Comment on Proposed California ELAP Regulations: Laboratory Standard
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Comments provided by:

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The following comments are submitted in response to a notice published by the California Water Resources Control Board on September 20, 2016.

These comments address the comments made by the public on October 6, 2016 on ELAP's proposal to use the TNI Standard, Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis (2016). These comments address specifically the following areas:

- The benefits of using the TNI standard in a laboratory accreditation program.
- Closure of municipal laboratories in Florida and New York.
- Misunderstanding on the TNI standard, including
    - Educational requirements for laboratory managers
    - Release of laboratory data to the public, and
    - Verification checks on laboratory equipment.
- The costs to implement the program.

1. Benefits of the TNI Standard

Each year, hundreds of millions of measurements are performed by over 5,000 environmental testing laboratories in the United States to determine whether or not a regulated entity is in or out of compliance, evaluate the extent and nature of environmental contaminants in air, soil and water, and to collectively provide information used to protect human health and environment. For example, a municipality may seek testing of their tap water to see if it is safe to drink; a wastewater treatment plan may test their discharge to demonstrate compliance with a permit limit, the Federal Government may test soil at its facility to determine if the site can be redeveloped, or a community may contract to test the air in its community to determine the impact of a new industrial activity that has moved into the area. These measurements are

performed by environmental testing laboratories that may be operated by local, state or federal government, or commercial for profit entities.

Many of these measurements are performed without adequate assurance and documentation to ensure that the measurements are reliable. Without this surveillance, government agencies and the public often make decisions that may be based on incomplete or inaccurate information. The accuracy of test results is commonly assumed, but not so often is it actually known. Such decisions

- Increase the anxiety over environmental contaminants where no such anxiety is justified, or provide assurance of no risks when such assurances cannot be proven,
- Result in unnecessary expenditure of funds to remedy a non-existent environmental concern, or insufficient actions taken when such remedies are needed,
- Result in devaluation of property when such devaluation is based on inaccurate measurements, and
- Result in over regulation of some industries when such regulation is not required.

Although there are stringent compliance monitoring requirements placed on regulated facilities, there is little oversight of the laboratories used to generate the data for compliance monitoring outside of the Drinking Water program. In order to strengthen California's environmental regulatory programs and provide a solid foundation for regulatory decisions, California regulators and the public need confidence that laboratory data of known and documented quality is used to make critical environmental management decisions.

Since 1978, EPA has implemented a certification program for laboratories performing drinking water analyses for compliance with regulations issued pursuant to the Safe Drinking Water Act. These laboratories include EPA Regional laboratories, certain Federal laboratories, Tribal Nation laboratories, principal State laboratories in primacy States, and drinking water laboratories in non-primacy States. EPA has concluded that laboratories that adopt the approaches discussed in this manual will generate reliable analytical data. Consequently, EPA recommends that States follow these procedures and criteria in their drinking water certification decisions.

In the wastewater program at EPA, dischargers are required to participate in Discharge Monitoring Report Quality Assurance (DMRQA) studies to demonstrate the quality of data submitted to this regulatory program. In this program, responsibility for data quality clearly falls upon the permitee or laboratory client.

The solid waste program has taken yet another approach to managing data quality by requiring waste generators to develop a sampling and analysis plan. The Agency provides guidelines for laboratory testing, but not the mandated protocols of the drinking water program. While many prefer this "performance approach," laboratory accreditation can address whichever methods or types of methods are utilized.

The Superfund program has relied on its Contract Laboratory Program, a *de facto* certification program, but without the rigor of a quality systems focus. The emissions monitoring program relies on mandated test methods, with no requirements for accreditation.

While all of these programs have some degree of effectiveness, the result for laboratories, regulated facilities and the public, is a fragmented system for assuring the quality of laboratory data that is used to make decisions that often have huge economic impacts. There is no comprehensive program in place at EPA to assure laboratory data quality by ensuring the competency of laboratories generating environmental data.

The Agency has recognized the limitations of the current regulations for laboratory analyses (see *Agency Policy Directive Number FEM-2011-01)* and requires organizations (e.g., laboratories, field sampling and measurement) generating environmental data under Agency-funded acquisitions submit documentation of their competency.

