# SUBGROUP 3

## Proposed Modifications of the TNI Standard

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# Recommendations for Changes to the Proposed Quality Management System For ELAP

## 1) Introduction

Environmental Laboratory Accreditation Program (ELAP) is proposing to adopt portions of The NELAC Institute's (TNI) documents as the basis for the Quality Management System (QMS) for a new Accreditation Standard. ELAP does not wish to use the entirety of Volume 1 of the 2016 TNI documents but only parts of it. ELAP has requested that the Environmental Laboratory Technical Advisory Committee (ELTAC) members submit suggestions for which portions should be included and which deleted. This paper is an attempt to address this request by two members of ELTAC.

This paper is divided into four parts. Part 1 addresses the principles that will be used to assess the TNI documents. Part 2 applies these principles to general issues in the TNI documents. Part 3 applies these principles to specific provisions of the TNI documents. Part 4 summarizes these recommendations.

## 2) Part 1 – Framework and Criteria

The question however is what are the criteria for assessing the literally hundreds of different provisions found in the TNI documents? Why should one provision be removed but a different one retained. No definitive criteria have as yet been provided linking particular needs to specific sections of the TNI documents. As a result, the first part of this paper will address this issue. The second part of the paper will list a variety of sections of the TNI document which can be removed and an explanation as to why based on the criteria in Part 1.

### a. Background

The ELAP accredits laboratories which report results to California regulatory agencies for compliance with the Safe Drinking Water Act, Clean Water Act, the Toxic Substance Control Act, Resource Conservation and Recovery Act, and Comprehensive Environmental Response, Compensation, and Liability Act. ELAP is required to only offer accreditation for methods approved by regulatory agencies which implement these laws.

**Wherever possible, provisions of the TNI documents that contradict ELAP's regulatory needs should be eliminated.**

### b. Goal

The goal of laboratory accreditation is to assess a laboratory's capabilities to perform a fixed list of analytical methods approved and regulated analytes established by the Regulatory Partners.

**Provisions of the TNI documents which do not advance this goal or hinder it should be eliminated.**

**c. Protection of Public Health**

ELAP seeks to ensure that laboratories have adequate capabilities so that public health and the environment can be protected. In some cases that means ensuring that there are an adequate number of accredited laboratories spread across the State of California to serve as wide a geographical areas as possible.

**Provisions of the TNI documents which do not advance this goal or hinder it should be eliminated.**

**d. Concerns with TNI**

Where TNI has been implemented in the past in a mandatory fashion, New York and Florida, a significant number of laboratories left the accreditations program, both government and commercial. The reason for this was the sheer volume of requirements; there are over 1,000 separate requirements in the TNI documents. The cost of implementing all of those requirements was prohibitive.

**To prevent this from happening in California, only the minimum number of requirements needed to maintain quality data should be implemented while removing unnecessary 'busy work.'**

**e. Concerns with ELAP**

Historically ELAP has a long history of difficulties in implementing their standards. There was a great deal inconsistency between one on–site assessment and another. Sometimes the same assessor will apply the same standard differently and sometimes different assessors will apply the same standard differently. It is thus imperative that the Quality Management System contain provisions which are clear and unambiguous.

**Only provisions which are clear and unambiguous should be included.**

**f. ELAP's Authority**

ELAP' authority is based upon the requirement that laboratories can only use analytical methods that are approved by a regulatory agency that uses the data. Methods for compliance monitoring for the Safe Drinking Water Act (SDWA) must be listed in 40 CFR 141 or approved by the Division of Drinking Water (e.g. the 123–Trichloropropane methods). ELAP itself has no authority to approve methods itself. ELAP has operated for over 20 year by having a list of approved methods listed in their regulations and on Field of Testing (FOT) forms. Laboratories could choose from among these approved methods but was prohibited from using others. This is based in the Environmental Laboratory Accreditation Act provision : *"100852. (a) Notwithstanding any other provision of law, the department may*

*issue a certificate to the owner of a laboratory in a field of testing or method adopted by the federal Environmental Protection Agency pursuant to Part 136 of Title 40 of the Code of Federal Regulations, as amended September 11, 1992, as published in the Federal Register (57 FR 41830), or Part 141 of Title 40 of the Code of Federal Regulations, as amended July 17, 1992, as published in the Federal Register (57 FR 31776), and as subsequently amended and published in the Federal Register."* This is the basis for the vast majority of ELAP's Technical Standard.

**Where ever possible, eliminating duplication of requirements in the Technical Standard and the QMS should be avoided.**

**g. Types of Laboratories**

No attempt has been made to focus on any one type of laboratory, large or small, commercial or governmental. All of the recommendations are based on the assumption that unnecessary or counter–productive regulations are detrimental to any laboratory irrespective of size or nature of ownership. The proposed new accreditation standard must apply equally to all laboratories.

**The comments here apply to all laboratories, large and small, commercial and governmental.**

**h. Standardless Requirements and Metric of Compliance**

Part of the difficulty in implementing TNI is that most of the requirements do not have clear standards; they are "standardless" in a word. By way of analogy, if someone wants to ride the Matterhorn at Disneyland, there are two requirements, to have a ticket and to be 117 cm tall. Each requirement has a clear standard that can be applied, an individual has a ticket or they do not, an individual is 117 cm tall or is not. Next to the entrance to the queue for the Matterhorn there is a scale where a guest of the park can stand and determine if he or she is or is not 117 cm tall. Anyone can look and see if they meet this requirement; the standard is clear and objective. In contrast, the vast majority of requirements in the TNI documents do not have similar standards. Each requirement placed upon a laboratory as a condition of accreditation should have an objective metric of compliance to assess whether the laboratory is complying with the requirement which both the laboratory and ELAP staff can . Without a metric of compliance a requirement is simply busy work.

**All requirements should be a definite standard with a metric of compliance.**

**i. Redundancy**

If there are already existing requirements found in other parts of ELAP's Accreditation Standard then having a second requirement in the Quality Management System regulations is counter–productive, unnecessary and burdensome.

**Redundant requirements should be eliminated.**

**j. Nature of the TNI Documents and Data Quality**

The TNI documents are not technical in the sense that they do tell laboratories how to perform laboratory functions. As is clearly stated: *"This Standard does not specify detailed procedural steps…"* (Volume 1 Page 102). It does not specify quality control or quality assurance standards, such as relative percent difference between duplicates or percent recovery for analyte or surrogate spike recoveries. The documents frequently state which quality control procedures are discussed: *"Results are compared to the acceptance criteria as published in the mandated method"* (e.g. Module 4 1.7.3.3). TNI does not create any quality control standards not already found in the methods that ELAP accredits for.

**Requiring laboratories to use the TNI document does not improve or degrade the quality or the data produced.**

**k. Legal Defensibility / Admissibility in Court**

In California courts the legal standard for admissibility is the Frye Standard (or Frye Test). This is based upon Frye v. United States, 293 F. 1013 (D.C. Cir. 1923). A court applying the Frye standard must determine whether or not the method by which that evidence was obtained was generally accepted by experts in the particular field in which it belongs. Since California law mandates the use of particular methods and the United States Environmental Protection Agency (USEPA) has conducted the peer review, under the Frye Standard, a laboratory using the above mentioned methods is at least admissible prima facie. The use of TNI documents for accreditation does not directly impact the admissibility of data generated by an accredited laboratory. In terms of defensibility of individual data sets, what is needed is documented adherence to the method from preservation, storage, calibration, standards to batch Quality Control (QC) which is currently occurring.

