Knowledge, Skills, and Abilities for a Certified Environmental Laboratory Quality Management Systems Professional

April 10, 2023

1.0 Summary

This document defines the knowledge, skills and abilities (KSAs), also called "competencies," for a Certified Environmental Laboratory Quality Management System (QMS) Professional. The objectives of this document are to:

1) enable training organizations to develop courses for TNI, and

2) allow TNI to develop a credential program for providing either a certificate or a digital badge.

2.0 Knowledges, Skills, and Attributes (KSAs)

The subsections below describe the KSAs for 12 categories with references to the TNI standard and other relevant references covering these topics:

1. Basic Quality Management System
2. Proficiency Testing
3. Data Integrity
4. Customer Service
5. Measurement Traceability
6. Internal Audits
7. Corrective Action
8. Records and Document Control
9. Method Validation
10. Sample Handling
11. Quality Control
12. Data Review and Reporting

2.1 Knowledges, Skills and Attributes (KSAs) for Basic Quality Management Systems

2.1.1 KSAs from the TNI Standard, Volume 1, Module 2

The Quality Systems Specialist knows or understands:

a. The laboratory's management system policies related to quality.
b. The laboratory's quality policy statement must include at least the following:
    i. The laboratory's commitment to good professional practice and to the quality of its testing in servicing its customers.
    ii. The laboratory's standard of service.
    iii. The purposes of the management system related to quality.
    iv. Knowledge of the quality documentation and the policies and procedures.
    v. The laboratory's commitment to continually improve the effectiveness of the management system.
c. The importance of meeting customer requirements as well as statutory and regulatory requirements at both the Federal and applicable State level.
d. How to implement a quality management system.
e. The role of a Quality Manager in serving as the focal point for Quality Assurance and Quality Control (QA/QC) and performing assessments without outside (e.g., managerial) influence.
f. How to conduct internal audits.

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g. How to notify laboratory management of deficiencies in the quality system and monitor corrective actions.
h. How to implement a plan for in-depth data monitoring to ensure data integrity.
i. The required elements of a Quality Manual and how to maintain it to be current with laboratory operations.

2.1.2 KSAs for Managing the Accreditation Process

2.1.2.1 Initial Application

The Quality Systems Specialist knows or understands:

a. How to submit an application for accreditation and who it should go to.
b. The required documents to accompany the application.
c. The Fields of Accreditation to request, ensuring they match the AB's offerings

2.1.2.2 Planning for an Assessment

The Quality Systems Specialist knows or understands how to:

a. Conduct a pre-assessment meeting, if needed.
b. Evaluate prior deficiencies, PT results, and corrective actions to be prepared.

2.1.2.3 Activities During the Assessment

The Quality Systems Specialists knows or understands:

a. How to manage the assessment including interviews and records review.
b. How to respond to preliminary findings.
c. The next steps in the process.
d. How to interact professionally with an assessor.

2.1.2.4 Developing a Corrective Action Plan

The Quality Systems Specialist knows or understands how to:

a. Address nonconformances, including root cause analysis.
b. Write a Corrective Action Plan.
c. Implement the promised corrective actions.

2.1.3 KSAs Relative to Technical Skills

2.1.3.1 Basic Technical Skills

The Quality Systems Specialist knows or understands:

a. How to assess the implementation of technology by the laboratory.
b. How a technology is used in various methods.
c. The key elements of data packages and raw data review.

2.1.3.2 Method-Specific Skills

The Quality Systems Specialist knows or understands:

a. Basic theoretical and operating principles of the analytical technology and associated instrumentation and software.
b. The critical steps and processes of the analytical technology and technique that must be executed to ensure quality data, including critical QC measures and acceptance criteria based on the technology.
c. The major sources of error and how to control them, for specific analytical technologies or techniques.

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d. How to identify inappropriate procedures or practices for the analytical technology or technique.
e. The key information required to document completely the reported results.
f. The essential elements for assessing data generated.
g. How to evaluate method outputs, from the raw data to reported results.
h. EPA and State program requirements for test methods applicable to the scope of the laboratory's services.

