Comments on a Proposed "Parallel Accreditation Program"
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The following comments are submitted in response to a "meeting packet" provided for the December 13, 2018 meeting of the California Environmental Laboratory Technical Advisory Committee (ELTAC). These comments address a proposal to create a "parallel" accreditation system in California. Page 41 of the meeting packet for the 12/13/18 meeting of ELTAC contains proposed language for a "California Quality Management System." TNI has reviewed this language relative to the 2016 TNI standard and offers up four comments.

1. 64808 (b) (4) and (c)

The proposed language selects some, but not all of section 4.2.8.4 and 4.2.8.3 relating to the quality manual. Attachment 1 has reorganized these two sections into two groupings, one showing what is proposed to be retained, and one showing what would be eliminated. For the language to be eliminated, the word "NOT", was added to show how this would become a non-requirement, and then comments added to several of these to show they are relevant. All of the language in these two sections should be retained completely.

2. 64808 (b) (5)

The proposed language appears to delete most of Sections 4 and 5 of the TNI standard, retaining only sections 5.3 and 5.5 thru 5.9. Using the approach Bruce La Belle offered up a few years ago, the missing language from sections 4 and 5 is shown in Attachment 2, with the word "NOT" added to show these requirements in the TNI standard would not apply to California laboratories. A review of this language shows how such an approach greatly weakens the laboratory requirements.

3. General Comment on a Parallel Accreditation Program

As stated in the slide on page 15 of the meeting packet, ELAP has a history of poor progress on revising their internal regulations for a parallel system. And this is a common problem with other state agencies. One of the major benefits of simply citing the TNI standard is that the state does not have to use their resources to revise regulations. They can rely on the 100 plus scientists and regulators involved in a TNI expert committee to perform this work. The TNI committees are open to anyone to participate and provide California laboratory professionals to work within the system to continuously improve the standard.

4. TNI Resources

One of the major reasons the Expert Panel endorsed using the TNI standard has to do with tools, templates and training TNI has developed to assist laboratories (and States) implement the standard. These are summarized in Attachment 3. No such resources exist for the parallel system thus placing undue burden on laboratories.

Note Regarding Appendix A

Pages 48 and 49 contain a "Quick Reference Guide" for policies and procedures, citing many sections of the TNI standard. However this document is not mentioned in the draft proposed regulation and its context is unknown.

Attachment 1: TNI Comments on proposed 6408 (b)(4) and (c)

4.2.8.4 The quality manual shall contain or reference:

a) all maintenance, calibration and verification procedures used by the laboratory in conducting tests;

b) major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests;

c) verification practices, which may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal QC schemes;

d) procedures for reporting analytical results;

e) the organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts;

f) procedures to ensure that all records required under this Standard are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all standard operating procedures (SOPs), manuals, or documents clearly indicate the time period during which the procedure or document was in force;

g) job descriptions of key staff and reference to the job descriptions of other laboratory staff;

h) procedures for achieving traceability of measurements;

i) a list of all methods under which the laboratory performs its accredited testing;

k) procedures for handling samples;

l) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

The quality manual shall NOT contain or reference:

j) procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

So, a lab could commit to performing testing for which it does not have the equipment to do so.

m) policy for permitting departures from documented policies and procedures or from standard specifications;

This clause is the escape valve that allows a lab to do go work even if things go wrong.

n) procedures for dealing with complaints;

o) procedures for protecting confidentiality (including national security concerns), and proprietary rights;

Every lab must have some system for ensuring results are not reported to those who are not authorized to receive them, even municipal labs would likely not send data to a TV station without some approval.

p) procedures for audits and data review;

q) procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training; and

So lab staff do not need to be trained in what they do?

r) policy addressing the use of unique electronic signatures, where applicable.

This has been an issue in many lab fraud cases where a supervisor logged in as an analyst and changed results.