**It is unclear what legally defensible or admissibility means in this context or how TNI impacts it.**

**l. Equity and Proportionality**

Failure to comply with a provision of a regulation must ultimately result in the suspension or revocation of accreditation. It is essential that the degree of significance of the provision to the protection of public health and the environment be equal or greater to the significance of the loss of accreditation. There should be proportionality between the severity of the

legal consequence of failure to comply with a provision and severity of the risk to public health and the environment.

**Consequences of ELAP actions should be proportional to the importance of the provisions that were not in compliance.**

### 3) Part 2 – General Comments and Recommendations

| Section | **Notes** |
|---|---|
| Provision | The notes given provide clarification of the text, examples and/or guidance. They do not contain requirements and do not form an integral part of this Standard. |
| Recommendation | Revise |
| Justification | This is extremely confusing since there are so many Notes but even more so because frequently the text says “see Note” which then suggests that the Note is indeed an integral part of the TNI requirements.<br><br>Module 2 4.1.5 j, 5.10.1, 5.10.4.1 c |

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|---|---|
| Section | **Module 1 Sections 5.4, 5.4.6.1, 5.5, Module 2 Sections 5.6.2.1.1, 5. 6. 2. 2. 2, 5.9, 5.10** |
| Provision | "All references to Calibration Laboratories and Calibration Methods in ISO/lEG 17025:2005 in these Clauses are not applicable to environmental testing."<br><br>"All references to Calibration Certificates in ISO/lEG 17025:2005 are not applicable to environmental testing."<br><br>"ISO/IEC Clauses 5.5.1 to 5.5.12 apply with respect to equipment in environmental testing laboratories."<br><br>Quality Assurance for Environmental Testing |
| Recommendation | Revise |
| Justification | Throughout the TNI documents two types of laboratories are referenced, Calibration Laboratories and Testing Laboratories (which it would appear, include environmental laboratories). Apparently there are somewhat different requirements for Calibration Laboratories than for Testing/Environmental Laboratories and at different points different instructions are provided to the two types of laboratories. In some cases the text says that a provision applies to only Calibration Laboratories and but in others they apply partially. This is all very confusing. The provision that apply to both should be re-written to exclude the provisions that address calibration laboratories and do not address environmental testing. |

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|---|---|
| Section | **Module 2 Section 5.1.1, 5.5.1, 5.8, 5.10** |
| Provision | "Calibration Items" and "Test Items" |
| Recommendation | Delete or Revise |
| Justification | These terms are used several times in several different provisions but they are not defined anywhere. It is unclear what they mean or how they apply to regulatory compliance testing, it at all. It is very confusing. |

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|---|---|
| Section | **Sections 4.1.2, 4.2.2 3, 4.2.6, 4.5.1, 4.5.4, 4.11.5, 4.14.1, 5.5.1, 5.10.7** |
| Provision | The Term "This International Standard" is used in all of the above sections not counting Notes. |
| Recommendation | Revise |
| Justification | This phrase refers to the entire set of TNI documents while California is not implementing all of that. ELAP is only implementing part of one volume of the TNI documents so the phrase conflicts with the actually document being referenced. For example, 4.1.2 says*:" It is the responsibility of the laboratory to carry out its testing and calibration 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."*<br><br>This is clearly states that the laboratory is complying with the entire TNI document, not just parts of it.<br><br>It should read "California Code of Regulations Title 22, Division 4 , Chapter 19" |

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|---|---|
| Section | **Module 1 Sections 4.2.4, 4.3.5, 4.3.7 a b c**<br>**Module 2 5.9.3**<br>**Module 4: 1.5.2.1 and 1.5.2.2– LOQ** |
| Provision | Term "Limit of Quantitation" or LOQ is defined as *"The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence"*<br>*There is a requirement* require that the laboratory to determine an LOQ for every analyte – method combination and conduct on–going verification of the LOQ. |
| Recommendation | Remove |
| Justification | The provisions The LOQ is never clearly defined.<br>None of the Regulatory Partners require laboratories to use the LOQ as a reporting threshold.<br>The Division of Drinking Water uses the Detection Limit for Reporting (DLR) or the Minimum Reporting Limit (MRL). The Division of Water Quality requires the Method Detection Limit (MDL) and the Minimum Level (ML) which in many cases are defined in regulation or individual methods.<br>These provisions serve no regulatory purpose, clash with, if not contradict California regulations<br>Unnecessary and redundant at best and confusing and counterproductive at worst. |

**4) Part 3 – Specific Comments and Recommendations**

| Section | **Module 1 – Performance Testing Study (PTS) Participation Frequency** |
|---|---|
| Provision | The text of Module 1 states in several places that a laboratory must complete two PTSs every year. |
| Recommendation | Revise |
| Justification | Two PTS per year is far too much work and cost with little or no benefit to the Regulatory Partners, ELAP, or the laboratories. It is not clear, is this every 12 months on a rolling basis or on a calendar year basis. |

| Section | **Module 1 Section 5.2.1.1 – PTS Assessment** |
|---|---|
| Provision | The laboratory shall maintain a history of two (2) successful (acceptable scores) PT studies out of the most recent three (3) attempts for each field of accreditation specified in Section 4.1.1 for which the laboratory holds accreditation. |
| Recommendation | Revise |
| Justification | The current system of assessment is more stringent. Each PTS is assessed on its own and laboratories either pass that study or they do not. It is also unnecessarily complicated; ELAP and laboratory staff has to maintain complex rolling assessments for each analyte – method – laboratory combination of results. |

| Section | **Module 2 Section 2 – Normative References** |
|---|---|
| Provision | The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO/lEG 17000, Conformity assessment– Vocabulary and general principles. VIM, International vocabulary of basic and general terms in metrology, issued by BIPM, lEC, IFCC, ISO, IUPAC, IUPAP and OIML. |
| Recommendation | Delete or Include the Actual Requirements in the Regulations |
| Justification | According to the text, the referenced documents are “indispensable” to using Volume 1. If this is accurate, then they need to be included in the regulations. |

| Section | **Module 2 Section 4.1.4 – List of Staff** |
|---|---|
| Provision | 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 to identify potential conflicts of interest. |
| Recommendation | Delete |
| Justification | Simply creating a list of individuals with potential conflicts of interest and nothing is pointless. Without some sort of follow–up action this provision serves no purpose. |

| Section | **Module 2 Section 4.1.5 b– Undue Influence** |
|---|---|
| Provision | The laboratory shall 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; |
| Recommendation | Delete |
| Justification | This is overly broad and general, it is extremely vague and ambiguous, it is standardless, and unenforceable and produces no benefits for the Regulatory Partners, ELAP, or the laboratories. What are arrangements? |

| Section | **Module 2 Section 4.1.5 c – Confidential Information** |
|---|---|
| Provision | The laboratory shall have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results; |
| Recommendation | Delete |
| Justification | This is overly broad and general, it is extremely vague and ambiguous, it is standardless, and unenforceable and produces no benefits for the Regulatory Partners, ELAP, or the laboratories. ELAP is not a consumer protection agency. This provision does not assess a laboratories ability to analyze samples. |

