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ENVIRONMENTAL LABORATORY SECTOR

VOLUME 1

MANAGEMENT AND TECHNICAL REQUIREMENTS FOR LABORATORIES PERFORMING ENVIRONMENTAL ANALYSIS

Module 2: Quality Systems General Requirements

Working Draft Standard
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PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) Quality Systems Committee. The TNI Board of Directors wishes to thank these committee members for their efforts in preparing this Standard as well as those TNI members who offered comments during the voting process.

It is conformant with the requirements of ISO/IEC 17025:2005(E). This publicly available TNI document does not contain the ISOI/IEC copyright protected language, but does reference applicable ISO clauses. In these situations, it is useful to read the TNI Standard along with the ISOI/IEC Standard. Wherever an ISO clause is referenced *(in italics),* the language from that clause is applicable. Any additional TNl language then follows, in plain text, as a NOTE or as an additional numbered Standard item.

TNI has an agreement with ASTM International and the American National Standards Institute (ANSI) to provide, to TNI members at a discounted rate, a version of this Standard with the ISO/IEC language included; contact Jerry Parr at TNI for more information.

This Standard may be used by any organization that wishes to implement a program for the accreditation of environmental laboratories.

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VOLUME 1, MODULE 2

Quality Systems General Requirements

Table of Contents

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VOLUME 1, MODULE 2

Quality Systems General Requirements

1.0 INTRODUCTION, SCOPE AND APPLICABILITY

1.1 Introduction

Each laboratory shall have a quality system. The laboratory's quality system is the means by which an organization ensures the quality of the products or services it provides and includes a variety of management, technical, and administrative elements such as:

a) policies and objectives,
b) procedures and practices,
c) organizational authority,
d) responsibilities, and
e) performance measures.

The quality system provides the framework for planning, implementing, assessing, and improving work performed by an organization so as to provide the client with data of known and documented quality, sufficient to evaluate the usability of the data to the clients needs. The quality system shall be documented in the laboratory's quality manual and related quality documentation, and shall be referenced in the quality manual.

This Standard contains detailed quality system requirements for consistent and uniform implementation by the laboratories conducting testing and the consistent and uniform evaluation of those laboratories by accreditation bodies. Each laboratory seeking accreditation under this Standard shall ensure that they are implementing their quality system and that all Quality Control procedures specified in this module are being followed. The Quality Assurance policies, which establish quality control procedures, are applicable to environmental laboratories regardless of size and complexity.

This Standard is consistent with ISO/IEC 17025:2005 requirements that are relevant to the scope of environmental testing services.

All items identified in this document shall be available for an on-site assessment.

1.2 Scope

The requirements in this document give the basis for a laboratory's quality system in order to carry out environmental tests. It covers testing performed using reference methods, non-reference methods, and laboratory-developed methods. This document contains the essential elements required to establish a quality system that produces data of known and documented quality, and demonstrates proficiency through the use of proficiency testing and employee training.

The general requirements of this document apply to all organizations performing environmental tests, regardless of the number of personnel or the degree of environmental testing activities. When the use of the data requires compliance with the Standards, these Standards shall be followed.

This document is for use by laboratories, clients, regulatory authorities, and accreditation bodies to ensure the laboratory has appropriate management and technical quality systems to perform environmental testing. This document specifies technical, managerial, and documentation requirements needed for assessment by organizations or accreditation bodies to grant approval. This document provides the requirements needed for laboratory accreditation. If the requirements of this document are met, the laboratory operates a quality system in conformance with the applicable clauses of ISO/IEC 17025:2005(E).

2.0 NORMATIVE REFERENCES *(ISO/IEC 17025:2005(E), Clause 2)*

3.0 TERMS AND DEFINITIONS

The relevant definitions listed in the referenced ISO/IEC documents apply when using those documents. Definitions related to this document, which are used differently or do not exist in the above references are defined below.

3.1 Additional Terms and Definitions

Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in requirement documents.

