Costs of NELAP Accreditation

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October 14, 2016

This document was prepared to present some basic information about the cost of becoming a laboratory accredited to the TNI standard as well as the annual costs to maintain this accreditation. This document is divided into three primary sections:

- Initial start-up costs,
- Annual costs paid to outside organizations, and
- Annual internal costs.

This document was prepared assuming the laboratory is a small laboratory performing microbiological and classical wet chemistry test only and only testing water. Note: "Wet Chemistry" refers to simple tests such as residual chlorine, nitrate, ammonia, BOD, etc. and excludes any testing for metals or organics.

1.0 Initial Costs

The initial costs to become accredited can vary widely, depending on where the laboratory is in implementing a quality system. A laboratory that has implemented a quality system will incur minimal costs. Laboratories that have not may have substantial internal or external costs to develop the Quality Manual and related Standard Operating Procedures (SOPs) required to document the quality system.

The TNI standard requires every laboratory to have a Quality Manual that describes the laboratory's policies related to quality. The standard requires nine specific items to be included in this document and references 23 other items that must be included or referenced. The list of items to be included in the quality manual are shown in Appendix A.

The TNI standard also uses words like procedure, process, or plan to imply a documented procedure exists that describes how the laboratory performs certain activities, such as sample disposal. These procedures are not the analytical test procedures used by the laboratory to analyze samples; rather, they are all the other procedures needed to ensure the competence of the laboratory's practices. A list of these procedures is appended to this document.

A laboratory has several avenues open to them to create the quality manual and related SOPs. If someone in the laboratory is familiar with quality systems and is well grounded in laboratory fundamentals, than that person can generate these documents simply by reading the standard. For example, Section 4.2.2 of the standard requires the laboratory to have a quality policy statement. Someone in the laboratory could read this requirement and then write a statement such as the one below:

> The objective of the management system and the commitment of management is to consistently provide our customers with data of known and documented quality that meets their requirements. Our policy is to use good professional practices, to maintain quality, to uphold the highest quality of service, and to comply with the TNI Standard. The laboratory ensures that personnel are free from any commercial, financial, and other undue pressures,

which might adversely affect the quality of work. This policy is implemented and enforced through the unequivocal commitment of management, at all levels, to the Quality Assurance (QA) principles and practices outlined in this manual. However, the primary responsibility for quality rests with each individual within the laboratory organization. Every laboratory employee must ensure that the generation and reporting of quality analytical data is a fundamental priority. Every laboratory employee is required to familiarize themselves with the quality documentation and to implement the policies and procedures in their work. All employees are trained annually on ethical principles and procedures surrounding the data that is generated. The laboratory maintains a strict policy of client confidentiality.

The second option would be to purchase TNI's Quality Manual Template and SOP template. These are fill-in-the-blank Microsoft Word documents that contain boiler plate language that the laboratory can use as a starting point. The quality policy statement shown above is an example of such language.

The third option would be to contract with a consultant who could help the laboratory prepare these documents. TNI has a listing of such consultants on its website.

The effort to complete the preparation of the quality manual and related SOPs is contingent on how advanced the laboratory's quality system is. For those laboratories that have a quality manual in place, and many SOPs reflecting laboratory operation, the effort should be minimal. If none of these documents exists, it could take six months for someone to create them all. This six month period could be shortened by using a consultant of one of TNI's templates.

In addition to the preparation of the quality documentation, there are some other minor up-front expenses. Most of these activities should have been performed already. For example, when a laboratory begins performing a new test method, they should have some data, termed by TNI a Demonstration of Capability, that documents the laboratory can perform the method correctly. The laboratory also has to verify that it Technical Manager (Laboratory Director or other similar term) meets specified experience and educational qualifications. For a small water laboratory, the Technical Manager must have two years of experience in the tests performed, at least an associate's degree in science, and at least 16 hours of college chemistry.

2.0 Annual Direct Costs

2.1. Accreditation Body Fees

These are the fees paid to the state agency. I picked Minnesota because it was easy to get to, but these are typical of all ABs except New York. These fees would cover most of the basic wet chemistry tests and microbiology.

Base Fee	450.00
Inorganic Chemistry - Clean Water Program	150.00
Microbiology - Safe Drinking Water Program	150.00

These fees may be understated if the laboratory analyzes both potable and non-potable water. Because EPA regulates these separately, a laboratory that analyzes both types of water would have to pay the fees for the appropriate program.