Using an accredited laboratory increases confidence that decisions regarding multiple facilities are based on comparable data. Costs associated with laboratory problems, including re-testing, re-sampling, and lost time are minimized and false positives and negatives, which can directly affect compliance with regulations, are minimized. An effective accreditation program will thus reduce the overall costs to laboratories due to improved processes and procedures that are implemented. Accreditation provides an objective way of showing clients, the community and the government that a laboratory has demonstrated capability to provide testing services.

TNI developed and will maintain a set of standards (the TNI Standard) based on international standards (ISO/IEC 17025, 17011, and 17043) that interpret the generic international laboratory standards for application to laboratories performing environmental testing.

TNI's program contains a number of unique attributes:

- Laboratories are periodically inspected by an authoritative, independent organization called an Accreditation Body, to ensure they have the staff, facilities, equipment, and professional practice to generate reliable data,
- Laboratories are held accountable to internationally-recognized requirements that have been supplemented by rigorous interpretive requirements specific to environmental testing as those essential for ensuring reliable data,
- Laboratories are periodically evaluated using proficiency test (PT) samples to evaluate the accuracy of their results. TNI regularly assesses the organizations that provide these test samples and evaluates the results to assure they are qualified to do so,
- Those organizations (Accreditation Bodies) that assess laboratories are monitored by TNI to ensure they have both the competency and the resources for the operation of an accreditation program.

No other organization has developed requirements specific for environmental testing that have the level of detail to ensure consistent application of the requirements of multiple state agencies. No other organization has established a system whereby state government agencies have confidence that laboratory assessors and accreditation bodies participating in the program have implemented the program to the same level of reliability. No other organization has established a comprehensive PT program that addresses all analytes and all media.

Standards used by TNI are developed through an ANSI-accredited consensus standards development process and as such meet the requirements of Office of Management and Budget (OMB) circular A -119 for use of consensus standards in federal regulations where available. Similar interpretive criteria are available and used internationally for another important public health area, food and pharmaceutical testing (AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals.)

EPA's Office of Water has already recognized NELAP accreditation in lieu of drinking water certification.

NELAP benefits the public by:

- Establishing a uniform set of standards by which environmental data is produced across the various states, agencies and programs that participate, thereby promoting comparability and defensibility.
- Being more cost effective, through the recognition and use of the accreditation status of a laboratory by multiple stakeholders and consequently reducing the number of assessments performed by accreditation bodies.
- Presenting greater opportunities for quality improvements. The TNI standards development process encourages the pooling of expertise from multiple agencies, states and various stakeholder groups in the private sector. This larger range of expertise has strengthened the quality concepts and practices upon which this environmental interpretation of international standards is based.
- Improving the quality of laboratory assessments by establishing uniform requirements for training assessors and facilitating opportunities for information exchange.
- Having the capability to expand the scope of accreditation programs to include emerging contaminants, field sampling activities, and additional environmental media as needed in the future.
- Making possible the "secondary uses of data" – combining data from multiple sources for the purpose of broader examinations of environmental conditions – by providing documentation of data quality and the purpose for which it was generated.

Laboratories benefit because adherence to TNI standards would:

- Replace redundant and often contradictory inspections with comprehensive standardized inspections, and thus lowers laboratory costs;
- Improve acceptability of data to regulators and customers due to documentation of data quality;

- Significantly reduce the substantial indirect costs associated with conflicting program requirements, especially for those laboratories that works across two or more EPA programs.
- Establish credibility of data; and
- Improve acceptability of data to regulatory agencies.

An independent survey of the effectiveness of the NELAP program was conducted in 2008. This survey was sent to over 1000 laboratories of all sizes and types. The program received high scores in most categories and had notable positive results in the following categories:

- 74% of the respondents believe the cost to implement and maintain the program is justified.
- 80% of the respondents believe all laboratories should be accredited.
- Over 80% of the respondents believe the program improved the laboratory's quality system, data defensibility, and data quality.

Participating ABs benefit from using the TNI standard by:

- Saving the resources and efforts that would be incurred in creating local or state accreditation standards.
- Having access to TNI resources to help implement the program.

In summary, requiring laboratory accreditation based on the TNI standard will ensure that environmental monitoring data are adequate for their intended purpose. If a laboratory is accredited to the TNI standards, it means that the laboratory has demonstrated its competence to produce data that are accurate, traceable and reproducible -- critical components in governmental decision-making. The TNI standard is presently the only environmental interpretive version of the international standard for environmental laboratories.

