counts	Not Found		V.5.4.2.8	No	OW CM does not discuss using only one microbiology analyst for duplicate plate counts in a laboratory.
Proficiency Test	EL-V1M2-2008 Section 5.0, EL-V1M5-2008 Sections		V.7.2, V.8.2	Yes	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Microbiology Testing Detailed Method Review					
	1.5, 1.71				
Target Organisms	Not Found		V.4, V.5	No	
Test methods	EL-V1M5-2008 Section 1.4		V.3, 4, 5, 6, 7	Yes	
Media	EL-V1M5-2008 Sections 1.7.3.5.a, 1.7.3.5.b, 1.7.3.5.d		V.5.1.6, III.11, V	Yes	
Product Shelf Life	EL-V1M5-2008 Section 1.7.3.5		V.5.1.6.1, 5.1.6.2, 5.1.6.3	Yes	OW CM notes that caked or discolored dehydrated media should be discarded. TNI mentions using media during its shelf life.
Media Documentation	EL-V1M5-2008 Section 1.7.3.5.d		V.5.1.6.2, 5.1.6.3	Yes	For media prepared in the laboratory and media prepared commercially, OW CM does not state that the manufacturer, the amount of media prepared, and the expiration date must be documented. TNI does not state that sterilization time and temperature must be recorded.
Selectivity	EL-V1M5-2008 Section 1.7.3.6		Not Found	No	OW CM does not mention the preservation, preparation, and use of reference stocks.
Lab Facilities	EL-V1M5-2008 Section 1.7.3.7.a		V.2	Yes	TNI does not require laboratory to maintain effective separation between areas where activities are incompatible.
Temperature Measuring Devices	EL-V1M5-2008 Section 1.7.3.7.b.i		V.3.3	Yes	OW CM states the actual calibration, record, etc. requirements for temperature measuring devices. TNI only discusses if devices are "appropriate". TNI requires at least

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Microbiology Testing Detailed Method Review					
					annual verification (see EL-V1M2-2008, Section 5.5.13.1) OW CM gives more detail.
Autoclaves	EL-V1M5-2008 Section 1.7.3.7.b.ii		V.3.5.1, V.3.5.2	Yes	OW CM does not discuss initial evaluation of the autoclave. TNI does not discuss time requirements for the autoclave.
Autoclave Temperature	EL-V1M5-2008 Section 1.7.3.7.b.ii		V.3.5.4	Yes	OW CM does not discuss the use of temperature sensitive tape.
Autoclave Records and Maintenance	EL-V1M5-2008 Section 1.7.3.7.b.ii		V.3.5.3	Yes	OW CM does not discuss or require a pressure check and calibration of the temperature device during annual maintenance of the autoclave. TNI lists the autoclave operation records that must be maintained. TNI requires annual maintenance and includes a pressure check and calibration of the temperature device.
Autoclave Timing	EL-V1M5-2008 Section 1.7.3.7.b.ii		V.3.5.5	Yes	TNI requires the autoclave mechanic timing device to be checked quarterly against a stopwatch and documented.
Autoclave Parts	Not Found		V.3.5.6	No	TNI does not mention autoclave door seals and drain screens.
Volumetric Equipment	EL-V1M5-2008 Section 1.7.3.7.b.iii		V.3	Yes	OW CM specifies types of volumetric equipment and requirements for each. TNI requires volumetric equipment with movable parts be verified for accuracy quarterly, other volumetric equipment verified once per lot prior to first use.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Microbiology Testing Detailed Method Review					
UV Instruments	EL-V1M5-2008 Section 1.7.3.7.b.iv		V.3.16.2	Yes	TNI requires UV instruments tested quarterly for effectiveness
UV Cleaning	Not Found		V.3.16.1	No	TNI does not discuss the frequency or process for cleaning the UV instruments.
UV Support Equipment	Not Found		V.3	No	OW CM specifies type of calibration requirements for support equipment. TNI specifies calibration according to the method specified requirements.
Incubator, Water Baths, and Ovens	EL-V1M5-2008 Section 1.7.3.7.b.v		V.3.4.1, 3.4.2, 3.6.1	Yes	OW CM specifies temperature and time in incubators, ovens, and water baths. TNI requires the temperature of incubators and water baths to be documented twice daily each day of use
Oven	EL-V1M5-2008 Section 1.7.3.7.b.v.2		V.3.6.3, 3.4.2, 3.6.3	Yes	TNI requires ovens to be checked for sterilization effectiveness monthly.
Glassware	EL-V1M5-2008 Section 1.7.3.7.b.vi		V.3.14.1	Yes	TNI does not discuss a description of plastic items.
Glassware Inhibitory Residue Test	EL-V1M5-2008 Section 1.7.3.7.b.vi.3		V.4.5.3	Yes	TNI requires annual testing and with every change in washing procedure
Glassware pH Reaction	EL-V1M5-2008 Section 1.7.3.7.b.vi.4		V.4.5.4	Yes	OW CM specifies the procedure for this test. TNI requires this test at least once daily each day of washing
Glassware Washing	EL-V1M5-2008 Section 1.7.3.7.b.vi		V.4.5.1	Yes	Similar, however TNI does not specify the use of distilled or deionized water for the final rinse.
Laboratory equipment and supplies	EL-V1M5-2008 Section 1.7.3.7.b		V.3.3, 3.5, 3.6, 3.13,	No	OW CM is more specific in discussing laboratory equipment in