| Section | **Module 2 Section 4.1.5 d – Confidence** |
|---|---|
| Provision | The laboratory shall have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity; |
| Recommendation | Delete |
| Justification | This is overly broad and general, it is extremely vague and ambiguous, it is standardless, and unenforceable and produces no benefits for the Regulatory Partners, ELAP, or the laboratories. |

| Section | **Module 2 Section 4.1.5 g – Adequate Supervision** |
|---|---|
| Provision | The laboratory shall provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results; |
| Recommendation | Delete |
| Justification | The term “adequate” is undefined, vague, ambiguous, and standardless. |

| Section | **Module 2 Section 4.1.5 i – Direct Access** |
|---|---|
| Provision | The laboratory shall appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources; |
| Recommendation | Delete |
| Justification | It is impossible in most cases for the quality manager to have “direct access to the highest levels of management”. The majority of accredited laboratories are not stand–alone facilities but are part of a larger organization where there is a legally defined chain of command and laboratory staff cannot have direct access to the highest levels of management. |

| Section | **Module 2 Section 4.1.5 j – Deputies** |
|---|---|
| Provision | The laboratory shall appoint deputies for key managerial personnel; |
| Recommendation | Delete |
| Justification | This is overly broad and general, it is extremely vague and ambiguous, it is standardless, and unenforceable and produces no benefits for the Regulatory Partners, ELAP, or the laboratories. |

| Section | **Module 2 Section 4.1.5 k – Relevance** |
|---|---|
| Provision | The laboratory shall ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.; |
| Recommendation | Delete |
| Justification | This is overly broad and general, it is extremely vague and ambiguous, it is standardless, and unenforceable and produces no benefits for the Regulatory Partners, ELAP, or the laboratories. |

| Section | **Module 2 Section 4.1.6 and 4.2.4– Communications** |
|---|---|
| Provision | 4.16 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.<br><br>4.2.4 Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements. |
| Recommendation | Delete |
| Justification | This is overly broad and general, it is extremely vague and ambiguous, it is standardless, and unenforceable and produces no benefits for the Regulatory Partners, ELAP, or the laboratories. How does a laboratory demonstrate that it's "communications process" is effectives? How does an ELAP assessor determine that the documentation provided by the laboratory is adequate. "Meeting customer requirements" is not one of ELAP's concerns. |

| Section | **Module 2 Section 4.1.7.1 b Quality Assurance Officer (QAO)** |
|---|---|
| Provision | Where staffing is limited, the technical manager and the quality manager may be the same person.<br><br>The laboratory's quality manager and/or his/her designee(s) shall:<br>b) have functions independent from laboratory operations for which they have QA oversight; |
| Recommendation | Delete b) |
| Justification | Section 4.1.7.1 b contradicts the introductory sentence; if the QA manager is independent he or she cannot also be the Technical Manager. |

| Section | **Module 2 Section 4.1.7.1 c Quality Assurance Officer** |
|---|---|
| Provision | The laboratory's quality manager and/or his/her designee(s) shall be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence; |
| Recommendation | Delete |
| Justification | In a great majority of cases this will be impossible as the QAO will be the technical manager as well. How does a laboratory demonstrate that the QAO has no "outside influences"? How does an ELAP assessor determine that there are no outside influences? |

| Section | **Module 2 Section 4.1.7.2 d Technical Manager** |
|---|---|
| Provision | The laboratory's technical manager(s), however named, and/or his/her designee(s) shall not be the technical manager(s) of more than one accredited environmental laboratory without authorization from the primary Accreditation Body. Circumstances to be considered in the decision to grant such authorization shall include:<br>i. the extent to which operating hours of the laboratories to be directed overlap,<br>ii adequacy of supervision in each laboratory, and<br>iii the availability of environmental laboratory services in the area served. |
| Recommendation | Delete |
| Justification | This provision services no purpose. Many laboratories under common ownership need to share resources and technical manager can be one of those resources. If laboratories can benefit from shared management, why should they be precluded from doing so? This will make it difficult for laboratories in underserved and geographically isolated areas to remain accredited while providing no improved data quality of legal defensibility. |

| Section | **Module 2 Section 4.2.2 – Quality Assurance Manual** |
|---|---|
| Provision | The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:<br>a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;<br>b) the management's statement of the laboratory's standard of service;<br>d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and |
| Recommendation | Delete or Revise |
| Justification | Simply requiring objectives to be written down in a document a set of general objectives serves no purpose. These objectives need to be tied to measures of data quality that can be quantified and assessed. This is a standardless requirement lacking a metric of compliance. |

| Section | **Module 2 Section 4.2.3 – Management Improvement** |
|---|---|
| Provision | Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. |
| Recommendation | Delete |
| Justification | What constitutes evidence of improving effectiveness of management? What is the metric of compliance? How much improvement is necessary to comply with How effective management is has no bearing on data quality or legal defensibility. ELAP's job is not assess management but laboratory performance. If laboratory fails to show improvement in management, should that laboratory lose accreditation? |

| Section | **Module 2 Section 4.2.8.1– Data Integrity System / 4.16 Data Integrity Investigations** |
|---|---|
| Provision | The laboratory shall establish and maintain a documented data integrity system. There are four (4) required elements within a data integrity system. These are 1) data integrity training, 2) signed data integrity documentation for all laboratory employees, 3) periodic in–depth data monitoring, and 4) data integrity procedure documentation. The data integrity procedures shall be signed and dated by top management. The requirements for data integrity investigation are listed in Section 4.16. The requirements for data integrity training and documentation are listed in Section 5.2.7. Management shall annually review data integrity procedures and update as needed. |
| Recommendation | Delete |
| Justification | What constitutes "in depth data monitoring"? What is a "data integrity procedure"? What sort of documentation is adequate? This entire section is full of undefined terms with no metric of compliance. How does this measure a laboratory's capabilities to produce data of sufficient quality that the Regulatory Partners can use it for decision making or admissibility to court? |

| Section | **Module 2 Section 4.3 – Document Control** |
|---|---|
| Provision | The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals. |
| Recommendation | Rewrite / Revise / Reduce |
| Justification | The basic concept is sound but this section overly verbose and complicated. There are far too many provisions that are not really necessary. 4.3.1 through 4.3.2.1 are probably alright by themselves but everything after that is excessively detailed and does not assess the laboratory's actual capabilities. These provisions provide little benefit in terms of data quality or legal defensibility but consume considerable resources. |

| Section | **TNI 2016 Module 2 Sections 4.4– Review of Requests, Tenders and Contracts** |
|---|---|
| Provision | *"[t]he laboratory shall establish and maintain procedures for the review of requests, tenders and contracts"*. There are record keeping requirements for noting *"Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer."* A laboratory that does not keep these record can be denied accreditation or have their accreditation revoked. There are also requirements that *"Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract."* |
| Recommendation | Remove |
| Justification | Does nothing to improve data quality or legal defensibility and is busy–work. Provides no benefit to laboratories, Regulatory Partners, or ELAP.<br>Very labor intensive. |

