A Quality Management System for ELAP

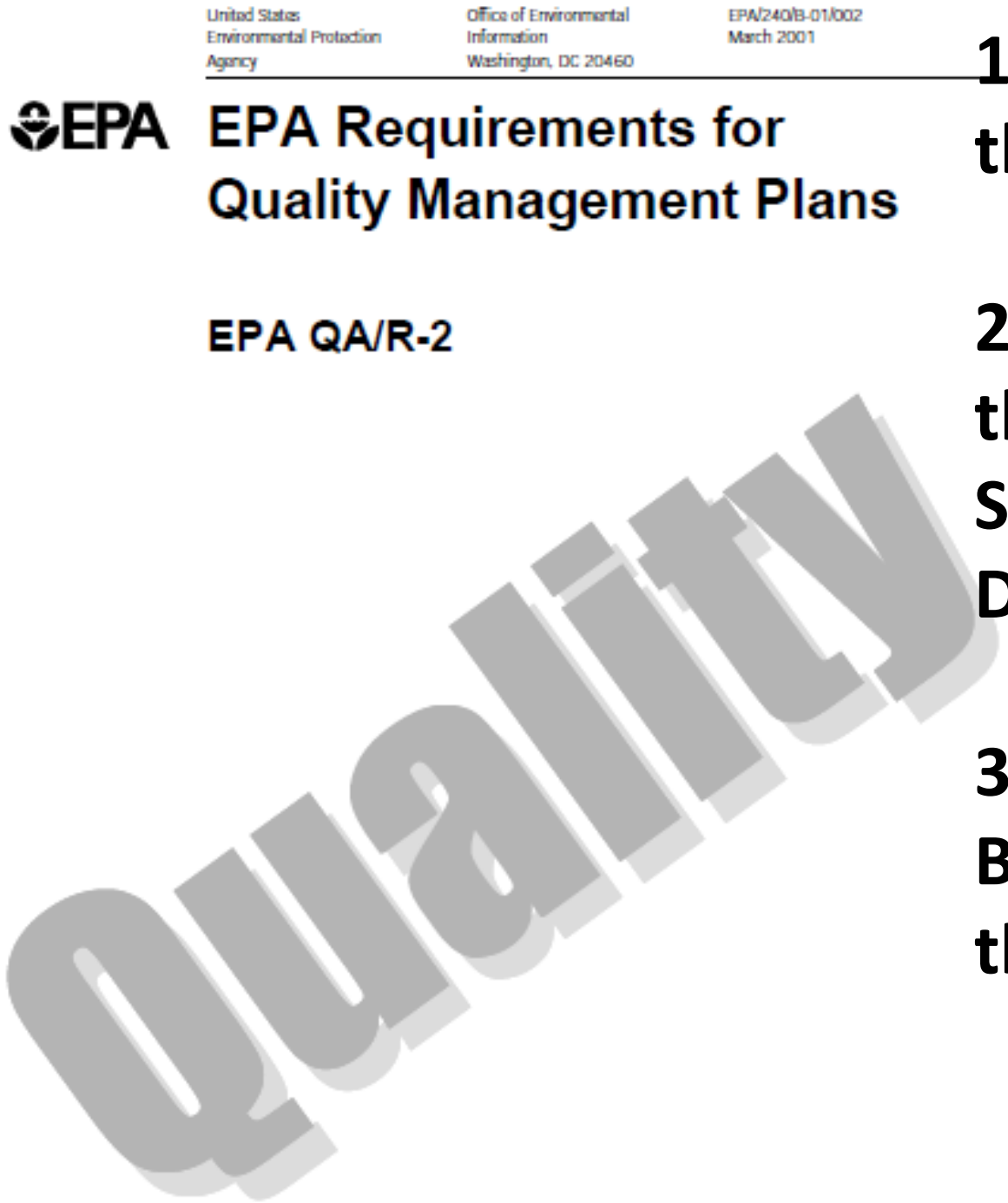
ELTAC Meeting August 24, 2016

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

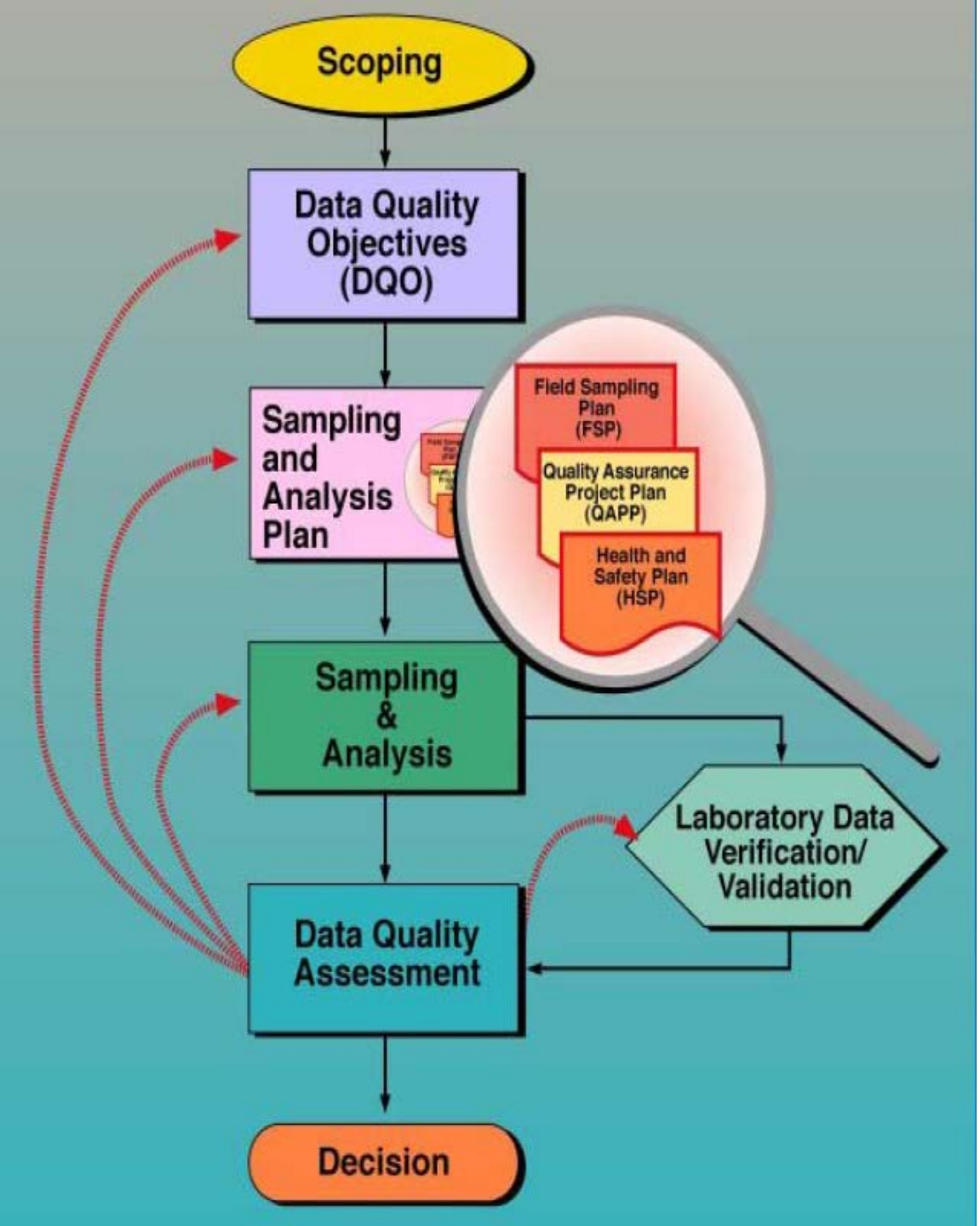
- USEPA
  - The EPA Quality System encompasses management and technical activities related to the planning, implementation, assessment and improvement of environmental programs that involve:
  - the collection, evaluation and use of environmental data
  - the design, construction and operation of environmental 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.