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Microbiology Testing Detailed Method Review					
			3.15, 3.17, V.3.1, 3.2, 3.7, 3.8, 3.9, 3.10, 3.11, 3.12, 3.14, 3.15, and 3.17		general. Such as the temperature monitoring devices, OW CM discusses having a QC record book for specific temperature device information; whereas, TNI does not. TNI and OW CM standards on pipettes differ, and OW CM specifies that they have a precision and accuracy within 2.5%. TNI discusses volumetric equipment as a whole and not pipettes specifically. OW CM contains separate sections in the standard for volumetric glass and pipettes. TNI discusses UV Instruments in general OW CM contains separate standards for each type. TNI does not discuss size of containers sufficient for fermentation media, legible markings in graduated cylinders and pipettes (2.5% tolerance), and tube closings. The listed OW CM sections that were not previously discussed regarding laboratory equipment and supplies are either not found or only briefly discussed in the TNI standard. In most cases, OW CM was more specific in the maintenance and calibration requirements.
General Laboratory Practices	Not Found		V.4.1, 4.4	No	Not found in TNI. In most cases, OW CM was more specific in the testing and notification requirements.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Microbiology Testing Detailed Method Review					
Analytical Methodology	EL-V1M5-2008 Section 1.4		Entire Section of V.5 (except 5.1.6 to 5.1.6.4, 5.4.1.2, 5.4.1.3, 5.4.2.8, and 5.6.1.4)	No	OW CM was more specific in the methods requirements. TNI does not list specific methods as a requirement, unless already prescribed to meet federal or local regulations.
Sample Collection, Handling, and Preservation	EL-V1M5-2008 Section 1.7.5		Entire Section of V.6 (except 6.5 and 6.6)	No	OW CM was more specific in the sampling/handling/preservation requirements.
Action Response to Laboratory Results	Not Found		Entire Section of V.9	No	Not found in TNI. In most cases, OW CM was more specific in the testing and notification requirements.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Radiochemical Analysis Detailed Method Review					
Laboratory Supervisor/Technical Manager	EL-V1M2-2008 Section 5.2.6.1		VI.1.1	Similar requirements for Laboratory Supervisor/Technical Manager.	TNI standard 5.2.6.1 requires a BS with 24 credit hours in chemistry and 2 years experience in analysis or only one year experience with a masters/doctoral. OW CM does not have credit hour requirements and requires only one year of experience. TNI does list several exceptions to this depending on the particular lab environment.
Laboratory Analyst	Not Found		VI.1.2	No	OW CM gives specific education, training and experience