| Section | **Module 2 Section 4.5 – Subcontracting** |
|---|---|
| Provision | When a laboratory subcontracts work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. |
| Recommendation | Rewrite / Revise / Reduce |
| Justification | The basic concept is sound but this section overly verbose and complicated. There are far too many provisions that are not really necessary and contains contradictory language.<br><br>4.5.1 allows the laboratory to select any competent laboratory while 4.5.5 requires that only TNI compliant labs may be subcontracted and 4.5.3 allows the use of non–TNI compliant laboratories if the customer or regulatory agency specifies the laboratory.<br><br>4.5.2 says that the customer needs to approve the used of subcontractors "when appropriate". Appropriate needs to be defined is this kept but this not a laboratory accreditation issue, ELAP is not a consumer protection agency.<br><br>4.5.4 says that laboratories can only use TNI compliant laboratories ("this International Standard") when it should read "accredited by ELAP". |

| Section | **Module 2 Sections 4.6– Purchasing Services and Supplies** |
|---|---|
| Provision | Requires laboratories have "…*policy and procedure(s) for the selection and* |

| | |
|---|---|
| | *purchasing of services and supplies"*.<br><br>There are record keeping requirements for noting *"These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained."*<br><br>There are requirements that *"Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release"* |
| Recommendation | Remove |
| Justification | There are no "specified requirements" specified. It is vague and ambiguous.<br>Does nothing to improve data quality or legal defensibility and is busy–work.<br>Provides no benefit to laboratories, Regulatory Partners, or ELAP.<br>Very labor intensive. |

| Section | **Module 2 Section 4.7.1 – Service to the Client**<br>**Module 2 Section 4.7.2** |
|---|---|
| Provision | 4.7.1 requires that laboratories "…*shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers."*<br><br>4.7.2 requires that laboratories "…*shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management system, testing and calibration activities and customer service."* |
| Recommendation | Remove |
| Justification | Does nothing to improve data quality or legal defensibility and is busy–work.<br>Provides no benefit to laboratories, Regulatory Partners, or ELAP.<br>ELAP's job is not to police "laboratory service" to customers, it is to ensure adequate quality of results to Regulatory Partners.<br>Labor intensive. |

| Section | **Module 2 Sections 4.8 – Complaints** |
|---|---|
| Provision | requires that laboratories "…*shall have* a *policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4. 11 )."* |
| Recommendation | Remove |
| Justification | Does nothing to improve data quality or legal defensibility and is busy–work.<br>Provides no benefit to laboratories, Regulatory Partners, or ELAP.<br>ELAP's job is not to police "laboratory service" to customers, it is to ensure adequate quality of results to Regulatory Partners.<br>Labor intensive. |

| Section | **Module 2 Section 4.9.1 – Control of Nonconforming Environmental Testing Work** |
|---|---|
| Provision | The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. |
| Recommendation | Delete or Revise |
| Justification | The basic concept is sound but this section is extremely vague. What is meant by "It's own procedures"? Does that include procedures for purchasing or tenders and offers? Are all procedures of equal importance. The focus should not be on customer needs but compliance with ELAP Technical Standards and the laboratory's Quality Assurance Manual. Quality control failures are better focus for efforts like this. |

| Section | **Module 2 Section 4.10 – Improvement** |
|---|---|
| Provision | The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. |
| Recommendation | Delete or Revise |
| Justification | This is vague, ambiguous, standardless and does not assess laboratory capabilities. How is "effectiveness" of management measured?. This provides no benefit to laboratories, Regulatory Partners, or ELAP. Should a laboratory lose accreditation if the laboratory does not improve its management system? |

| Section | **Module 2 Section 4.12 – Preventive Action** |
|---|---|
| Provision | 4. 12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.<br>4.12.2 Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective. |
| Recommendation | Delete or Revise |
| Justification | What is the metric of compliance for this provisions? How can a laboratory document success with this provision? Should a laboratory lose accreditation if the laboratory does cannot prevent problems? |

| Section | **Module 2 Section 4.13 – Control of Records** |
|---|---|
| Provision | The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.. |
| Recommendation | Revise |
| Justification | The principle involved is important and regulation are needed for this. However this section far too long an convoluted. 4.13.3 if far too detailed and verbose. |

| Section | **Module 2 Sections 4.14 – Internal Audits** |
|---|---|
| Provision | The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard. The internal audit programme shall address all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. |
| Recommendation | Remove |
| Justification | This is unnecessary. There is constitutes a great deal of work on the part of the laboratory and is redundant with the on-site assessments of ELAP. If ELAP staff are conducting on-site assessments every two years, two more identical audits by the laboratory? Should a laboratory lose accreditation if the laboratory does not periodically conduct internal audits? |

| Section | **Module 2 Sections 4.15 – Management Reviews** |
|---|---|
| Provision | requires that laboratories *"[i]n accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements."* |
| Recommendation | Remove |
| Justification | This is vague, ambiguous, standardless and does not assess laboratory capabilities. Unclear what 'suitability and effectiveness' means in this context. There is no metric of compliance. This provides no benefit to laboratories, Regulatory Partners, or ELAP. Should a laboratory lose accreditation if the laboratory does not periodically review its management system? |

| Section | **Module 2 Sections 5.2.1 – Competence** |
|---|---|
| Provision | The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required. |
| Recommendation | Remove |
| Justification | This is vague, ambiguous, standardless and does not assess laboratory capabilities. The term "appropriate" is used but it is not defined. What is an appropriate level of supervision? What is an appropriate level of education, training, or experience? How does a laboratory demonstrate compliance and how does ELAP staff assess compliance. |

| Section | **Module 2 Sections 5.2.2 – Training** |
|---|---|
| Provision | The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated. |
| Recommendation | Remove |
| Justification | This is vague, ambiguous, standardless and does not assess laboratory capabilities. How is the effectiveness of training assessed? What is the metric of compliance for policies and procedures? What is an acceptable education and training policy and what is not? How a laboratory trains its staff is outside of ELAP's purview. |

| Section | **Module 2 Sections 5.2.3 – Employment** |
|---|---|
| Provision | The laboratory shall use personnel who are employed by, or under contract to, the laboratory. 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. |
| Recommendation | Remove |
| Justification | This is vague, ambiguous, standardless and does not assess laboratory capabilities. It is also unclear what the provision actually intends to achieve. Is there a problem with laboratories having analytical methods performed by people who do not work for the laboratory? This provision seems pointless. It is also outside the purview of ELAP's authority. A laboratory's employment practices are part of ELAP's job to assess. |

| Section | **Module 2 Sections 5.2.5 – Authorized Personnel** |
|---|---|
| Provision | 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 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. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed. |
| Recommendation | Remove |
| Justification | This is vague, ambiguous, standardless and does not assess laboratory capabilities. There are no metrics for compliance. What is "competence, educational and professional qualifications, training, skills" for any given analytical method? There are no specific details. How is a laboratory to demonstrate compliance and how is an ELAP assessor to assess a laboratories authorization procedures? A better approach is to require that every individual performing a specific analytical method complete a Demonstration of Capability with specific and detailed requirements. |