4.2.8.3 The quality manual shall contain:

a) document title;

b) laboratory's full name and address;

c) name, address (if different from above), and telephone number of individual(s) responsible for the laboratory;

d) identification of all major organizational units that are to be covered by this quality manual and the effective date of the version;

f) the signed and dated concurrence (with appropriate names and titles), of all responsible parties including the quality manager(s), technical manager(s), and the agent who is in charge of all laboratory activities, such as the laboratory director or laboratory manager;

h) the laboratory's official quality policy statement, which shall include quality system objectives and management's commitment to ethical laboratory practices and to upholding the requirements of this Standard; and

i) a table of contents, and applicable lists of references, glossaries and appendices.

The quality manual shall NOT contain:

e) identification of the laboratory's approved signatories;

Same as r above; this is critical information to identify the analyst and is so easy to implement with a simple signature card.

g) the objectives of the quality system and contain or reference the laboratory's policies and procedures;

This is a one-time event with a simple statement such as this: "Our policy is to use good professional practices, to uphold the highest level of quality of service and to comply with the TNI standard…."

Attachment 2: Proposed TNI language to be removed from California QMS stated in the negative

4.0 Management Requirements

4.1 Organization *(ISO/IEC 17025:2005, Clause 4.1)*

4.1.1 The laboratory or the organization of which it is part shall NOT *be an entity that can be held legally responsible.*

4.1.2 It is NOT *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.*

4.1.3 The management system shall cover NOT *work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.*

4.1.4 If the laboratory is part of an organization performing activities other than testing, the responsibilities of key personnel in the organization that have an involvement or influence on the testing activities of the laboratory shall NOT *be defined in order to identify potential conflicts of interest.*

4.1.5 The laboratory shall NOT*:*

a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests, and to initiate actions to prevent or minimize such departures (see also Section 5.2);

b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) 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;

d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;

e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

g) 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;

h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

i) 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;

j) appoint deputies for key managerial personnel (see Note);

k) 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.

4.1.6 Top management shall NOT *ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.*

4.1.7.2 The laboratory's technical manager(s), however named, and/or his/her designee(s) shall NOT:

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

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

c) have duties that include:

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

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

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

i. the extent to which operating hours of the laboratories to be directed overlap,

ii adequacy of supervision in each laboratory, and

iii the availability of environmental laboratory services in the area served.

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

f) meet qualification requirements as specified in Section 5.2.6.1.

4.2 Management

4.2.1 The laboratory shall NOT establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall NOT be defined in a quality manual. 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:

a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;

b) the management's statement of the laboratory's standard of service;

c) the purpose of the management system related to quality;

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

e) the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system.

4.2.3 Top management shall NOT provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

4.2.4 Top management shall NOT communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

4.2.5 The quality manual shall NOT include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.

4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall NOT be defined in the quality manual.

4.2.7 Top management shall NOT ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

4.2.8 Additional Management System Requirements

4.2.8.1 The laboratory shall NOT 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.

a) Laboratory management shall NOT provide a procedure for confidential reporting of data integrity issues in their laboratory. A primary element of the procedure is to assure confidentiality and a receptive environment in which all employees may privately discuss ethical issues or report items of ethical concern.

b) In instances of ethical concern, the procedure shall NOT include a process whereby laboratory management is to be informed of the need for any further detailed investigation.

4.2.8.5 Laboratories shall NOT maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods.

a) These documents, for example, may be equipment manuals provided by the manufacturer, or internally written documents with adequate detail to allow someone similarly qualified, other than the analyst, to reproduce the procedures used to generate the test result.

b) The relevant SOPs shall NOT be readily accessible to all personnel.

c) Each SOP shall NOT clearly indicate the effective date of the document, the revision number, and the signature(s) of the approving authority.

d) Documents that contain sufficient information to perform the tests, do not need to be supplemented or rewritten as internal procedures if the documents are written in a way that they can be used as written. Any changes, including the use of a selected option, shall NOT be documented and included in the laboratory's records.

e) The laboratory shall have and maintain an SOP for each accredited analyte or method.