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Radiochemical Analysis Detailed Method Review					
					requirements for an analyst. TNI does not give specific requirements for an analyst, but does for a technical director in 5.2.6.1
Technician	Not Found		VI.1.3	No	See above comment for laboratory analyst.
Sampling Personnel	Not Found		VI.1.4	No	See above comment for laboratory analyst and technician.
Initial and Ongoing Demonstration of Proficiency for Analysts and Technicians	EL-V1M6-2008 Section 1.6.2		VI.1.5	Ongoing DOCs can be performed via QC or the method by which the initial DOC was performed.	The OW CM describes specific means by which an initial DOC must be performed. TNI gives ways to complete an initial DOC if not specified by the method or regulation.
Method Blanks	EL-V1M6-2008 Section 1.7.3.1		VI.1.5	Both required a background check daily.	OW CM mentions instrument and reagent blanks. OW CM requires an instrument blank to check background analyzed on each day. Instrument must be placed out of service if blank is out of control. TNI requires at a minimum one method blank per batch (of no more than twenty samples). Data with a failing method blank should be reprocessed for analysis or flagged with the appropriate data-qualifying codes.
Data Produced by Analysts and Technicians in Training	Not Found		VI.1.6	No	OW CM states that this data must be reviewed by a fully qualified analyst or the lab supervisor. TNI requires final data review and release by a Technical Director.
Waiver of Academic	EL-V1M2-2008		VI.1.7	Yes	OW CM offers an academic waiver

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Radiochemical Analysis Detailed Method Review					
Training	Section 5.2.6.2.c				to highly-experienced analysts. TNI does not have a "waiver", but does require twelve months prior laboratory management experience at the time of application for certification if academic requirements are not met.
Positive, negative, and other controls	EL-V1M6-2008 Section 1.7.3		VI.3.1.5, VI.4.2, VI.7.3	Yes	See method blank discussion above concerning negative controls. Positive controls have specific criteria in the OW CM, while NELAC details these as "laboratory control samples" that are spiked with an analyte of interest and analyzed to meet specific performance criteria. OS CW details matrix spike requirements for field collection, which TNI omits. TNI includes criteria for surrogate spikes, which the OS CW omits.
Radiation Counting Instruments	EL-V1M6-2008 Section 1.7.1		VI.3.1	Detection limits are similar.	TNI does not provide detailed information on the overall process of calibration of each type of radioactivity counter, while the OW CM does. OW CM does not address background levels measurement. TNI goes into specific detail about this.
Liquid Scintillation Counting (LSC) system Background Check	EL-V1M6-2008 Sections 1.7.1.a, 1.7.1.b, 1.7.1.c		VI.3.1.1	Both agree that background checks should be performed daily.	TNI does not describe the check process in detail.
Gas~flow	EL-V1M6-2008		VI.3.1.2	Both agree that background	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Radiochemical Analysis Detailed Method Review					
Proportional Counting System Background Check	Section 1.7.1.c			checks should be performed daily.	
Alpha Scintillation Counting System Background Check	Not Found		VI.3.1.3	No	TNI does not describe the background check process in detail. OW CM mandates a background check performed each time a set of compliance monitoring samples is analyzed, or weekly.
Scintillation Cell System Background Check	EL-V1M6-2008 Section 1.7.1.c		VI.3.1.4	No	TNI states that background checks must be performed daily. OW CM states they must be performed each time a set of compliance monitoring samples is analyzed. OW CM provides more information about this technology.
Gamma Spectrometer Systems Background Check	EL-V1M6-2008 Section 1.7.1.c		VI.3.1.5	Both agree that background checks should be performed monthly.	
Alpha Spectrometer Systems Background Check	EL-V1M6-2008 Section 1.7.1.c		VI.3.1.6	Both agree that background checks should be performed monthly.	
Other Radiation Instrumentation Background Checks	Not Found		VI.3.1.7	No	OW CM states that the calibration and background checks should be consistent with the method being used and the manufacturer's recommendation. NELAC wrote the section on Radiation Counting Instruments to be all-inclusive, thus this is not applicable to that standard.
Chemicals/reagents	EL-V1M6-2008 Section 1.7.2.5		VI.4.1	Yes	OW CM does not discuss standards for purchasing from outside US