| Section | **Module 2 Section 5.2.6.1 f – Radon in Air** |
|---|---|
| Provision | Any technical manager of an accredited environmental laboratory engaged in the examination of radon in air shall have at least an associate's degree or two (2) years of college and one (1) year of experience in radiation measurements, including at least one (1) year of experience in the measurement of radon and/or radon progeny. |
| Recommendation | Remove |
| Justification | Unnecessary as ELAP does not regulate air or radon testing. |

| Section | **Module 2 Sections 5.2.6.2 a and c – Technical Manager Qualification Exceptions** |
|---|---|
| Provision | a. Notwithstanding any other provision of this Section, a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational requirements as the technical manager. A technical manager shall have two (2) year testing experience devoted exclusively to the testing of environmental samples specified in the scope of the facility's regulatory permit. Such accreditation for a water treatment facility and/or a sewage treatment facility shall be limited to the scope of that facility's regulatory permit.<br>b. Persons who do not meet the education credential requirements, but possess the requisite experience of Section 5.2.6.1, shall qualify as technical manager(s) subject to the following conditions.<br>i. The person shall be a technical manager of the laboratory on the date the laboratory applies for accreditation and/or becomes subject to accreditation under this Standard, and shall have been a technical manager in that laboratory continuously for the previous twelve (12) months or more.<br>ii. The person will be approved as a technical manager for only those fields of accreditation for which he/she has been technical manager in that laboratory for the previous twelve (12) months or more.<br>iii. A person who is admitted as a technical manager under these conditions, and leaves the laboratory, will be eligible for hire as a technical manager for the same fields of accreditation in another accredited laboratory. |
| Recommendation | Remove |
| Justification | Under current California regulation and TNI, every laboratory has to have someone in charge, a “laboratory director” in current regulations or “Technical Manager” in the TNI parlance. Both require that this individual possess a college degree in a laboratory science (e.g. chemistry, biology, microbiology, etc). California regulation however allows certain exceptions. Section 64817(2)(b) allows laboratory directors of drinking water or wastewater utilities to substitute a Cal-NV AWWA or CWEA Laboratory Analyst Certificate in lieu of possession of a college degree in a laboratory science. This exception is provided as it is often difficult for small facilities to get someone with the requisite degree to be a laboratory director.<br><br>TNI Volume 1 Module 2 Section 5.2.6.2 Technical Manager Qualification Exceptions also has an exception. It does not include the laboratory analyst certificate exception found in current ELAP regulation, but TNI does include possession of a treatment operators certificate as an exception to possessing of a college degree in a laboratory science. Having an operator certificate does not qualify someone to be a laboratory director. The TNI provision completely misses the point, small utilities need someone with some training to be a laboratory director even if they do not have a college degree. Further, current ELAP regulation requires increasing levels of certification. For example a Grade I Laboratory Analyst Certificate holder can be a laboratory director only for laboratories accredited in basic chemistry and microbiological Fields of |

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| | Accreditation 101, 108, and some of 102 and 109. A Grade 2 certificate is required for more advanced chemistries and microbiological tests in FOT 109, and a Grade 3 Certificate is required for even more advanced testing in FOTs 102, 103, 104, 109, 110, and 111.<br><br>In contrast the TNI document would allow any operator without any laboratory training at all to be a laboratory director. Further, this individual can only be grandfathered in, i.e. he or she has to have been in the employ of the utility as the laboratory director when it became TNI compliant. Once that individual leaves, all future Technical Managers have meet the college degree. It is a one-time exception.<br><br>The TNI language is far weaker than current California regulations but then creates a very large problem a few years from adoption as existing certified laboratory directors retire. |

| Section | **Module 2 Section 5.2.7 Data Integrity Training** |
|---|---|
| Provision | *"Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis for all current employees. Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution."* |
| Recommendation | Remove or modify |
| Justification | There are no specific unethical or disallowed practices are provided.<br>These requirements need specific details about what sorts of actions cannot be ethically used. It would be best to provide definitions and examples for *"Time Travel"*, *"Dry–Labbing"*, and *"Curve Shaving."* This is an example of 'standardless requirement.' |

| Section | **Module 2 Section 5.3 Accommodation and Environmental Conditions** |
|---|---|
| Provision | Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations. The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented. |
| Recommendation | Remove or modify |
| Justification | While the general concept is useful this actual language lacks any specific standards that are applicable. How does a laboratory demonstrate or document that it is complying with this provision? How does an ELAP assessors assess this. It is all much to vague and general to be applicable. This approaching the problem from the wrong end. This needs to be written in a way that it starts with a data quality problem and if the laboratory identifies a data quality problem that is caused by environmental conditions, then it needs to rectify those conditions. For example it is not uncommon for the voltage provided by utilities to "sag" during the middle of the day and analytical instruments can be have a required minimum voltage. If this voltage is not maintained the instruments may not function within acceptable parameters and quality control will not be met. |

| Section | **Module 2 Section 5.4.1 –Environmental Methods and Method Validation** |
|---|---|
| Provision | Describes the issue of which methods laboratories can use. However the approach laid out is exactly the opposite of what ELAP uses. Section 5.4.1 allows the laboratory to choose whatever method that it deems appropriate. It also allows laboratories to deviate from the selected method if the customer approves: "Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer." |
| Recommendation | Remove |
| Justification | These provisions contradict 100852 and how ELAP has historically conducted accreditation as well as how it has stated that it plans to do so in the future. ELAP has never allowed deviations from methods with or without the authorization of the customer. |

| Section | **Module 2 Section 5.4.2 – Selection of Methods** |
|---|---|
| Provision | *The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used."* |
| Recommendation | Remove |
| Justification | Not an improvement in data quality. Risk of lower quality data that is more difficult to audit. Laboratories have never been allowed to use methods other than those specified by the USEPA or California Regulatory Partners.<br>Section makes no mention of a list of methods approved by ELAP, or any accreditation body. |

| Section | **Module 2 Section 5.4.3 – 5 –Environmental Methods and Method Validation** |
|---|---|
| Provision | 5.4.3 Allows the use of "Laboratory–Developed Methods"<br>5.4.4 Allows for the use of "Non–Standard Methods"<br>5.4.5 5.4.5 Explains how these non–standard methods are validated for us by laboratories without ELAP playing any role prior to implementation |
| Recommendation | Remove |
| Justification | The use of methods other than those listed in ELAP's Fields of Accreditation is contrary to past practice, future plans, and current law. Laboratories cannot simply make up their own methods or use methods that others make up.<br>Note: In each of Modules 3 – 7, there is a section 1.5 Method Validation which explains how non–standards are to be selected and validate which references back to 5.4.5. |

| Section | **Module 2 Sections 5.5.1, 5.5.2, 5.5.3 Calibration Requirements** |
|---|---|
| Provision | 5.5.1 requires that the laboratory be "furnished with all items of sampling, measurement and test equipment" necessary to perform the required tests.<br>5.5.2 states that the equipment must capable of producing the required accuracy and specification of the method.<br>5.5.3 states that only authorized personnel shall operate equipment and they shall have up–to–date instructions. |
| Recommendation | Remove |
| Justification | This is redundant as methods that require calibration already have provisions requiring this.<br>USEPA Methods have requirements for EQUIPMENT AND SUPPLIES, REAGENTS AND STANDARDS and Quality Control requirements.<br>5.5.3 is redundant and already described in a different section of the TNI, Module 2 4.2.8.4 (Quality Assurance Manual), 4.2.8.5 (Standard Operating Procedures), and 5.2 Personnel.<br>Note: Not all methods require calibration but those that do require calibration already have the requirements spelled out in the method.<br>Example of 'standardless requirement.' |