4.3 Document Control

4.3.1 General

The laboratory shall NOT 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.

4.3.2 Document Approval and Issue

4.3.2.1 All documents issued to personnel in the laboratory as part of the management system shall NOT be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and shall be readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The procedure(s) adopted shall NOT ensure that:

a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.3 Management system documents generated by the laboratory shall be NOT uniquely identified. Such identification shall NOT include the date of issue and/or revision identification, page numbering, and the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

4.3.3 Document Changes

4.3.3.1 Changes to documents shall NOT be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

4.3.3.2 Where practicable, the altered or new text shall be NOT identified in the document or the appropriate attachments.

4.3.3.3 If the laboratory's document control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall NOT be defined. Amendments shall NOT be clearly marked, initialled and dated. A revised document shall NOT be formally re-issued as soon as practicable.

*4.3.3.4 Procedures shall **NOT** be established to describe how changes in documents maintained in computerized systems are made and controlled.*

4.4 Review of Requests, Tenders and Contracts

4.4.1 The laboratory shall NOT establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing shall ensure that:

a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);

b) the laboratory has the capability and resources to meet the requirements;

c) the appropriate test method is selected and is capable of meeting the customers' requirements (see 5.4.2).

Any differences between the request or tender and the contract shall be NOT resolved before any work commences. Each contract shall NOT be acceptable both to the laboratory and the customer.

4.4.2 Records of reviews, including any significant changes, shall NOT 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.

4.4.3 The review shall NOT also cover any work that is subcontracted by the laboratory.

4.4.4 The customer shall NOT be informed of any deviation from the contract.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall NOT be repeated and any amendments shall be communicated to all affected personnel.

4.5 Subcontracting of Environmental Tests

4.5.1 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 NOT be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.

4.5.2 *The laboratory shall* NOT *advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.*

4.5.3 *The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.*

4.5.4 *The laboratory shall* NOT *maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.*

4.5.5 When a laboratory subcontracts work, this work shall NOT be placed with a laboratory accredited to this Standard for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed. The laboratory performing the subcontracted work shall be indicated in the final report. The laboratory shall make a copy of the subcontractor's report available to the client when requested.

4.6 Purchasing Services and Supplies

4.6.1 *The laboratory shall* NOT *have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.*

4.6.2 *The laboratory shall* NOT *ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.*

4.6.3 *Purchasing documents for items affecting the quality of laboratory output shall* NOT *contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.*

4.6.4 *The laboratory shall* NOT *evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.*

4.7 Service to the Client

4.7.1 *The laboratory shall* NOT *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.*

4.7.2 *The laboratory shall* NOT *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.*

4.8 Complaints

The laboratory shall NOT *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).*

4.9 Control of Nonconforming Environmental Testing Work

4.9.1 *The laboratory shall* NOT *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. The policy and procedures shall* NOT *ensure that:*

a) *the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;*

b) *an evaluation of the significance of the nonconforming work is made;*

c) *correction is taken immediately, together with any decision about the acceptability of the nonconforming work;*

d) *where necessary, the customer is notified and work is recalled;*

e) *the responsibility for authorizing the resumption of work is defined.*

4.9.2 *Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall* NOT *be promptly followed.*

4.10 Improvement

The laboratory shall NOT *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.*

4.11 Corrective Action

4.11.1 *General*

The laboratory shall NOT *establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.*

4.11.2 *Cause Analysis*

The procedure for corrective action shall NOT *start with an investigation to determine the root cause(s) of the problem.*

4.11.3 *Selection and Implementation of Corrective Actions*

Where corrective action is needed, the laboratory shall NOT *identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.*

Corrective actions shall NOT *be to a degree appropriate to the magnitude and the risk of the problem.*

The laboratory shall NOT *document and implement any required changes resulting from corrective action investigations.*

4.11.4 *Monitoring of Corrective Actions*

The laboratory shall NOT *monitor the results to ensure that the corrective actions taken have been effective.*

4.11.5 *Additional Audits*

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall NOT *ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.*

4.11.6 The laboratory shall NOT have documented procedure(s) to address Sections 4.11.1 and 4.11.3 through 4.11.5. These procedure(s) shall also include:

a) which individual(s) or positions are responsible for assessing each QC data type; and

b) which individual(s) or positions are responsible for initiating and/or recommending corrective actions.