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Radiochemical Analysis Detailed Method Review					
					commercial suppliers.
Reagent Water	EL-V1M6-2008 Section 1.7.2.5		VI.4.2	No	TNI requires that reagent water meet the standards of the method in use. OW CM has more specific parameters required for reagent water.
Glassware/Plasticware	EL-V1M6-2008 Section 1.7.2.7.b		VI.4.3	Both state that glassware should be washed in accordance with the method in use.	TNI states if there is no specification in the method, then the washing procedure should be documented. OW CM includes a specific procedure to wash glassware when the correct procedure is not documented in the method.
Safety	Not Found		VI.4.4	Both standards state that proper safety measures should be addressed in the laboratory standard operating procedures.	The TNI standard does not address safety specifically for radiochemical analysis.
Analytical Methods: Standard Operating Procedures (VI.5.1)	EL-V1M2-2008 Sections 3.0, 4.2.8.5		VI.5	Yes	The OW CM states that the methods cited in 40 CFR parts 141.25 (a) and (b) must be used. OW CM also includes a table listing those methods. TNI does mention requirements for SOPs in general.
Sample Collection, Handling, and Preservation: Composited Samples (VI.6)	Not Found		VI.6.1	No	TNI does not include composite samples.
Matrix spikes and duplicates (replicates),	EL-V1M6-2008 Sections 1.7.2.3.a,		VI.7.7.1, VI.7.7.2,	Yes	See above discussion about positive controls for matrix spike

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Radiochemical Analysis Detailed Method Review					
low level samples	1.7.2.3.b		VI.7.2.12		comparison. Duplicates in the OW CM are described as replicate analysis of the same sample, however TNI defines this as a replicate piece of sample carried through the entire sample process. The OW CM also describes the process in more detail. Concerning low level samples, the OW CM states that target levels below the MRL should not be reported. TNI asks that an instrument duplicate be run to determine data reproducibility to assess the accuracy of low level samples.
Laboratory control samples	EL-V1M6-2008 Sections 1.6.1, 1.6.2.2, 1.6.3, 1.7.2.2		VI.7.7.3	Yes	TNI does not state that the batch has to be thrown away if samples are recounted and LCS (if LCS assessments have already exceeded the limits) assessment is still unsatisfactory. TNI requires at a minimum one per batch. TNI does not describe the process in detail.
Activity level and source of matrix spikes and LCS	EL-V1M6-2008 Sections 1.7.2.2.g, 1.7.2.3.a.vii		VI.7.72	Yes	The TNI states that the matrix spikes should be spiked at a level five times the minimum detectable activity (MDA) and an LCS should be spiked at ten times the MDA. The OM CW requires the matrix spikes to be spiked at ten times the anticipated sample activity level and handles the LCS samples in the same way. The TNI also states that a matrix spike can be used in place