| Section | **Module 2 Section 5.6 – Measurement Traceability** |
|---|---|
| Provision | *All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.* |
| Recommendation | Remove |
| Justification | The exact purpose of this provision is unclear. It seems to mandate that laboratory equipment be calibrated before it is used. This seems completely redundant with 5.5 and with the requirements in the Technical Standard. It may be that this has something to do with Calibration Items but it is unclear. |

| Section | **Module 2 Section 5.7 – Collection of Samples** |
|---|---|
| Provision | *"The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results."* |
| Recommendation | Remove |
| Justification | This is outside the purview of ELAP's authority. Aside from the fact that the vast majority of samples are not collected by laboratory staff, the word "sampling" occurs nowhere in the Environmental Laboratory Accreditation Act. ELAP's job is not to regulate how samples are collected. Further the term "appropriate statistical methods" are undefined. How would a laboratory demonstrate that an appropriate statistical method had been used and how ELAP |

| Section | **Module 2 Section 5.8 – Handling Samples and Test Items** |
|---|---|
| Provision | *The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.* |
| Recommendation | Remove and simplify and make more specific. |
| Justification | As noted above the terms "test item" and "calibration "item" are undefined and unclear if they apply to regulatory compliance testing. These terms should be removed.<br><br>While sample handling requirements are important this set of requirements but these are so general and vague it is difficult to see how they apply in a concrete fashion. This section can be expressed much more concisely and directly to California regulatory needs. |

| Section | **Module 2 Section 5.9.1 – Control Charts** |
|---|---|
| Provision | *The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:*<br>*a) regular use of certified reference materials and/or internal quality control using secondary reference materials;*<br>*b) participation in interlaboratory comparison or proficiency-testing programmes;*<br>*c) replicate tests or calibrations using the same or different methods;*<br>*d) retesting or recalibration of retained items;*<br>*e) correlation of results for different characteristics of an item.* |
| Recommendation | Remove |
| Justification | This provision requires that laboratories perform some sort of control charting. However it does not specify any sort of acceptance or rejection criteria or action levels. It simply requires that temporal trends be recorded and statistically analyzed. Control charts are not needed to produce accurate or precise results. They provide no benefits to the Regulatory Partners, to ELAP, or the laboratories. Further not all procedures are amendable to control charting, the microbiological test for example. This is a classic case of busy work. |

| Section | **Module 2 Section 5.9.2 – Quality Control Data** |
|---|---|
| Provision | *Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.* |
| Recommendation | Remove |
| Justification | Without some sort of requirement for what the criteria are, this provision provides no benefit to the Regulatory Partners, ELAP, or to laboratories. This requires significant amounts of work to produce results that no one will examine or use. It is unclear what this requires the laboratory to do or what ELAP staff will use to assess this requirement. |

| Section | **Module 2 Section 5.9.3 – Essential Quality Control Procedures** |
|---|---|
| Provision | *These general QC principles shall apply, where applicable, to all testing laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (i.e., asbestos, chemical, microbiological, radiological, toxicity) and are further described in Technical Modules. The standards for any given test type shall assure that the applicable principles are addressed:* |
| Recommendation | Remove |
| Justification | What criteria are used to assess which principles apply to which test and which laboratory? Who decides which principle are applicable? Further, in there are no acceptance or rejection criteria in this provision nor in the corresponding Modules. This confusing, ambiguous, standardless, and will consume considerable amounts of time and labor without improving data quality or legal defensibility. This is busy work. |

| Section | **Module 2 Section 5.10 – Reporting the Results** |
|---|---|
| Provision | requires that: *"The results shall be reported, usually in a test report or a calibration certificate (see Note 1), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4. In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5. 10. 2 to 5. 10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations."* |
| Recommendation | Remove |
| Justification | Outside the purview of ELAP's authority.<br>Unnecessary— In California, regulatory agencies determine how their laboratory results are presented.<br>Laboratories reporting Safe Drinking Water Act are required to prepare reports using the Electronic Data Transfer software "Writeon".<br>Laboratories reporting to the Regional Boards or the State Board use California Integrated Water Quality System (CIWQS).<br>How data is reported is dependent upon the relationship between the customer and laboratory. |

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| Section | **Module 2 Section 3.1**<br>**Module 4 Section 1.5.2.1–3** |
| Provision | Module 2 Section 3.1: Definitions – Method Detection Limit (MDL): One way to establish a Limit of Detection.<br>Module 4 Secton 1.5.2.1–3 If a mandated test method or applicable regulation includes protocols for determining detection limits, they shall be followed. The laboratory shall document the procedure used for determining the MDL. If the method or regulation does not contain specific directions for determination of the detection limit, the following requirements shall apply. MDL determinations are not required for methods/analytes for which a detection limit is not applicable such as pH, color, odor, temperature, titrimetric, or dissolved oxygen. MDL determinations based on spikes are not required for analytes for which no spiking solutions are available such as total suspended solids. If results are not reported below the limit of quantitation (LOQ), an initial MDL determination is required, but ongoing verification is not." |
| Recommendation | Remove or Modify |
| Justification | The term Method Detection Limit (MDL) has a specific definition in Federal Regulation (40 CFR 136 Appendix B) and in a variety approved methods.<br>The term Method Detection Limit (MDL) also has specific regulatory meaning in California for compliance with the Clean Water Act. None of this is present in these sections.<br>Example of 'standardless requirement'<br>Redundant with method specific requirements and regulations.<br>If this section is maintained, then the entire section should be re–written to include actual uses by California laboratories and regulatory agencies. |

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| Section | **Module 2 Section 3.1 Verification**<br>**Module 4, 1.5.2.1.2 Ongoing verification of the MDL.**<br>**Module 4 1.5.2.2.2 Ongoing verification of the LOQ,**<br>**Module 4 1.7.1.2 Continuing Calibration Verification (CCV)** |
| Provision | The term and concept of verification occurs several times in the document.<br>3.1 "Verification: Confirmation by examination and objective evidence that specified requirements have been met."<br>1.5.2.1.2 Ongoing verification of the MDL<br>1.5.2.2.I Initial verification of the LOQ<br>1.5.2.2.2 Ongoing verification of the LOQ<br>1.5.2.3 Verification of MDL/LOQ<br>1.7.1.1 n Initial Calibration Verification (ICV)<br>1. 7.1.2 Continuing Calibration Verification (CCV) |
| Recommendation | Remove or Modify |
| Justification | The definition of verification is overly broad and vague. Further it does not match how it is used in different parts of the document. In Section 1.5 in Module 2 the verification procedures have nothing to do with what an MDL as actually used by laboratories reporting results to California Regulatory Agencies and of course the same is true of the LOQ.<br>The ICV and CCV requirements do not provide any specific details for acceptance or rejection of a calibration or the requirement for re–calibration.<br>Extensive text but no change in the quality of data. |