2.1.4 References

TNI Standard Module 2, 4.1.5(j), 4.1.7.1 (b-e), 4.2.2, 4.2.4, 4.2.8.1, 4.14.1

DOD/DOE Quality Systems Manual: Module 2, 4.2.8.4

2.2 Proficiency Testing (PT)

2.2.1 KSAs from the TNI Standard, Volume 1, Module 2

The PT Specialist knows or understands:

a. The requirement to participate in PT studies for each Field of Proficiency Testing (FoPT) adopted by TNI for which the laboratory seeks to obtain or maintain accreditation.
b. How to schedule PT studies and how to use a PT Provider accredited to Volume 3 of the TNI Environmental Laboratory Sector Standard.
c. Requirements for not sharing information with other laboratories or otherwise attempting to obtain the assigned value.
d. Requirements to handle and prepare the PT samples in accordance with the instructions provided by the PT Provider.
e. Requirements to analyze PT samples in accordance with the laboratory's routine standard operating procedures using the same quality control, acceptance criteria and staff as used for the analysis of routine environmental samples.
f. For chemical analyses, how to evaluate results where the laboratory's Limit of Quantitation (LOQ) is below the PT Reporting Limit (PTRL).
g. For chemical analyses, how to re-scale the initial calibration curve to bracket the concentration of the PT sample result or report results outside the range of the initial calibration curve, without qualification to the PT Provider.
h. How to report PT study results to the PT Provider on or before the closing date of the study using the reporting format offered by the PT Provider.
i. How to direct the PT Provider to report the PT study performance results directly to the AB(s) designated by the laboratory.
j. How to report results in such a way that there is a specific match between the analytical result for the FoPT and the corresponding Field of Accreditation for which the PT sample was analyzed.
k. That except for drinking water analytes referenced in 40 CFR 141, the laboratory may choose to analyze and report a single method to represent a technology in a single PT study for a particular analyte, but in doing so knows an evaluation of *not acceptable* for one method will be applied to all methods reported with that technology.
l. Chemistry PT study results are to be reported to the PTRL as established by the TNI FoPT tables, unless the laboratory LOQ is below the PTRL.
m. Radiochemistry results are to be reported as measured, including zero, negative, and positive results, and not be censored or reported as "less than" values. All records necessary to facilitate reconstruction of the preparation, processing, and reporting of analytical results for PT samples must be retained for a minimum of five years.

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n. That for initial accreditation the laboratory must achieve a history of two successful (acceptable scores) PT studies out of the most recent three attempts for each field of accreditation for which the laboratory seeks accreditation.
o. That two PT studies must be performed no more than eighteen (18) months prior to obtaining initial accreditation.
p. The opening date of the second study must be at least seven (7) calendar days after the closing date of the first study.
q. The closing date of the most recent successful PT study cannot be more than six (6) months prior to the application.
r. The laboratory must continue to participate in PT studies at least semi-annually (no more than seven months apart between consecutive attempts) from that point on.
s. The laboratory must maintain a history of two successful (acceptable scores) PT studies out of the most recent three attempts for each field of accreditation for which the laboratory holds accreditation, and knows that failure to do so may result in suspension of the affected field of accreditation,
t. Opening and closing dates for PT studies.
u. How to take corrective action and determine the root cause for PT failures, document the root cause investigation and subsequent corrective action, and provide the root cause investigation and corrective action documentation to laboratory's Primary Accreditation Body (AB).
v. How to submit questions about PT samples or evaluations made by the PT Provider to the PT Provider, how to appeal evaluations, and how to submit questions to the laboratory's AB, if necessary.

2.2.4 References

TNI Standard Volume 1, Module 1.