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Radiochemical Analysis Detailed Method Review					
					of an LCS.
LCS or matrix spike for more than one isotope	EL-V1M6-2008 Sections 1.7.2.2.g, 1.7.2.3.a.vii		Not Found	No	The OM CW does not address this issue.
Initial demonstration of capability	EL-V1M6-2008 Section 1.6.2		VI.1.5	Both standards require an IDC to be performed for each instrument and at times when a change of personnel or method occurs.	
PT	EL-V1M2-2008 Section 5.0, EL-V1M5-2008 Sections 1.5, 1.71		VI.7.4	No	TNI does not discuss in detail mixed alpha and mixed beta/gamma PT studies.
Instrument calibration (general)	EL-V1M6-2008 Section 1.7.1.1		III.11.6	No	TNI goes into far more detail about instrument calibration, while the OW CM standard only describes the basic components of instrument calibration requirements.
Alpha and gamma spectroscopy calibration	EL-V1M6-2008 Sections 1.7.1.b.i, 1.7.1.b.ii		VI.3.1.5, VI.3.1.6	Yes	TNI does not describe the calibration process in detail for any particular analysis.
Gas~proportional and liquid scintillation calibration	EL-V1M6-2008 Section 1.7.1.b.iii		VI.3.1.2, VI.3.1.1	Yes	TNI does not describe the calibration process in detail for any particular analysis.
Scintillation counters calibration	EL-V1M6-2008 Section 1.7.1.b.iv		VI.3.1.3	Yes	TNI does not describe the calibration process in detail for any particular analysis.
Background measurements	EL-V1M6-2008 Section 1.7.1.c		VI.3.1, VI.3.1.5, VI.3.1.6, VI.3.1.2, VI.3.1.1, VI.3.1.3,	Neither standard provides specific procedures to determine background measurements for radiation counting instruments.	TNI does not state background measurements for every type of radiation counting instrument.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Radiochemical Analysis Detailed Method Review					
			VI.7.8		
Detection limit	EL-V1M6-2008 Section 1.5.2.1		VI.3.1, VI.3.1.5, VI.3.1.6, VI.3.1.2, VI.3.1.1, VI.3.1.3	Yes	The OW CM does not list specific procedures for detection limit determination or requirements other than the limits mentioned in the CFR. TNI describes very specific requirements for detection limits.
Results with uncertainties reported	EL-V1M6-2008 Section 1.5.4		VI.8.4	No	TNI states that uncertain results should be flagged appropriately. There is no specific mention of this in the OW CM.
QC program maintain and establish provisions for radionuclide standards	EL-V1M6-2008 Section 1.6.2.2		Not Found	No	The OW CM does not mention radionuclides in relation to QC programs. TNI mentions radionuclides in LCS samples where gamma-ray spectrometry is used.
Issues of purchase and labels of standards and reagents	EL-V1M6-2008 Section 1.7.2.5		VI.4.1	Yes	See above "Reagent" discussion for major differences. In addition, the OW CM does not mention reagent labeling specifically.
Cross~contamination and background checks	EL-V1M6-2008 Section 1.7.2.7.c		VI.3.1.2, VI.3.1.5, VI.3.1.6	Yes	OW CM does not mention ways to prevent cross~contamination. OW CM does not make clear that background checks for gamma spectrometry are conducted each day of use.
Laboratory facilities (general for radiochemical)	EL-V1M6-2008 Section 1.7.3.7		VI.2, VI.4.4, VI.4.3	No	The OW CM is more specific in its expectations of cleanliness, instrument placement, etc. TNI only requires the laboratory facilities to be in such a state as not to affect testing results.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Radiochemical Analysis Detailed Method Review					
Aspects of records and data reporting	EL-V1M6-2008 Section 4.13		VI.8.2, VI8.3, and parts of VI.8.4, VI.8.5, VI.8.6	No	TNI specifies a five-year hold time on all data, while the OW CM requires ten years. The OW CM also specifies on what medium data may be backed up.
Instrument and Method Performance Charts/Records	EL-V1M6-2008 Section 1.7.1.b		VI.7.8	Both discuss control charting.	TNI specifies control charting methods for each type of radiation counting instrument.
Action Response to Noncompliant Laboratory Results	Not Found		VI.9	No	Action taken in response to non-compliant results is discussed only briefly in the TNI standard, however, the OW CM states that the appropriate authorities must be notified when non-compliant results are reported.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Air Testing Detailed Method Review					
Air Testing			Not Found	No	OW CM only applies to laboratories dealing with water.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
Asbestos Testing					
Asbestos Testing			Not Found	No	OW CM only applies to laboratories dealing with water.

The 2016 TNI Laboratory Accreditation Standard

August 4, 2016

TNI's Consensus Standards Development Program has released a new consensus standard for the accreditation of environmental laboratories, *Management and Technical Requirements for Laboratories performing Environmental Analyses*, Revision 2.0. The standard has not been adopted into TNI's National Environmental Laboratory Accreditation Program (NELAP) at this time, but is being provided now so laboratories and Accreditation Bodies can begin plans for implementation. Note this is Volume 1 of the Environmental Laboratory sector standards. Volumes 2, 3, and 4, that relate to other aspects of NELAP, are nearing conclusion and should be released within the next few months.

This standard consists of seven modules:

- Module 1: Proficiency Testing, Revision 2.0
- Module 2: Quality Systems General Requirements, Revision 2.1
- Module 3: Quality Systems for Asbestos Testing, Revision 2.0
- Module 4: Quality Systems for Chemical Testing, Revision 2.0
- Module 5: Quality Systems for Microbiological Testing, Revision 2.0
- Module 6: Quality Systems for Radiochemical Testing, Revision 2.0
- Module 7: Quality Systems for Toxicity Testing, Revision 1.0

Module 7 was not revised, but is included in the standard for completeness. Changes to the other six modules are summarized below.

Summary of Substantive Changes for Module 1: Proficiency Testing

- Changed definition of Accreditation Body (AB):

  > The organization having responsibility and accountability for environmental laboratory accreditation and which grants accreditation under this program.
- Removed all references and requirements related to Experimental Fields of Proficiency Testing.
- The proficiency testing (PT) reporting requirement has been reverted back to Proficiency Testing Reporting Limit (PTRL) reporting. Laboratories are required to evaluate and report results to the PTRL and the use of the less than (<) sign when the analyte is present in the PT sample will be evaluated as "Not Acceptable".
- The tracking of PT frequency is now based on the closing date and the required time between the closing date of one PT study and the opening date of a subsequent PT study is now 7 days.
- New sections have been added for Radiochemistry, Whole Effluent Toxicity (WET), and Cryptosporidium/Giardia analysis based on input from these committees.