4.11.7 Cause analysis described in Section 4.11.2 applies to failures that indicate a systematic error.

4.12 Preventive Action

4.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall NOT *be identified. When improvement opportunities are identified or if preventive action is required, action plans shall* NOT *be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.*

4.12.2 Procedures for preventive actions shall NOT *include the initiation of such actions and the application of controls to ensure that they are effective.*

4.13 Control of Records

4.13.1 General

4.13.1.1 The laboratory shall NOT *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.*

4.13.1.2 All records shall NOT *be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.*

4.13.1.3 All records shall NOT *be held secure and in confidence.*

4.13.1.4 The laboratory shall NOT *have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.*

4.13.2 Technical Records

4.13.2.1 The laboratory shall NOT *retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall* NOT *contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall* NOT *include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.*

4.13.2.2 Observations, data and calculations shall NOT be recorded at the time they are made and shall be identifiable to the specific task.

4.13.2.3 When mistakes occur in records, each mistake shall NOT be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall NOT be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

4.13.3 Additional Requirements

a) The laboratory shall NOT establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. This system shall NOT produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.

b) The laboratory shall NOT retain all records for a minimum of five (5) years from generation of the last entry in the records.

c) Records shall NOT be available to the accreditation body.

d) Records that are stored only on electronic media shall NOT be supported by the hardware and software necessary for their retrieval.

e) Access to archived information shall NOT be documented with an access log.

f) All information necessary for the historical reconstruction of data shall NOT be maintained by the laboratory.

i. all raw data, whether hard copy or electronic, for calibrations, samples and QC measures, including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records);

ii. a written description or reference to the specific method used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;

iii. laboratory sample ID code;

iv. date of analysis;

v. time of analysis is required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., extractions and incubations);

vi. instrumentation identification and instrument operating conditions/parameters (or reference to such data);

vii. all manual calculations;

viii. analyst or operator initials/signature or electronic identification;

ix. sample preparation, including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;

x. test results;

xi. standard and reagent origin, receipt, preparation, and use;

xii. calibration criteria, frequency and acceptance criteria;

xiii. data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;

xiv. QC protocols and assessment;

xv. electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;

xvi. method performance criteria including expected QC requirements;

xvii. proficiency test results;

xviii. records of demonstration of capability for each analyst; and

xix. a record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record.

g) All generated data, except those that are generated by automated data collection systems, shall NOT be recorded legibly in permanent ink.

i. An individual making corrections to records shall NOT date and initial the correction.

ii. Corrections due to reasons other than transcription errors shall NOT specify the reason for the correction.

h) The laboratory shall NOT have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business. In addition, appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

4.14 Internal Audits

4.14.1 The laboratory shall NOT 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 program shall NOT 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 NOT be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

4.14.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test, the laboratory shall NOT take timely corrective action, and shall NOT notify customers in writing if investigations show that the laboratory results may have been affected.

4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them shall NOT be recorded.

4.14.4 Follow-up audit activities shall NOT verify and record the implementation and effectiveness of the corrective action taken.

4.14.5 Additional Items

a) The laboratory shall NOT have a policy that specifies the time frame for notifying a client of events that cast doubt on the validity of the results.

b) The laboratory management shall NOT ensure that these actions are discharged within the agreed time frame.

c) The internal audit schedule shall NOT be completed annually.