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| Section | **Module 4 1.7.1.1 Initial Calibration** |
| Provision | "sample results shall be quantitated from the initial calibration and may not be quantitated from any continuing calibration verification unless otherwise required by regulation, method, or program" |
| Recommendation | Remove |
| Justification | Redundant as methods that require calibration already have provisions requiring this.<br>Not all methods require calibration but those that do require calibration already have the requirements spelled out in the method. |

| Section | **Module 4 1.7.2 - Sample Specific Controls** |
|---|---|
| Provision | The laboratory shall document procedures for determining the effect of the sample matrix on method performance. These procedures relate to the analyses of quality system matrix specific QC samples and are designed as data quality indicators for a specific sample using the designated method. These controls alone are not used to judge laboratory performance. Examples of matrix-specific QC include: Matrix Spike (MS), Matrix Spike Duplicate (MSD), sample duplicates, and surrogate spikes. The laboratory shall have procedures in place for tracking, managing, and handling matrix-specific QC criteria, including spiking appropriate components at appropriate concentrations, calculating recoveries and relative percent difference, and evaluating and reporting results based on performance of the QC samples. |
| Recommendation | Remove |
| Justification | This material is redundant with ELAP's Technical Standard. The individual methods already cover how matrix spikes are handled. Further there is no metric for compliance. Additionally there are no actions to follow up the data collection. Laboratories are expected to collect data but not actually use it make changes in laboratory activity. Even if a laboratory wanted to follow these requirements there are no thresholds for acceptance or rejection of data. This a standardless requirement and busy work. |

| Section | **Module 4 1.7.2.3.1 - Matrix spike; matrix spike duplicates** |
|---|---|
| Provision | Matrix-specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch.<br>b) The frequency of the analysis of matrix spikes are as specified by the method or may be determined as part of the contract review process.<br>c) The components to be spiked shall be as specified by the mandated method. Any permit specified analytes, as specified by regulation or client requested analytes, shall also be included. If there are no specified components, the laboratory shall spike per the following:<br>i. For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike shall be chosen that represents the chemistries and elution patterns of the components to be reported.<br>ii. For those methods that have extremely long lists of analytes, a representative number may be chosen using the following criteria for choosing the number of analytes to be spiked. However, the laboratory shall insure that all targeted components are included in the spike mixture over a two (2) year period.<br>a. For methods that include one (1) to ten (1 0) targets, spike all components.<br>b. For methods that include eleven (11) to twenty (20) targets, spike at least ten (10) components or 80%, whichever is greater.<br>c. For methods with more than twenty (20) targets, spike at least sixteen ( 16) components. |
| Recommendation | Remove |

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|---|---|
| Justification | This provision does not actually provide any acceptance and merely defers to ELAP's Technical Standard. Where the method provides no acceptance criteria, neither does this provision. This provision provides no benefits to the Regulatory Partners, ELAP, or the laboratories. |

| Section | **Module 4 1.7.2.3.2 - Matrix duplicates** |
|---|---|
| Provision | Matrix duplicates are defined as replicate aliquots of the same sample taken through the entire analytical procedure. The results from this analysis indicate the precision of the results for the specific sample using the selected method. The matrix duplicate may provide a usable measure of sample homogeneity. It may also provide<br>a) measure of precision when target analytes are present.<br>b) The frequency of the analysis of matrix duplicates are as specified by the method or may be determined as part of the contract review process.<br>c) Matrix duplicates are performed on replicate aliquots of actual samples. The composition is usually not known. |
| Recommendation | Remove |
| Justification | This provision does not actually provide any acceptance and merely defers to ELAP's Technical Standard. Where the method provides no acceptance criteria, neither does this provision. This provision provides no benefits to the Regulatory Partners, ELAP, or the laboratories. |

| Section | **Module 4 1.7.2.3.3 – Surrogate Spikes** |
|---|---|
| Provision | a) Surrogates, when required, are chosen to reflect the chemistries of the targeted components of the method and are added prior to sample preparation/extraction.<br>b) Except where the matrix precludes its use or when not commercially available, surrogate compounds shall be added to all samples, standards, and blanks for all appropriate methods.<br>c) Surrogate compounds are chosen to represent the various chemistries of the target analytes in the method. They are often specified by the mandated method and are deliberately chosen for their being unlikely to occur as an environmental contaminant. Often this is accomplished by using deuterated analogs of select compounds. |
| Recommendation | Remove |
| Justification | This provision does not actually provide any acceptance and merely defers to ELAP's Technical Standard. Where the method provides no acceptance criteria, neither does this provision. This provision provides no benefits to the Regulatory Partners, ELAP, or the laboratories. |

| Section | **Module 4 1.7.3 Data Acceptance/Rejection Criteria** |
|---|---|
| Provision | This section ostensibly establishes acceptance and rejection criteria for various quality control tests, positive, negative, and sample specific. |
| Recommendation | Remove |
| Justification | In none of the three sub–sections are any acceptance or rejection criteria established. This is a lot of text to read and implement, it is difficult to understand, and it does not actually provide any improvement in data quality. |

| Section | **Module 4 1.7.3.1 Negative Control – Method Performance: Method Blank** |
|---|---|
| Provision | 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:<br><br>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;<br>b) the blank contamination otherwise affects the sample results as per the method requirements **OR** the individual project data quality objectives; **AND**<br>c) a blank is determined to be contaminated. |
| Recommendation | Delete |
| Justification | **To summarize, IF** the value of an analyte found in a blank is (EITHER a method based reporting limit OR regulation based reporting limit) and (EITHER is greater than $1/10^{th}$ of any result from any sample OR project specific DQOs) AND (a blank is determined to be contaminated) **THEN** BOTH the source of the contamination will be identified, minimized, or eliminated AND the affected samples will be processed OR the data will be qualified. This is incredibly confusing, it does not provide any actual requirements, qualified data cannot be submitted in many, if not most, cases for regulatory compliance. |

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| Section | **Module 4 1.7.3.2 a – Positive Control –Method Performance: Laboratory Control Sample (LCS)** |
| Provision | The results of the individual batch LCS are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria.<br>The laboratory shall document the calculation.<br>The individual LCS is compared to the acceptance criteria as published in the mandated method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits or utilize client specified assessment criteria.<br>An LCS that is determined to be within the criteria effectively establishes that the analytical system is in control and validates system performance for the samples in the associated batch. Samples analyzed along with an LCS determined to be "out of control" shall be considered suspect and the samples reprocessed and re–analyzed or the data reported with appropriate data qualifying codes. This includes any allowable marginal exceedance as described in b) below.<br>i. when the acceptance criteria for the positive control are exceeded high (i.e., high bias) and there are associated samples that are non–detects, then those non–detects may be reported with data qualifying codes; or<br>ii. when the acceptance criteria for the positive control are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit decision level with data qualifying codes. |
| Recommendation | Delete |
| Justification | **To summarize, no actual acceptance criteria are offered and there are no data qualifiers in many, if not most cases**. It is also complicated, vague, ambiguous and provides no benefits to the data users, ELAP, or the laboratories except where it is redundant with the existing Technical Standard. It is for the most part a standardless requirement. |