Rationale for Changes

1. The new AB definition allows for different types of ABs, including non-governmental ABs.
2. Experimental Fields of Proficiency Testing have been incorporated as Accreditation Fields of Proficiency Testing or removed from the PT Program.
3. The 2009 TNI standard required that laboratories evaluate and report PT results to the lowest calibration standard or Limit of Quantitation (LOQ). The standard allowed laboratories to report a less than (<) value for an analyte that was present and be scored "Acceptable" as long as the value

reported with the less than (<) sign was within the acceptance range. This evaluation of less than (<) values was a major stumbling block for many of the accrediting bodies (ABs). At the Seattle TNI conference the committee received many comments to move back to the PTRL reporting set of requirements.

4. The 2009 version of the standard required tracking PT results via analysis date for each analyte. This was an onerous requirement for the ABs as well as the laboratories. The 2009 standard also set a minimum timeframe between PT studies at 15 days. The timeframe was shortened to allow laboratories to regain or obtain new scope(s) of accreditation more quickly.
5. These sections are long overdue additions to the volume.

Summary of Substantive Changes for Module 2: Quality Systems General Requirements

- Added ISO language to Section 1.2 indicating that Notes are guidance and not requirements.
- Added the following new definitions: Analyte, Data Integrity, In-depth Data Monitoring, Lot, Physical Parameter, and Reference Method.
- Revised the definitions for Demonstration of Capability, Limit of Detection, and Selectivity.
- Section 4.1.7 was clarified to indicate the quality manager and the technical manager can be the same person.
- Removed the Note in 4.1.7.1, and added the text in the Note to the beginning of the section.
- Added in Sections 5.4.4 and 5.5.5 from ISO 17025.
- Added in missing subsections from Section 5.4.6 of ISO 17025.
- Clarified that Sections 5.5.1 and 5.5.2 apply to environmental laboratories.
- Added in missing sections 5.6.1 and 5.6.2 from ISO 17025.
- Removed the Note from 5.8.7.3(b) thus making the note a requirement.
- Added in missing subsections from Section 5.10.4 of ISO 17025.
- Revised Section 5.5.13.1 to clarify the daily check for support equipment.

Rationale for Changes

The 2009 Standard had moved some language from ISO 17025 into the Technical Modules 3-7, but in an inconsistent manner and some language from 17025 was omitted. The 2016 standard faithfully contains all of 17025 in Module 2. The revised definition for Limit of Detection is consistent with the definition of Method Detection Limit in 40 CFR Part 136. Several "Notes" contained requirements and so the word "Note" was removed. The ISO 17025 language stating that Notes are guidance only was added back in to Section 1.2. Section 5.5.13.1 was clarified to allow laboratories to use a single-point calibration check for support equipment. Other changes to definitions were made for clarity.

Summary of Substantive Changes for Module 3: Quality Systems for Asbestos Testing

- Sections 1.4 and 1.5 on Method Selection and Validation were revised to be consistent with other modules.
- Section 1.6, Demonstration of Capability, was revised for clarity and to allow for more options. The revised section reinforces that this demonstration applies to each individual that performs the test.

Summary of Substantive Changes for Module 4: Quality Systems for Chemical Testing

- Sections 1.4 and 1.5 on Method Selection and Validation were revised to be consistent with other modules.
- Section 1.5.2 on detection and quantitation limits was significantly revised to be consistent with the EPA MDL procedure in 40 CFR Part 136 and to reflect best professional practice.
- Section 1.6, Demonstration of Capability, was revised for clarity and to allow for more options. The revised section reinforces that this demonstration applies to each individual that performs the test.
- Sections 1.7.1 and 1.7.2 on instrument calibration have been extensively revised, describing various calibration options, discussing how to drop calibration points, and introducing a new quality control measure for evaluating calibration curves.

Rationale for Changes

- The revised section on method validation and selections has clear language on how to add a new analyte to an existing method.
- The new procedures for detection and quantitation limits corrects problems with the existing EPA procedure in 40 CFR Part 136, most importantly allowing for the use of blank results where appropriate, and allows one set of spikes to serve to determine both a limit of detection and a limit of quantitation.
- The new section on calibration points was added based on comments from stakeholders.