TNI V1M1 2016 Standard Update Guidance on Proficiency Testing Reporting Limit (PTRL)

2.3 Data Integrity

2.3.1 KSAs from the TNI Standard

a. New employee and annual refresher data integrity training is provided.
b. The data integrity training includes adjustments of instrument time-clocks, inappropriate changes in concentrations of standards, written ethics agreements, examples of improper practices and improper chromatographic manipulations.

The Data Integrity Specialist knows or understands:

a. Requirements for external ethics program training and any external resources available to employees.
b. How to provide a procedure for confidential reporting of data integrity issues in their laboratory.
c. The differences between improper, illegal, and unethical practices and laboratory errors.
d. How the TNI data integrity requirements can protect the laboratory from a bad judgement by an employee.
e. Root causes of improper practices and techniques to avoid or discourage them.
f. What "cherry picking" is and how to avoid it.
g. The differences between improper practices and fraud.
h. The importance of clear and accurate records.
i. What constitutes a non-conformance and an out-of-control condition.
j. How and when to initiate a Corrective Action.
k. Why SOPs are important and when they need to be revised.
l. How to be alert and sensitive to actions by staff that may be improper, illegal or in violation of ethics policies and practices.

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m. How to identify occurrences of departures from the management system or from the procedures for performing tests and how to initiate actions to prevent or minimize such departures.
n. The procedures used to protect laboratory customers' confidential information, including procedures for protecting the electronic storage and transmission of results.
o. How to recognize activities that could diminish confidence in the competence, impartiality, judgement or operational integrity of the laboratory.
p. The relevance and importance of his or her activities and how they contribute achieving the objectives of the management system.
q. The organization's mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, and how and when to report data integrity issues.
r. How to conduct all data integrity issue investigations in a confidential manner until they are completed.
s. How to establish and maintain a documented data integrity system including:
    i. Data integrity training.
    ii. Signed data integrity documentation for all laboratory employee.
    iii. Periodic in-depth data monitoring.
    iv. Data integrity procedure documentation.

2.3.2.2 References

TNI Standard Module 2, Section 4.1.5 (b), 4.1.5 (c), 4.1.5 (d), 4.1.5(k), 4.2.1, 4.2.5, 4.2.8.1, 4.2.8.2, 4.3.1, 4.3.2, 4.3.3, 4.16, 5.1.7

DOD/DOE Quality Systems Manual: Module 2, 4.2.8, 4.16, 5.2.7.1, 5.4.7.1, 5.4.7.2

Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks, EPA OIG Report 2006-P-00036, September 21, 2006 (https://www.epa.gov/sites/production/files/2015-11/documents/20060921-2006-p-00036.pdf)

2.4 Customer Service

2.4.1 KSAs in the TNI Standard

The Customer Service Specialist knows or understands:

a. The importance of using a competent subcontractor.
b. To seek feedback, both positive and negative, from customers.
c. The actions needed to resolve complaints received from customers or other parties.
d. The laboratory's responsibility to review a request to ensure it can be met and how this review is to be documented, including the components required to accomplish a successful review and the generation and maintenance of the documentation of any requested new work, tender and contract.
e. What constitutes new work in the commercial, captive, and public laboratory and what is considered routine work.
f. How to provide feedback to the client.
g. The procedures for the resolution of complaints received from customers.
h. The laboratory's policies and procedures to enact when any aspect of its testing does not conform to its own procedures or the agreed requirements of the customer.
i. How to assess and evaluate QC results, including corrective actions, as needed.
j. Basic statistical concepts and techniques used for the collection, organization, analysis, and presentation of various types of laboratory data, including methods for calculation of QC results.
k. The process for amending a test report after issue.
l. How to report results to clients.
m. How to review data and test results and how to determine if data is appropriate for intended use.
n. Data qualifiers and their applicability.
o. How to record and retain technical records.