| Section | **Module 4 1.7.3.2 b – Allowable Marginal Exceedances** |
|---|---|
| Provision | Allowable Marginal Exceedances. If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits. This may not indicate that the system is out of control, therefore corrective action may not be necessary. Upper and lower marginal exceedance (ME) limits can be established to determine when corrective action is necessary. A ME is defined as being beyond the LCS control limit (three (3) standard deviations). but within the ME limits. ME limits are between three (3) and four (4) standard deviations around the mean. The number of allowable marginal exceedances is based on the number of analytes in the LCS. If more analytes exceed the LCS control limits than is allowed, or if any one analyte exceeds the ME limits, the LCS fails and corrective action is necessary. This marginal exceedance approach is relevant for methods with long lists of analytes. It will not apply to target analyte lists with fewer than eleven analytes. |
| Recommendation | Delete |
| Justification | To summarize, this provision actually weakens the QC of these methods. It allows laboratories to fail a certain number of analytes when LCSs are analyzed. The term “analyte list” is unclear. Does this mean the list of analytes listed in the approved method, the list of analytes listed in the Standard Operating Procedure, the list of analytes on the ELAP issued Certificate of Accreditation? |

| Section | **Module 5 1.7.3.7 a Laboratory Facilities** |
|---|---|
| Provision | Floors and work surfaces shall be non-absorbent and easy to clean and disinfect. Work surfaces shall be adequately sealed. Laboratories shall provide sufficient storage space, and shall be clean and free from dust accumulation. |
| Recommendation | Delete |
| Justification | What is the standard of absorbency, how absorbent is too absorbent? What is the measure of “easy”, how difficult is too difficult? How much storage space is “sufficient”? This provision is full of undefined terms, vague, ambiguous, and standardless requirements, with not metrics of compliance. |

| Section | **Module 5 1.7.3.7 b i Temperature Measuring Devices** |
|---|---|
| Provision | The laboratory shall use temperature measuring devices such as liquid-in-glass thermometers, thermocouples, or platinum-resistance thermometers to assess and document equipment temperatures. The temperature measuring devices shall be appropriate quality to meet specification(s) in the method.<br>The graduation and range of the temperature measuring devices shall be appropriate for the required accuracy of the measurement. Temperature measuring devices shall be verified to national or international standards for temperature. Verification shall be performed at least annually (see TNI Volume 1, Module 2, Section 5.5.13.1 ). This verification may be accomplished by a single point provided that it represents the method mandated temperature and use conditions.. |
| Recommendation | Delete |
| Justification | This is entirely redundant with requirements found in ELAP's Technical Standard i.e. the individual methods but without any specifications. |

| Section | **Module 5 1.7.3.7 b ii a Autoclaves** |
|---|---|
| Provision | 1. The laboratory shall evaluate the performance of each autoclave initially by establishing its functional properties and performance, for example, heat distribution characteristics with respect to typical uses. Autoclaves shall meet specified temperature tolerances. Pressure cookers shall not be used for sterilization of growth media.<br>2. The laboratory shall demonstrate proper sterilization temperature by use of a continuous temperature recording device or by use of a maximum registering thermometer with every cycle. The laboratory shall, at least once during each month that the autoclave is used, demonstrate the effective sterilization through the use of appropriate biological indicators. The selected biological indicator shall be effective at the sterilization temperature and time needed to sterilize lactose-based media. Thelaboratory shall use temperature-sensitive tape with the contents of each autoclave run to indicate that the autoclave contents have been processed.<br>3. The laboratory shall maintain records of autoclave operations 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.<br>4. Autoclave maintenance, internally or by service contract. shall be performed annually, and shall include a pressure check and verification of temperature device. Records of the maintenance shall be maintained in equipment logs. When it has been determined that the autoclave has no leaks, pressure checks can be documented using the formula PV = nRT.<br>5. The laboratory shall check the autoclave mechanical timing device quarterly against a stopwatch and document the actual time elapsed. |
| Recommendation | Delete |
| Justification | This is entirely redundant with requirements found in ELAP's Technical Standard i.e. the individual methods but without any specifications such a temperatures or durations.<br><br>How can pressure checks in an autoclave be documented using the Ideal Gas law? |

| Section | **Module 5 1.7.3.7 b iii Volumetric Equipment** |
|---|---|
| Provision | The laboratory shall verify equipment used for measuring volume as follows:<br>a. Equipment with movable parts, such as automatic dispensers, dispensers/ diluters, and mechanical hand pipettes, shall be verified for accuracy quarterly.<br>b. Equipment. such as filter funnels, bottles, non-Class A glassware, and other containers with volumetric markings (including sample analysis vessels), shall be verified once per lot prior to first use.<br>c. The volume of the disposable volumetric equipment, such as sample bottles and disposable pipettes, shall be checked once per lot.<br>d. Verification of volume shall be considered acceptable if the accuracy is within 2.5% of expected volume. This verification can be volumetric as compared to Class A or gravimetric. |
| Recommendation | Delete |
| Justification | This is completely unnecessary. It is a tremendous amount of work to check every volumetric piece of equipment and it provides no benefits to the Regulatory Partners, ELAP, or the laboratory. |

| Section | **Module 5 1.7.5.1 Sample Handling – Thermal Preservation** |
|---|---|
| Provision | Samples that require thermal preservation shall be considered acceptable if the arrival temperature of a representative sample container meets the method or mandated temperature requirement. Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of this section or the method or the regulatory requirement. In these cases, the samples may be considered acceptable if the samples are received on ice with evidence that the cooling process has begun. |
| Recommendation | Delete |
| Justification | This is completely unnecessary. This is redundant with the method requirements found in Technical Standard. |

| Section | **Module 5 1.7.5.2 Sample Handling - Dechlorination** |
|---|---|
| Provision | Microbiological samples from known chlorinated sources (such as wastewater effluent), unknown sources where disinfectant (e.g. chlorine) usage is suspected (such as a new client or a new source), and all potable water supplies (including source water) shall be checked for absence of disinfectant residual in the laboratory unless all of the following conditions are met:<br>a. The laboratory can show that the received sample containers are from its laboratory or have been appropriately tested and documented;<br>b. Sufficient sodium thiosulfate was in each container before sample collection to neutralize at minimum 5 mg/L of chlorine for drinking water and 15 mg/L of chlorine for wastewater samples;<br>c. One (1) container from each batch of laboratory-prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 mg/L chlorine or 15 mg/L chlorine as appropriate and the check is documented;<br>d. Disinfectant residual is checked in the field and actual concentration is documented with sample submission. |
| Recommendation | Delete |
| Justification | This is completely unnecessary. It is a tremendous amount of work to check every volumetric piece of equipment and it provides no benefits to the Regulatory Partners, ELAP, or the laboratory. |

**5) Part 4 – Conclusions**

This set of recommendations is a first attempt to take from the TNI documents a set of requirements for a quality management system for ELAP. There are great many and terms that are used but for which there are no definitions. Because the TNI documents are intended to provide requirements for a broad array of laboratories, many of the provisions are not applicable either in part or in entirety. However it is often unclear where those distinctions are applied. These sources of ambiguity need to removed. It also seem inequitable in many cases for a laboratory's accreditation to depend upon requirements that have little or no significance to the data quality needs of the regulatory partners, the protection of public health and the environment. A very significant number of these requirements have nothing to do with actual laboratory competence. Other of the provisions are redundant with the