Summary of Substantive Changes for Module 5: Quality Systems for Microbiological Testing

This module was substantially revised to add clarity, reinforce the concept of minimum requirements and default to the use of the data. Section 1.5 on Method Validation was revised to allow the use of a statistically better method and allow for improvement. The Quality Control section (1.7) was reorganized to separate the activities done before analysis from those done during analysis. There are many other minor changes.

Summary of Substantive Changes for Module 6: Quality Systems for Radiochemical Testing

Module 6 was substantially revised by the Radiochemistry Expert Committee. While the substance of the 2009 standard was overall retained, the text underwent substantial reorganization and reformulation to add clarity and better address less well-developed concepts. The revised standard now better reflects current practices in environmental radiochemistry laboratories.

Changes in the revised Module 6 include the following:

- Definitions for key terms were added to Section 1.3.
- Requirements for method validation in Section 1.5 were refined to better address laboratory-developed/modified methods and to evaluate uncertainty and method performance at background (zero) activity.
- Section 1.6 requirements for Demonstrations of Capability include analysis of blanks, once again to address method performance at background activity.
- Technical requirements in Section 1.7 were reorganized to logically parallel set-up, calibration, calibration verifications, and quality control of instrumentation.
- Section 1.7.1 provides requirements for mathematical calibration methods, and for several approaches to background determination, both of which are in common use but

neither of which are currently permitted.

- The most substantial change to method quality controls in Section 1.7.2, the Radiation Measurements Batch, was introduced to eliminate substantial confusion, and inconsistent implementation of batch quality controls for non-destructive analyses such as gamma spectrometry.
- Section 1.7.3 contains requirements for evaluating chemical yield which were not included in previous revisions. It also addresses reporting requirements for uncertainty.

Appendix: TNI's Standard Development and Adoption Process

Accreditation standards are developed by Expert Committees using a consensus process that includes the elements of openness, balance, due process, and consensus as established by Circular A-119 published by the US Office of Management and Budget.

Circular A-119 defines a voluntary consensus standards body as one having the following attributes:

> *(i)openness; (ii) balance of interest; (iii) due process; (iv) an appeals process; and (v) consensus, which is general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reason(s) why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.*

Standards are developed by the TNI Consensus Standards Development Program (CSDP), in conformance with TNI's Procedures Governing Standards Development. The American National Standards Institute (ANSI) has approved the TNI process for standards development indicating that TNI meets the ANSI requirements. This means the TNI standards are developed through an open consensus process in which all members and the public may provide input and have their position considered, preventing dominance by any one group of stakeholders by assuring a balance of interests among the committee members who develop the standards. The Expert Committees each develop a **Working Draft Standard** that is presented to the membership and the public. As a result of input received during and following an open meeting, the Expert Committees modify their Working Draft Standard to produce the **Voting Draft Standard**. All TNI members may then vote electronically, providing comments in support of their positive or negative votes. The Expert Committees must allow for public debate on every comment. The Expert Committees hold meetings to rule each comment persuasive or non-persuasive. Persuasive comments require the Expert Committees to revise the standard in response to the comment.

Committees must resolve every persuasive comment, which may require modification of the standard. Some comments may suggest major changes to the standard (e.g., reduce proficiency test frequency to once per year instead of twice per year), and they may be placed on hold until the next standards revision cycle to allow consideration and debate by the membership and the public.

When persuasive comments are resolved and the standard modules are approved by a majority vote of the Committee Members, the standard then becomes final as the **TNI Standard**.

For the next revision of the standards, which may be expected within 4-5 years, a revised *Procedures Governing Standards Development* will be in use (this may be found on the TNI website as SOP 2-100, Version 2.0). This will improve, and in many cases shorten, the standards development process by providing substantial stakeholder outreach up front, and inviting input that will allow the expert

committees to avoid the Working Draft Standard stage and to move straight into a Voting Draft Standard. This new procedure will take extra steps to assure stakeholder concerns are satisfied before finalizing the standard.

After a standard has been adopted by an expert committee, it undergoes an editorial review for consistency and then is published on the TNI website along with the Response-to-Comments document explaining the resolution of all written comments that accompanied the vote on the standard.