4.15 Management Review

4.15.1 In accordance with a predetermined schedule and procedure, the laboratory's top management shall NOT 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. The review shall NOT take account of:

- *the suitability of policies and procedures;*
- *reports from managerial and supervisory personnel;*
- *the outcome of recent internal audits;*
- *corrective and preventive actions;*
- *assessments by external bodies;*
- *the results of interlaboratory comparisons or proficiency tests;*
- *changes in the volume and type of the work;*
- *customer feedback;*
- *complaints;*
- *recommendations for improvement;*
- *other relevant factors, such as quality control activities, resources, and staff training.*

4.15.2 Findings from management reviews and the actions that arise from them shall NOT be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

4.15.3 Management review shall NOT be completed on an annual basis.

4.16 Data Integrity Investigations

All investigations resulting from data integrity issues should NOT be conducted in a confidential manner until they are completed. These investigations shall NOT be documented, as well as any notifications made to clients receiving any affected data.

5.0 Technical Requirements

5.1 General

5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

- *human factors (5.2);*
- *accommodation and environmental conditions (5.3);*
- *test and calibration methods and method validation (5.4);*
- *equipment (5.5);*

— *measurement traceability (5.6);*

— *sampling (5.7);*

— *the handling of test and calibration items (5.8).*

5.1.2 *The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall NOT take account of these factors in developing test methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.*

5.2 Personnel

5.2.1 *The laboratory management shall NOT 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 NOT be provided. Personnel performing specific tasks shall NOT be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.*

— *relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;*

— *knowledge of the general requirements expressed in the legislation and standards; and*

— *an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.*

5.2.2 *The management of the laboratory shall NOT formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall NOT have a policy and procedures for identifying training needs and providing training of personnel. The training program shall NOT be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall NOT be evaluated.*

5.2.3 *The laboratory shall NOT 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 NOT ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.*

5.2.4 *The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved NOT in tests and/or calibrations.*

5.2.5 *The management shall NOT 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.*

5.2.7 Data Integrity Training

Data integrity training shall NOT 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 NOT 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. The initial data integrity training and the annual refresher training shall NOT have a signature attendance sheet or other form of documentation that demonstrates all staff have participated and understand their obligations related to data integrity.

Data integrity training requires emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient. The topics covered in such training shall NOT be documented in writing (such as an agenda) and provided to all trainees. At a minimum, the following topics and activities shall NOT be included:

a) organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues, and record keeping;

b) training, including discussion regarding all data integrity procedures;

c) data integrity training documentation;

d) in-depth data monitoring and data integrity procedure documentation; and

e) specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time-clocks, and inappropriate changes in concentrations of standards.

The data integrity procedures may also include written ethics agreements, examples of improper practices, examples of improper chromatographic manipulations, requirements for external ethics program training, and any external resources available to employees.

5.4 Environmental Methods and Method Validation

5.4.1 General

The laboratory shall NOT *use appropriate methods and procedures for all tests within its scope. These include sampling, handling, transport, storage and preparation of items to be tested, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test data.*

The laboratory shall NOT *have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing, where the absence of such instructions could jeopardize the results of tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shal* NOT *l be kept up to date and shall be made readily available to personnel (see 4.3). Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.*

5.4.2 Selection of Methods

The laboratory shall NOT *use test methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests it undertakes. Methods published in international, regional or national standards shall* NOT *preferably be used. The laboratory shall* NOT *ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.*

When the customer does not specify the method to be used, the laboratory shall NOT *select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. The laboratory shall* NOT *confirm that it can properly operate standard methods before introducing the tests. If the standard method changes, the confirmation shall be repeated.*

The laboratory shall NOT *inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.*

5.4.3 Laboratory-Developed Methods

The introduction of test methods developed by the laboratory for its own use shall NOT *be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.*

Plans shall NOT *be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.*

5.4.4 Non-Standard Methods

When it is necessary to use methods not covered by standard methods, these shall NOT *be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall* NOT *have been validated appropriately before use.*

5.4.4.2 The laboratory shall NOT ensure that once the method has been developed, a Standard Operating Procedure as outlined in 4.2.8.5 f shall be written.