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p. The procedures for the transportation, receipt, handling, protection, storage, retention or disposal of samples, including all provisions necessary to protect the integrity of the sample, and the interests of the laboratory and the customer.
q. The system for identifying samples and how samples are to be labeled.
r. How abnormalities or departures from normal or specified conditions, as described in the test method, are recorded when the sample is received and what actions are needed.
s. The types of sample containers to be used, any preservation requirements, and sample holding times.
t. The procedures and appropriate facilities for avoiding deterioration, loss or damage to samples during storage, handling and preparation.
u. The differences between a chain of custody record and legal chain of custody forms and procedures used for evidentiary or legal purposes.
v. The process by which a law becomes a regulation, the major EPA statutes that require monitoring, and the specific testing requirements, including test methods and analytes, in each regulation, as applicable to the scope of work of the laboratory.
w. How to amend contracts when needed.

The Customer Service Specialist for ensures:

a. The requirements, including the methods to be used, are adequately understood, and the appropriate test method is selected and is capable of meeting the customers' requirements.
b. Test reports contain the following:
    i. Deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions.
    ii. Where relevant, a statement of compliance or non-compliance with requirements and specifications.
    iii. Where applicable, a statement on the estimated uncertainty of measurement 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.
    iv. Where appropriate and needed, opinions and interpretations.
    v. Additional information which may be required by specific methods, customers, or group of customers.

2.4.2 Other KSAs

The Customer Service Specialist for knows or understands:

a. How to translate the customer’s request into laboratory-specific test methods or protocols.
b. How to communicate effectively with customers on any technical or process issues including failed QC, reports not delivered in a timely manner, or any other issue that may affect the laboratory-customer relationship.

2.4.3 References

TNI Standard Module 2: 4.4, 4.5, 4.7, 4.8, 4.9, 4.11, 4.12, 4.10, 5.8, 5.9, 5.10; Section 1.7 in the relevant Technical Modules

DOD Quality System Manual: Module 2: 4.7, 4.9, 4.11.8, 5.4.7.1, 5.4.7.2, 5.8.4, 5.8.7, 5.8.8, 5.8.9, 5.10.3.1, 6.4, Appendix A

EPA Handbook for Quality Control in Water and Wastewater Laboratories, EPA-600/4-709-019, 1979

2.5 Measurement Traceability

2.5.1 KSAs in the TNI Standard

The Measurement Traceability Specialist knows or understands:

a. The laboratory's policies and procedures for the selection and purchasing of services and supplies it uses that affect the quality of the tests, including the purchase, reception and storage of reagents and laboratory consumable materials.
b. How to evaluate suppliers of critical consumables, supplies and services which affect the quality of testing.
c. The procedure for the calibration of reference standards, how they are to be used, and the importance of traceability to SI units of measurement, or to certified reference materials.
d. The procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.
e. The procedures for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory.
f. The requirements for calibration of all devices that may not be actual test instruments, but are necessary to support laboratory operations, including, but not limited to balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal and pressure sample preparation devices, and mechanical volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices).
g. The calibration or verification specifications required for which this equipment is used.
h. How to define the specifications for acceptability if none exist in method or regulation.
i. When equipment must be removed from service.
j. The calibration or verification specifications required for which this equipment is used.
k. How to check and verify the acceptability for use or continued use of balances, ovens, refrigerators, freezers, incubators, and water baths.
l. The requirements for calibration or verification of temperature measuring devices.
m. How to verify volumetric measuring devices.
n. The types of volumetric glassware used in the laboratory, specifications for glassware, how to clean glassware, and when to use disposable glassware.

The Measurement Traceability Specialist ensures:

a. Purchased supplies and reagents and consumable materials that affect the quality of tests 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 concerned.
b. That for original containers, if an expiration date is provided by the manufacturer or vendor, the date shall be recorded on the container.
c. All containers of prepared standards, reference materials, and reagents bear a unique identifier and expiration date.
d. Prepared reagents meet the requirements of the method.
e. Standards, reference materials, and reagents are not used after their expiration dates unless their reliability is verified.