Using an accredited laboratory benefits government and regulators by increasing confidence in data that are used to establish baselines for key analyses and decisions, and reducing uncertainties associated with decisions that affect the protection of human health and the environment. Using an accredited laboratory increases public confidence, because accreditation is a recognizable indication of competence, and it eliminates the need for multiple and sometimes redundant reviews and improves the efficiency of the assessment process, which reduces costs.

Using an accredited laboratory also increases confidence that decisions regarding multiple facilities are based on comparable data. Costs associated with laboratory problems, including re-testing, re-sampling, lost time and false positives/negatives, which can directly affect compliance with regulations, are minimized.

2. Closure of municipal laboratories in Florida and New York

One presenter at the public hearing showed data that indicated many laboratories in Florida and New York had closed since those states adopted the TNI standard, and suggested the reason is that the TNI standard is too expensive to implement. We do not know why these laboratories closed, but have observed similar closures in states where municipal laboratories are not required to be accredited. It could be a management decision to use contract laboratories that can provide the testing more effectively. It could be that these laboratories simply were not competent, and had no means for achieving competency. It could be a number of reasons. The fact is, many very small municipal laboratories have been able to implement the standard.

3. Misunderstandings of the TNI Standard

As someone who participated in this event remotely, TNI did not capture all the statements made at the public hearing that demonstrate that the California laboratory community does not fully understand the requirements, and in several cases, misstated what the actual requirements are. Three examples are provided below. We believe all of these types of issues can be addressed with the compliance assistance effort ELAP has planned.

3A. Educational Requirements for Laboratory Managers

Someone at the public hearing stated that the laboratory manager must have a degree in chemistry. This is simply not true. Even for the most complex laboratory, testing a wide variety of environmental media using many different technologies, there is no requirement for the manager to have a chemistry degree. The standard states:

a) Any technical manager of an accredited environmental laboratory engaged in chemical analysis shall be a person with a bachelor's degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least twenty-four (24) college semester credit hours in chemistry and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

b) Any technical manager of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in the chemical, physical or environmental sciences, or two (2) years of equivalent and successful college education, with a minimum of sixteen (16) college semester credit hours in chemistry. In addition, such a person shall have at least two (2) years of experience performing such analysis.

c) Any technical manager of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of sixteen (16) college semester credit hours in general microbiology and biology and at least two (2) years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

> A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four (4) college semester credit hours in general microbiology may be the technical manager(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, E. coli, and standard plate count. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one (1) year of experience in microbiological analyses.

In addition, the standard provides an exception to the education requirements for municipal laboratories, stating:

> … a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational requirements as the technical manager. A technical manager shall have two (2) year testing experience devoted exclusively to the testing of environmental samples specified in the scope of the facility's regulatory permit. Such accreditation for a water treatment facility and/or a sewage treatment facility shall be limited to the scope of that facility's regulatory permit.

3B. Release of Laboratory Data to the Public

At least one commenter stated that section 4.1.5 c does not apply to municipal laboratories since they must be able to release information to the public on request. This section states:

> 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;

Most, if not all public utilities are required to make information available to the public upon request. However, this process has a defined procedure to protect the unauthorized release of information, and that is all this section states. The laboratory must have a procedure for protecting information. That procedure could involve release of information to the public through a defined process.

3B. Verification of Lab Volumetric Equipment

At the public hearing one individual objected to the verification checks in section 5.5.13.1 (e), indicating that these check were not necessary. That is not true. There have been documented cases of issues related to such equipment, especially mechanical pipettes. The standard has minimal requirements, checking mechanical devices once per quarter and all other volumetric ware (excluding class A glassware) once per lot. These checks would take less than a minute to perform and document and would ensure such equipment is accurate.

4. Implementation Costs

A number of speakers expressed concerns about the costs of coming into compliance with the TNI standard. In September this year, TNI prepared a document to assist tribal nations in exploring options for becoming accredited. See Attachment 1.

As discussed in this document, the initial costs could vary greatly depending on how well a particular laboratory has documented its policies and procedures. A laboratory that has implemented some type of quality system would have much lower implementation costs than a laboratory that has not.

This document also describes the resources TNI can provide to assist laboratories in this initial phase. With California considering a phased implementation approach, these initial costs could be spread over a two to three year period, and should be easily affordable in most laboratories.

Attachment 1
Costs of NELAP Accreditation

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, using sd sm example. 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)	$60
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