5.4.5 Validation of Methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2 The laboratory shall NOT *validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall* NOT *be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall* NOT *record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.*

5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall NOT *be relevant to the customers' needs.*

5.4.5.4 All methods used by the laboratory, whether non-standard or standard (reference) methods shall NOT be validated before use to ensure that the laboratory has the capability of using the method for its intended use.

5.4.6 Estimation of Analytical Uncertainty

Environmental testing laboratories shall NOT have a procedure(s) for estimating analytical uncertainty. Quality control measurement data may be used to determine analytical uncertainty.

5.4.6.1 A testing laboratory performing its own calibrations, shall NOT *have and shall* NOT *apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.*

5.4.6.2 Testing laboratories shall NOT *have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall* NOT *at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty.*

Reasonable estimation shall NOT *be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.*

5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall NOT *be taken into account using appropriate methods of analysis.*

5.4.7 Control of Data

5.4.7.1 Calculations and data transfers shall NOT *be subject to appropriate checks in a systematic manner.*

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory shall NOT *ensure that:*

a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

5.10 Reporting the Results

5.10.1 General

The results of each test, or series of tests carried out by the laboratory shall NOT *be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.*

The results shall NOT *be reported, usually in a test report, and shall* NOT *include all the information requested by the customer and necessary for the interpretation of the test 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 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 NOT *be readily available in the laboratory which carried out the tests.*

5.10.2 Test Reports

Each test or calibration certificate shall NOT *include at least the following information, unless the laboratory has valid reasons for not doing so:*

a) a title (e.g. "Test Report");

b) the name and address of the laboratory, and the location where the tests were carried out, if different from the address of the laboratory;

c) unique identification of the test report (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report, and a clear identification of the end of the test report;

d) the name and address of the customer;

e) identification of the method used;

f) a description of, the condition of, and unambiguous identification of the item(s) tested;

g) the date of receipt of the test where this is critical to the validity and application of the results, and the date(s) of performance of the test;

h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;

i) the test results with, where appropriate, the units of measurement;

j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report;

k) where relevant, a statement to the effect that the results relate only to the items tested.

5.10.3 Test Reports

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall NOT*, where necessary for the interpretation of the test results, include the following:*

a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;

b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;

d) where appropriate and needed, opinions and interpretations (see 5.10.5);

e) additional information which may be required by specific methods, customers or groups of customers.

5.10.3.2 In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall NOT *include the following, where necessary for the interpretation of test results:*

a) the date of sampling;

b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);

c) the location of sampling, including any diagrams, sketches or photographs;

d) a reference to the sampling plan and procedures used;

e) details of any environmental conditions during sampling that may affect the interpretation of the test results;

f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.10.5 Opinions and interpretations

When opinions and interpretations are included, the laboratory shall NOT document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall NOT be clearly marked as such in a test report.

5.10.6 Testing results obtained from subcontractors

When the test report contains results of tests performed by subcontractors, these results shall NOT be clearly identified. The subcontractor shall NOT report the results in writing or electronically.

5.10.7 Electronic transmission of results

In the case of transmission of test by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall NOT be met (see also 5.4.7).

5.10.8 Format of reports

The format shall NOT be designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.

5.10.9 Amendments to test reports

Material amendments to a test report after issue shall NOT be made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report, serial number... [or as otherwise identified]", or an equivalent form of wording. Such amendments shall meet all the requirements of this International Standard. When it is necessary to issue a complete new test report, this shall NOT be uniquely identified and shall contain a reference to the original that it replaces.

5.10.10 Exceptions

Some regulatory reporting requirements or formats, such as monthly operating reports, may not require all items listed in 5.10.2 and 5.10.3 above; however, the laboratory shall NOT provide all the required information to their client for use in preparing such regulatory reports.