2.5.2 References

TNI Standard Module 2: 4.6, 5.5, 5.6

DOD/DOE Quality Systems Manual: Module 2, 4.6, 5.5.13

ISO 17025 2017: 8.8.2, 8.9.2, 8.9.3

EPA Handbook for Quality Control in Water and Wastewater Laboratories, EPA-600/4-709-019, 1979

2.6 Internal Audit Specialist

2.6.1 KSAs in the TNI Standard

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The Internal Audit Specialist knows or understands:

a. The requirements to perform and the importance of an annual internal audit to verify that laboratory operations continue to comply with the requirements of the quality management system and to introduce necessary changes or improvements.
b. The importance of an annual review of the laboratory's management systems to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The responsibilities and accountabilities for meeting the standard requirements and prerequisites for conducting these activities.
c. How to implement effective procedures and tools to facilitate management of records and documents.
d. How to craft and use the findings and results from these tools to not only react to problems, but also to drive quality improvement and communication.
e. That when audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory must take timely corrective action, and notify customers in writing if investigations show that the laboratory results may have been affected.
f. That the area of activity audited, the audit findings and corrective actions that arise from them are to be recorded.

2.6.2 References

TNI Standard Module 2: 4.8, 4.9, 4.11, 4.12, 4.14, 4.15

DOD Quality System Manual: Module 2: 4.11.8, 4.2.8.4, 4.14.6-4.14.8

ISO 17025 2017: 8.7.1, 8.8.2, 8.9.2, 8.9.3

TNI Quality Systems Checklist

2.7 Corrective Action

2.7.1 KSAs in the TNI Standard

The Corrective Action Specialist knows or understands:

a. That follow-up audit activities are used to verify and record the implementation and effectiveness of the corrective action taken.
b. The laboratory's policies and procedures to enact when any aspect of its testing does not conform to its own procedures or the agreed requirements of the customer.
c. That when an evaluation of the significance of the nonconforming work indicates it could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, a corrective action is performed.
d. The procedures for the resolution of complaints received from customers or other parties.
e. How to record complaints on the investigations and corrective actions taken by the laboratory.
f. The procedures for corrective action including investigations to determine the root causes of problems.
g. Corrective actions should be appropriate to the magnitude and the risk of the problem.
h. How to monitor results to ensure that the corrective actions taken have been effective.
i. How to identify improvements and potential sources of nonconformities, either technical or concerning the management system.
j. That when improvement opportunities are identified or if preventive action is required, how to develop, implement, and monitor action plans to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.
k. How to resolve negative findings quickly and effectively for continuous improvement, reducing costs and fostering efficiency.

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l. How to assure deficiencies are resolved, and that their resolution provides value and benefit to project goals and operations long term.

2.7.2 References

TNI Standard Module 2: 4.8, 4.9, 4.11, 4.12, 4.14, 4.15

DOD Quality System Manual: Module 2: 4.11.8, 4.2.8.4, 4.14.6-4.14.8

ISO 17025 2017: 8.7.1, 8.8.2, 8.9.2, 8.9.3

TNI Quality Systems Checklist

2.8 Records and Document Control

2.8.1 KSAs in the TNI Standard

The Records and Document Control Specialist knows or understands:

a. The laboratory's policies, systems, procedures, and instructions to the extent necessary to assure the quality of test results, including SOPs that accurately reflect all phases of current laboratory activities, such as, but not limited to:
   i. Assessing data integrity.
   ii. Corrective actions.
   iii. Handling customer complaints.
   v. Test methods.
b. The importance, and is familiar with, the types of documents that form part of the management system, such as, but not limited to:
   i. Regulations.
   ii. Standards.
   iii. Test methods.
   iv. Drawings.
   v. Software.
   vi. Specifications
   vii. Instructions.
   viii. Manuals.
c. How and when policies and procedures are revised.
d. How to develop and manage policies and procedures so as to add value.
e. The processes for reviewing and controlling SOPs.
f. How to effectively write and review documents so they reflect requirements and are written for bench-level use.
g. How to assure that analysts are following the currently approved versions of all documents
h. How to write a clear, concise, and comprehensive method SOPs.
i. How to ensure the procedural section of an SOP is detailed, clear, and includes all the information required.
j. How to assure laboratory SOPs reflect the actual current practice in the laboratory.
k. The procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records.
l. The procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.
m. The types of technical records to be controlled, including records such as original observations, derived data and sufficient information to establish an audit trail, calibration records, and a copy of each test report issued.
n. Record retention requirements, including requirements from outside sources such as contracts, permits, or state and/or federal regulations.
o. The data required for proper historical reconstruction.