Accreditation: The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

Accuracy: The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations; a data quality indicator.

Analyst: The designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

Analytical Uncertainty: A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis.

Analyte: The substance being measured in an analytical procedure.

Assessment: The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of laboratory accreditation).

Audit: A systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives.

Batch: Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one (1) to twenty (20) environmental samples of the same quality systems matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four (24) hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed twenty (20) samples.

Bias: The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

Blank: A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include:

Method Blank: A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

Calibration: A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

1) In calibration of support equipment the values realized by standards are established through the use of reference standards that are traceable to the International System of Units (SI).

2) In calibration according to methods, the values realized by standards are typically established through the use of Reference Materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

Calibration Curve: The mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.

Calibration Standard: A substance or reference material used for calibration.

Certified Reference Material (CRM): Reference material, accompanied by a certificate, having a value, measurement uncertainty, and stated metrological traceability chain to a national metrology institute.

Chain of Custody Form: Record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses. See also Legal Chain of Custody Protocols.

Confirmation: Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to: Second column confirmation, Alternate wavelength, Derivatization, Mass spectral interpretation, Alternative detectors, or Additional cleanup procedures.

Data Reduction: The process of transforming the number of data items by arithmetic or statistical calculation, standard curves, and concentration factors, and collating them into a more useful form.

Demonstration of Capability: A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision.

Field of Accreditation: Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

Finding: An assessment conclusion referenced to a laboratory accreditation standard and supported by objective evidence that identifies a deviation from a laboratory accreditation standard requirement.

Holding Times: The maximum time that can elapse between two (2) specified activities.

Internal Standard: A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes and taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a reference method. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

Legal Chain of Custody Protocols: Procedures employed to record the possession of samples from the time of sampling through the retention time specified by the client or program. These procedures are performed at the special request of the client and include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by the laboratory. In addition, these protocols document all handling of the samples within the laboratory.

Limit(s) of Detection (LOD): A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility.

Limit(s) of Quantitation (LOQ): The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

Matrix: The substrate of a test sample.

Matrix Duplicate: A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision.

Matrix Spike (spiked sample or fortified sample): A sample prepared, taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a referenced method, by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Matrix Spike Duplicate (spiked sample or fortified sample duplicate): A replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

Measurement System: A method, as implemented at a particular laboratory, and which includes the equipment used to perform the test and the operator(s).

Method: A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.

Mobile Laboratory: A portable enclosed structure with necessary and appropriate accommodation and environmental conditions for a laboratory, within which testing is performed by analysts. Examples include but are not limited to trailers, vans, and skid-mounted structures configured to house testing equipment and personnel.

National Institute of Standards and Technology (NIST): A federal agency of the US Department of Commerce's Technology Administration that is designed as the United States national metrology institute (NMI).

Parameter: a measurable quantity, e.g. temperature, that determines the result of a scientific experiment and can be altered to vary the result

Precision: The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.

Preservation: Any conditions under which a sample must be kept in order to maintain chemical and/or biological integrity prior to analysis.

Procedure: A specified way to carry out an activity or process. Procedures can be documented or not.

Proficiency Testing: A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

Proficiency Testing Program: The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

Proficiency Test Sample (PT): A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.

Protocol: A detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed.

Quality Assurance: An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality Control: The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality.

Quality Control Sample: A sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control.

Quality Manual: A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

Quality System: A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance (QA) and quality control (QC) activities.

Quality System Matrix: These matrix definitions are to be used for purposes of batch and quality control requirements:

Air and Emissions: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device.

Aqueous: Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, ground water effluents, and TCLP or other extracts.

Biological Tissue: Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Chemical Waste: A product or by-product of an industrial process that results in a matrix not previously defined.

Drinking Water: Any aqueous sample that has been designated a potable or potential potable water source.

Non-Aqueous Liquid: Any organic liquid with <15% settleable solids.

Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Solids: Includes soils, sediments, sludges and other matrices with >15% settleable solids.

Raw Data: The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records.

Reference Material: Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

Reference Method: A reference method is a method issued by an organization generally recognized as competent to do so. (When ISO refers to a standard method, that term is equivalent to reference method). When a laboratory is required to analyze a analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology. Reference Methods do not require validation as outlined in 5.4.5 of this standard, but must follow the applicable technical requirements found in Section 1.5.1 of Modules 3-7.

Reference Standard: Standard used for the calibration of working measurement standards in a given organization or at a given location.

Sampling: Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.

Selectivity: The ability to analyze, distinguish, and determine a specific analyte or parameter from another component that may be a potential interferent or that may behave similarly to the target analyte or parameter within the measurement system.

Sensitivity: The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest.

Standard: The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of standard setting and meets the approval requirements of standard adoption organizations procedures and policies.

Standard Operating Procedures (SOPs): A written document that details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine or repetitive tasks.

Technology: A specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

Traceability: The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

Verification: Confirmation by examination and objective evidence that specified requirements have been met.

NOTE: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete. In all cases, it is required that a written trace of the verification performed shall be kept on the measuring instrument's individual record.

3.2 Sources

40CFR Part 136 Guidelines Establishing Test Procedures for the Analysis of Pollutants

American Society for Quality Control (ASQC), Definitions of Environmental Quality Assurance Terms, 1996

American National Standards Institute (ANSI), Style Manual for Preparation of Proposed American National Standards, Eighth Edition, March 1991

ANSI N42.23-1995, Measurement and Associated Instrument Quality Assurance for Radiobioassay Laboratories

International Vocabulary of Basic and General Terms in Metrology (VIM): 1984. Issued by Bureau International des Poids et Mesures (BIPM), International Electrotechnical Commission (IEC), International Organization for Standardization (ISO)/IEC and International Organization of Legal Metrology (OIML)

National Institute of Standards and Technology (NIST)

National Environmental Laboratory Accreditation Conference (NELAC), July 2003 Standards

Random House College Dictionary

United States Environmental Protection Agency (US EPA) Quality Assurance Management Section (QAMS), Glossary of Terms of Quality Assurance Terms, 8/31/92 and 12/6/95

Webster's New World Dictionary of the American Language

Uniform Federal Policy for Quality Assurance Project Plans (UFP QAPP) March 2005

VIM – Draft edition October 2005

TNI Technical Modules, as follows:

Volume 1, Module 3 Quality Systems for Asbestos Testing

Volume 1, Module 4 Quality Systems for Chemical Testing

Volume 1, Module 5 Quality Systems for Microbiological Testing

Volume 1, Module 6 Quality Systems for Radiochemical Testing

Volume 1, Module 7 Quality Systems for Toxicity Testing

3.3 Exclusions and Exceptions

Reserved

4.0 MANAGEMENT REQUIREMENTS

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

4.1.7 Additional Requirements for Laboratories

4.1.7.1 The laboratory's quality manager and/or his/her designee(s) shall:

a) serve as the focal point for QA/QC and be responsible for the oversight and/or review of quality control data;

b) have functions independent from laboratory operations for which they have quality assurance oversight;

c) be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;

d) have documented training and/or experience in QA/QC procedures and the laboratory's quality system;

e) have a general knowledge of the analytical methods for which data review is performed;

f) arrange for or conduct internal audits as per Section 4.14 annually;

g) notify laboratory management of deficiencies in the quality system; and

h) monitor corrective actions.

NOTE: Where staffing is limited, the quality manager may also be the technical manager.

4.1.7.2 The laboratory's technical manager(s), however named, and/or his/her designee(s) shall:

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

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

c) have duties that include:

i. monitoring standards of performance in quality control and quality assurance, and

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

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

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

ii adequacy of supervision in each laboratory, and

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

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

f) meet qualification requirements as specified in Section 5.2.6.1.