Laboratories operated solely to provide data for compliance purposes (in-house or captive laboratories) shall NOT have all applicable information specified in Section 5.10 readily available for review by the accreditation body. However, formal reports detailing the information are not required if:

a) the in-house laboratory is itself responsible for preparing the regulatory reports; or

b) the laboratory provides information to another individual within the organization for preparation of regulatory reports. The facility management shall ensure that the appropriate report items are in the report to the regulatory authority, if such information is required; or

c) see Section 5.10.1, paragraph 3.

5.10.11 Additional Requirements

a) Time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to seventy-two (72) hours.

b) Results that are reported on a basis other than as received (e. g., dry weight).

c) Any non-accredited tests shall be clearly identified as such to the client when claims of accreditation to this Standard are made in the analytical report or in the supporting electronic or hardcopy deliverables.

d) Clear identification of numerical results with values outside the calibration range.

Attachment 3
TNI Resources for Implementation

To support this the implementation of the 2016 standard, TNI has developed, or is currently developing, a number of tools and other resources to help both the laboratories and the organizations that accredit laboratories.

Training Courses

TNI held four webinars in 2018 on Modules 1 (Proficiency Testing), 2 (Quality Systems), 4 (Chemistry) and 5 (Microbiology) in the fall of 2018. Recording of these webinars are available at: https://nelac-institute.org/content/eds-home.php. A course on Module 6 (Radiochemistry) was conducted in 2017 and a recording of this course is also available.

Revised Small Laboratory Handbook

This document is intended to help explain the requirements of the 2016 Standard and to provide environmental laboratories, especially small laboratories, with clear, simple guidance on how to develop the policies and procedures that will allow them to become accredited to the TNI Standard. This handbook is NOT a substitute for reading and understanding the TNI Standard. The revised handbook includes much more "How to" information. The revised handbook also contains a discussion of the accreditation process and several appendices with useful information, including common findings, SOP templates, and answers to standard interpretation requests. https://nelac-institute.org/content/NELAP/howto.php

2016 Quality Manual Template

The 2016 TNI Quality Manual Template is a tool designed for laboratories to help prepare a Quality Manual in compliance with the 2016 TNI Standard. The prefabricated sections of the Quality Manual follow the ISO/IEC 17025 outline but are completely fluid so that you can put sections, examples, links or references anywhere. The Template includes helpful notes, examples and text that can be edited to match each laboratory's particular circumstances. It can be used by a laboratory to create a Quality Manual from scratch or ideas and sections can be used to update a current Quality Manual. The primary change in this revised template was combining the multiple files into one file to make the template easier to edit and replacing the reference to the 2009 standard to the 2016 standard. Since both the 2009 and 2016 standards have the same organization and very comparable content, anyone who purchased the 2009 version, or has an existing Quality Manual, does not need to obtain the 2016 version. https://nelac-institute.org/content/NELAP/howto.php

Checklist

TNI has published a Checklist to allow laboratories to do an internal gap analysis for the TNI 2016 Standard. This checklist may be downloaded online if you own a copy of the TNI Standard. This analysis will laboratories to see where they might need to add policies, procedures, or other documentation. https://nelac-institute.org/content/NELAP/qscheck2016-access.php

New Guidance Documents

TNI is in the process of finalizing three guidance documents on these specific topics.

- Proficiency Testing Reporting Limit (PTRL)
- Detection and Quantitation
- Instrument Calibration

These documents are at the Final Draft stage and should be published by January 2019.

Standard Interpretation Requests (SIRs)

TNI has established an avenue for resolution of questions submitted electronically on interpretation of the Standards. Answers to the requests are currently organized by standard: 2003, 2009, or 2016. Some are now obsolete. Some of 2003 and 2009 SIRs are applicable to 2016. Expert Committees now reviewing status of all SIRs to map to 2016 where applicable. This effort is expected to be complete by January 2019. http://www.nelac-institute.org/content/NELAP/interpret.php