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p. How to consider technology, storage mechanisms, and traceability for archiving and retrievable of records.
q. Differences between paper and electronic records and the use of Laboratory Information Management Systems (LIMS).
r. What needs to be recorded, how to record it, and how to manage and store records for easy access and to minimize resource needs.

The Records and Document Control Specialist ensures:

a. Records for each test contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original.
b. Records include the identity of personnel responsible for the sampling (if applicable), performance of each test and checking of results.
c. Observations, data and calculations are recorded at the time they are made and identifiable to the specific task.
d. That when mistakes occur in records, each mistake is crossed out, not erased, made illegible or deleted, and the correct value entered alongside.
e. All alterations to records are signed or initialed by the person making the correction.
f. That in the case of records stored electronically, equivalent measures are taken to avoid loss or change of original data.
g. A record keeping system that allows the history of the sample and associated data is readily understood through the documentation, including 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.
h. All information necessary for the historical reconstruction of data is maintained, including:
    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 observations into reportable analytical values.
    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 or 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.

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

All generated data, except those that are generated by automated data collection systems, are recorded legibly in permanent ink, that the individual making corrections to records dates and initials the correction, and that corrections due to reasons other than transcription errors specify the reason for the correction.

2.8.2 References

TNI Standard Module 2: 4.2.1, 4.2.5, 4.3.1, 4.3.2, 4.3.3, 4.13

DOD Quality System Manual: Module 2: 5.6.4

Note: While Section 4.13 addresses records in general, Table A shows requirements in other parts of the standard for specific records.

Table 2. Records Required by TNI

Section	Requirement Module 2 (unless otherwise specified)
M1: 4.4.1	Records from PT sample analyses.
4.4.2	Records for reviews of tenders, requests, and contracts.
4.5.4	A list of all subcontractors and evidence of their compliance to the Standard.
4.5.6	Records of the evaluation of suppliers.
4.9	Records of complaints.
4.14.4	Audit findings and corrective actions from internal audits.
4.14.5	Record the implementation and effectiveness of the corrective action.
4.15.2	Findings from management reviews and actions taken.
4.16	Results from investigations into data integrity issues.
5.2.4	Job descriptions for managerial, technical, and key support personnel.
5.2.5	Records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.
5.2.7	Documentation that demonstrates all staff have participated and understand their obligations related to data integrity.
5..3.2	Records of environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results.
5.5.5	Records relating to equipment and software.
5.5.13.1	Records associated with checks of support equipment.
5.6.4.2	Documentation and labeling of standards, reagents, and reference materials.
5.8.5	Documentation related to sample handling.
5.8.7.2	Documentation related to sample acceptance or rejection.
5.8.7.2	All documents provided to the laboratory by the sample transmitter.

2.9 Method Validation

2.9.1 KSAs in the TNI Standard

The Method Validation Specialist knows or understands:

a. How to select appropriate methods and procedures.

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b. How and when deviations from test methods can occur.
c. The importance of having a Standard Operating Procedure (SOP) for each test method.
d. The requirement to ensure the laboratory has the capability of using the method for its intended use.
e. The procedures for estimating uncertainty of measurement.
f. That when computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data the computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use.
g. The procedures for protecting the data, including but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing.
h. That computers and automated equipment must be maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test data.
i. The basic concepts of both initial and continuing demonstration of capability (IDC, ODC) for the relevant scientific disciplines.