2,2. Proficiency Testing Fees

For every analyte for which accreditation is sought, the laboratory must successfully analyze two proficiency test samples per year. Using the example table below, the annual cost for purchasing these samples would be $722. If he laboratory test both potable and non-potable water, then the fees would double since separate PTs are required for each program.

Analyte	**Price per Sample***
Simple Nutrients (Ammonia, Nitrate/Nitrite, o-Phosphorous)	S60
Conductivity	$60
Turbidity	$70
Residual Chlorine	$69
Micro (Fecal coliform, Total Coliform, e. coli)	$102
Total	$361

* Published price from Phenova, one of the approved PT providers.

3.0 Annual Internal Costs

The TNI standard requires the laboratory perform several activities to monitor the effectiveness of its quality system, such as an annual internal audit and an annual review of its record keeping system. These types of activities are fairly easy to implement, and one average, would require 3-5 hours of effort per month. Every two years the laboratory is inspected by the Accreditation Body in what is termed an assessment. This assessment would involve a 1-2 day inspection by a laboratory assessor and then the laboratory must respond to any deficiencies identified in this assessment with a corrective action report. Most laboratories like to have an individual shepherd the laboratory assessor during the assessment. Thus, the effort to participate in this assessment and prepare the corrective action report is estimated to be 3-4 days every two years.

4.0 Summary

As shown above, there may be some significant up-front costs to become compliant to the TNI requirements, but after that the direct costs should be around $1000 per year and indirect costs should require less than 80 hours per year.

Appendix A: Requirements for the Quality Manual

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 which are to be covered by this quality manual and the effective date of the version;

e) identification of the laboratory's approved signatories;

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;

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

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.

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 quality control 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;

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;

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;

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

n) procedures for dealing with complaints;

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

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

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

Appendix B: Specific References to Procedures in the TNI Standard

4.1.5.c Policies and procedures to ensure protection of customers' confidential information and proprietary rights, including procedures for protecting electronic storage and transmission of results

4.1.5.d Policies and procedures to avoid involvement in activities that would diminish confidence in the laboratory's competence, impartiality, judgment, or operational integrity

4.1.5.e Relationship between management, technical operations, support services, and quality system

4.2.8.1 Procedures for establishing and maintaining data integrity, including training, documentation, and monitoring

4.2.8.5 SOPs that accurately reflect all phases of current lab activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods

4.6.1 Procedures for selection and purchasing of services and supplies; procedures for purchase, reception, and storage of reagents and consumables

4.13.1.1 Procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records

4.13.1.4 Procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records

4.13.3.h Plan to ensure that records are maintained or transferred according to clients' instructions in the event the laboratory transfers ownership or goes out of business

4.14.1.5 Procedures addressing internal audits, findings, and corrective actions that ensure these actions are completed within the agreed time frame

4.15.1 Procedures for conducting a review of the laboratory's management system and testing and/or calibration activities by laboratory's top management

5.4.7.2.b Procedures for protecting the data, including integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing

5.5.6 Program for safe handling, transport, storage, use, and planned maintenance of measurement equipment

5.5.11 Procedures to ensure where calibration gives rise to a set of correction factors that copies (e.g. in computer software, for thermometers) are correctly updated

5.6.3.1 Program and procedure for the calibration of the laboratory's reference standards

5.6.3.4 Procedures for safe handling, transport, storage, and use of reference standards and reference materials

5.6.4 Procedures for purchasing, receiving, and storing materials used in technical operations of the laboratory

5.7.1, Sampling plan & procedures, if applicable, availability of plan at the sampling location 5.7.3 Procedures for recording relevant data and operations relating to sampling

5.7.1 Procedures and appropriate techniques for obtaining representative subsamples as part of the test method

5.8.1 Procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of samples

5.8.4 Procedures to avoid deterioration, contamination, or damage to samples during storage, handling, preparation, and testing

5.8.5.a System for uniquely identifying samples to be tested, including samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates

5.8.6.a-e Written sample acceptance policy

5.8.6.f-g Procedures followed when samples who signs of damage, contamination or inadequate preservation; and qualification of data

5.8.9.c Procedures for disposal of samples, digestates, leachates, extracts, and other sample prep products

5.9.1 Quality control procedures for monitoring the validity of environmental tests and calibrations undertaken

5.9.3.a Written protocols to monitor quality controls

5.9.3.c Procedures for development of quality control acceptance/rejection criteria