After resolution of appeals, the standard may be used by any organization. However, for use within TNI's National Environmental Laboratory Accreditation Program (NELAP), the TNI Laboratory Accreditation System Committee (LASC) reviews the adopted TNI Standard and develops supplementary documents (guidance, SOPs, etc.), when needed. The LASC then forwards the standards to the TNI NELAP for this program to adopt the standard for use by all Accreditation Bodies (ABs). TNI expects NELAP ABs will require a lead time of about two years to amend regulations and implement the standard. Because modifying regulations is restrictive and time-consuming, some NELAP ABs may possibly continue to accredit laboratories the 2009 version of the standards until their regulations are finalized.

The NELAC Institute (TNI) Procedures for Expert Committee Operations describe how any TNI member may participate, as an Associate Committee Member, in conference calls of any Expert Committee. The dates/times of scheduled calls are listed on each Expert Committee's web page as well as on the Event Calendar.

In order to participate in TNI committee meetings, any member may register with the chair of the Expert Committee(s) of interest. You will then receive an invitation to each conference call, together with an abbreviated agenda and any documentation pertinent to the meeting. If you wish to attend, you must so notify the chair at least 24-hours in advance of the meeting. You will then be provided with the call-in number and a telephone line will be made available for you.

TNI “Light”

Christine Sotelo

TNI “Light”

- TNI as a base
- Remove or modify pieces that are problematic for laboratories
- Virginia is an example
  - 350 laboratories in the “light” program
- Comparable certifications
  - DW, WW, HW
- You asked what changes Virginia made

Virginia's modifications to the 2003 NELAC standard

- Technical Manager / Laboratory Manager qualifications
- Management review
- Document Control

Virginia's implementation of TNI "Light"

Virginia identified the main areas laboratories needed assistance to meet the Standards:

- Management reviews
- Data integrity training/systems implementation
- Document control systems and writing documents such as SOPs for administrative/QA system procedures
- Corrective action systems/processes/root cause analysis
- Sample handling
- Standards traceability
- Internal audits

ITEM 6
Close

Review Action Items

AGENDA ITEM #6

Close

1. Review Action Items

PROPOSED ELTAC CALENDAR

Key

Proposed Meeting Dates	
Event	
Lab Accreditation Standard	
FOT Worksheets	
Fee Structure	
Communications Update	
Enforcement Briefing	
Other	

JULY

S	M	T	W	Th	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	**27**	28	29	30
31						

27 ELTAC Meeting
Lab Accreditation Standard
FOT Worksheets
Fee Structure

AUGUST

S	M	T	W	Th	F	S
	1	2	3	4	5	6
7	8	9	**10**	11	12	13
14	15	16	17	18	19	20
21	22	23	**24**	25	26	27
28	29	30	31			

10 ELAP Session at TNI Conference
24 ELTAC Meeting
Lab Accreditation Standard

MARCH

S	M	T	W	Th	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	**23**	24	25	26
27	28	29	30	31		

23 ELTAC Meeting
Lab Accreditation Standard
FOT Worksheets

SEPTEMBER

S	M	T	W	Th	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

APRIL

S	M	T	W	Th	F	S
					1	2
3	4	**5**	6	**7**	8	9
10	11	12	13	14	15	16
17	18	**19**	20	21	22	23
24	25	26	27	28	29	30

5 TNI Workshop – Nor. Cal
7 TNI Workshop – So. Cal
19 SWRCB Board Meeting on Training Contract Funds

OCTOBER

S	M	T	W	Th	F	S
						1
2	3	4	**5**	**6**	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

6 State Water Board Workshop – Laboratory Accreditation Standard
24-27 CANV AWWA meeting

MAY

S	M	T	W	Th	F	S
1	2	3	4	5	6	7
8	9	10	**11**	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	**27**	28
29	30	31				

11 ELTAC Meeting
Lab Accreditation Standard
FOT Worksheets
Fee Structure

NOVEMBER

S	M	T	W	Th	F	S
		1	**2**	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

2 Tentative ELTAC Meeting
Fee Structure

JUNE

S	M	T	W	Th	F	S
			1	2	3	4
5	6	**7**	8	9	10	11
12	13	14	**15**	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

7 ERP Quarterly Progress Webinar
15 ELTAC Meeting
Lab Accreditation Standard
FOT Worksheets
Fee Structure
Other: Checklists

DECEMBER

S	M	T	W	Th	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31