2.9.2 Other KSAs

The Method Validation Specialist knows or understands:

a. The theory and practical considerations associated with selecting and validating test methods.
b. The "life cycle" of measurements and the part that proper selection and validation of test methods plays in the overall process used to generate of data of known and documented quality.
c. EPA requirements, TNI Standard requirements, validation requirements from other sources such as Standard Methods, and the various options for validation.
d. The requirements for documenting and retaining validation data.
e. The concept of "legally defensible data" and how and why method validation is a key component for ensuring legal standing.
f. Which approved methods have method flexibility or approved modifications and which ones do not.
g. What the various EPA programs or states require the laboratory to do when validating or utilizing a modified test method, where applicable.
h. How to document and record the validation of method modifications.
i. The potential negative impacts of using unapproved or non-validated method modifications have on test results, accreditation or usability for regulatory compliance purposes.
j. The data integrity implications of intentionally modifying a test method SOP without prior approval or validating the modified test method, especially, if the unapproved modification is intentionally concealed.

2.9.3 References

TNI Standard Module 2: 5.4; Technical Modules 1.4, 1.5, 1.6

DOD Quality System Manual: Module 4: 1.5.1, 1.6.2

ISO 17025 2017: 7.2.1.5, 7.2.1.6

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Parr, J. and Pagliaro, T., *Implementing a Performance Based Measurement System*, February 11, 2000

2.10 Sample Handling

2.10.1 KSAs in the TNI Standard

The Sample Handling Specialist knows or understands:

a. The procedures for the transportation, receipt, handling, protection, storage, retention and disposal of samples, including all provisions necessary to protect their integrity, and to protect the interests of the laboratory and the customer
b. The system (e.g., logbook, LIMS) for identifying samples.
c. How samples are to be labeled
d. How abnormalities or departurd.es from normal or specified conditions, as described in the test method, are recorded when the sample is received and what actions are needed.
e. Sample acceptance procedures in place.
f. EPA or State program requirements for acceptance of samples
g. The types of sample containers to be used and any sample container preparation needed, preservation requirements, and sample holding times.
h. The procedures and appropriate facilities for avoiding deterioration, loss or damage to the sample during storage, handling and preparation.
i. How samples are to be stored including temperature requirements and how to prevent cross contamination.
j. The procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products.
k. The differences between chain of custody and legal chain of custody procedures used for evidentiary or legal purposes.
l. The documentation required to maintain a receipt-to-disposal record of all actions taken with samples.
m. That samples cannot be confused physically or when referred to in records or other documents.

2.10.2 References

TNI Standard Module 2: 5.8

DOD Quality System Manual: Module 2: 5.8.4, 5.8.7, 5.8.8, 5.8.9, 6.4

2.11 Quality Control

2.11.1 KSAs in the TNI Standard

The Quality Control Specialist knows or understands:

a. How to use and evaluate the following controls appropriate to each scientific discipline, including:
    i. Positive and negative controls as applicable to the tests, such as blanks, matrix spikes, and referent toxicants.
    ii. Tests to define the variability or repeatability of laboratory results, such as replicates.
    iii. Measures to assure the accuracy of the method, including initial and continuing calibrations, use of certified reference materials, proficiency test samples, or other measures.

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iv. Measures to evaluate method capability, such as limit of detection (LOD) and limit of quantitation (LOQ), or range of applicability, such as linearity.
v. Selection of appropriate formulae to reduce raw data to final results, such as regression analysis, comparison to internal or external standard calculations, and statistical analyses (e.g., control charts and trend analysis).
vi. Measures to assure the selectivity of a test for its intended purpose.

b. Basic QC measures, how each should be prepared, and the rationale behind the frequency of analysis, and how the results impact the related sample set.
c. Why QC is important to assess and improve overall laboratory data quality.
d. How to assess and evaluate sample results based on QC results, including corrective actions as needed.
e. Basic statistical concepts and techniques used for the collection, organization, analysis, and presentation of various types of laboratory data, including methods for calculation of QC results.
f. Numerical and categorical types of data in the laboratory.
g. The terms “population”, “batch”, “sample”, “precision”, and “bias”.
h. How to calculate relative error, relative standard error, %RSD, % recovery, control limits, and percent differences.
i. Significant figures and rounding.

Note: Modules 3 through 7 of the TNI Laboratory Standard contain specific requirements based on the type of testing performed: asbestos, chemical, microbiological, radiochemistry, and whole effluent toxicity (WET). An individual would need to earn a badge for each separate discipline as applicable. The basic QC requirements for each scientific discipline performed by the laboratory as described in Modules 3-7 and summarized in Table B below.

Table 3. Technical Requirements for Modules 3-7.

	Module 3 Asbestos	**Module 4 Chemistry**	**Module 5 Microbiology**	**Module 6 Radiochemistry**	**Module 7 Aquatic Toxicity**
Method Selection	x	x	x	x	x
Method Validation	x	x	x	x	x
Demonstration of Capability (DOC)	x	x	x	x	x
Calibration	x	x	x		
Continuing Calibration		x	x		
Instrument Set-up, Calibration, Performance Checks, and Background Measurements				x	
Quality Control	x	x	x	x	x
Test Variability/Reproducibility	x				
Other Quality Control Measures	x				
Analytical Sensitivity	x				
Quality of Standards and Reagents	x				
Data Acceptance/Rejection Criteria	x	x	x		x
Data Evaluation and Reporting				x	

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Constant and Consistent Test Conditions Sample and Sampling Requirements	x				
Sample Handling		x	x	x	x

2.11.2 References

TNI Standard Module 2: 5.9, and Sections 1.4 - 1.7 in the Technical Modules

ISO 17025 2017: 7.7.1, 7.7.2

EPA Handbook for Quality Control in Water and Wastewater Laboratories, EPA-600/4-709-019, 1979

2.12 Data Review and Reporting

2.12.1 KSAs in the TNI Standard

The Data Review and Reporting Specialist knows or understands:

a. How to report results accurately, clearly, unambiguously, and objectively, and in accordance with any specific instructions in the method.
b. The process for amending a test report after issue.
c. How to review calibration curve calculations, maintain data records, report results to clients, apply internal data review procedures, and evaluate quality control results.
d. How to review data and test results and determine if data is appropriate for the intended use.
e. Data qualifiers and their applicability.
f. How to record and retain technical records.
g. How to review quality control results and take appropriate actions.
h. Basic statistical concepts and techniques used for the collection, organization, analysis, and presentation of various types of laboratory data, including methods for calculation of QC results.
i. Numerical and categorical types of data in the laboratory.
j. The terms “population”, “batch”, “sample”, “precision”, and “bias”.
k. And calculate relative error, relative standard error, %RSD, % recovery, control limits, and percent differences. Understands significant figures and rounding.
l. That when computers or automated equipment are used for the acquisition, processing, reviewing, recording, reporting, storage, or retrieval of tests, the computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use.
m. The procedures for protecting the data, including but not limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing; and that 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 data.

The Data Review Reporting Specialist ensures test reports contain 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 or non-compliance with requirements or specifications.
c. Where applicable, a statement on the estimated uncertainty of measurement if information on uncertainty.
d. Where appropriate and needed, opinions and interpretations.
e. Additional information which may be required by specific methods, customers or groups of customers.

2.12.2 References

TNI Standard Module 2: 5.10

DOD Quality Systems Manual Module 2: 4.7, 5.4.7.1, 5.4.7.2, 5.10.3.1, Appendix A

ISO 17025 2017: 7.8.1.1, 7.8.1.2, 7.11.1-7.11.5

EPA Handbook for Quality Control in Water and Wastewater Laboratories, EPA-600/4-709-019, 1979

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