4.2 Management *(ISO/IEC 17025:2005(E), Clause 4.2)*

4.2.8 Additional Management System Requirements

4.2.8.1 The laboratory shall establish and maintain a documented data integrity system. There are four (4) required elements within a data integrity system. These are 1) data integrity training, 2) signed data integrity documentation for all laboratory employees, 3) in-depth, periodic monitoring of data integrity, and 4) data integrity procedure documentation. The data integrity procedures shall be signed and dated by top management. The requirements for data integrity investigation are listed in Section 4.16. The requirements for data integrity training and documentation are listed in Section 5.2.7. Management shall annually review data integrity procedures and update as needed.

a) Laboratory management shall provide a procedure for confidential reporting of data integrity issues in their laboratory. A primary element of the procedure is to assure confidentiality and a receptive environment in which all employees may privately discuss ethical issues or report items of ethical concern.

b) In instances of ethical concern, the procedure shall include a process whereby laboratory management is to be informed of the need for any further detailed investigation.

4.2.8.2 The quality manager shall be responsible for maintaining the currency of 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.

4.2.8.5 Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods.

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

b) The relevant SOPs shall be readily accessible to all personnel.

c) Each SOP shall clearly indicate the effective date of the document, the revision number, and the signature(s) of the approving authority.

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

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

f) The SOP may be a copy of a published or referenced method or may be written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each method shall include or reference the following topics where applicable:

i. identification of the method;
ii. applicable matrix or matrices;
iii. limits of detection and quantitation;
iv. scope and application, including analytes and parameters to be analyzed;
v. summary of the method;
vi. definitions;
vii. interferences;
viii. safety;
ix. equipment and supplies;
x. reagents and standards;
xi. sample collection, preservation, shipment and storage;
xii. quality control;
xiii. calibration and standardization;
xiv. procedure;
xv. data analysis and calculations;
xvi. method performance;
xvii. pollution prevention;
xviii. data assessment and acceptance criteria for quality control measures;
xix. corrective actions for out-of-control data;
xx. contingencies for handling out-of-control or unacceptable data;
xxi. waste management;
xxii. references; and
xxiii. any tables, diagrams, flowcharts and validation data.

4.3 Document Control *(ISO/IEC 17025:2005(E), Clause 4.3)*

4.4 Review of Requests, Tenders and Contracts *(ISO/IEC 17025:2005(E), Clause 4.4)*

4.5 Subcontracting of Environmental Tests *(ISO/IEC 17025:2005(E), Clause 4.5)*

4.5.5 When a laboratory subcontracts work, this work shall be placed with a laboratory accredited to this Standard for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed. The laboratory performing the subcontracted work shall be indicated in the final report. The laboratory shall make a copy of the subcontractor's report available to the client when requested.

4.6 Purchasing Services and Supplies *(ISO/IEC 17025:2005(E), Clause 4.6)*

4.7 Service to the Client *(ISO/IEC 17025:2005(E), Clause 4.7)*

4.8 Complaints *(ISO/IEC 17025:2005(E), Clause 4.8)*

4.9 Control of Nonconforming Environmental Testing Work *(ISO/IEC 17025:2005(E), Clause 4.9)*

4.10 Improvement *(ISO/IEC 17025:2005(E), Clause 4.10)*

4.11 Corrective Action *(ISO/IEC 17025:2005(E), Clause 4.11)*

4.11.6 The laboratory shall have documented procedure(s) to address Sections 4.11.1 and 4.11.3 through 4.11.5. These procedure(s) shall also include:

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

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

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

4.12 Preventive Action *(ISO/IEC 17025:2005(E), Clause 4.12)*

4.13 Control of Records *(ISO/IEC 17025:2005(E), Clause 4.13)*

4.13.3 Additional Requirements

a) The laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.

b) The laboratory shall retain all records for a minimum of five (5) years from generation of the last entry in the records.

c) Records shall be available to the accreditation body.

d) Records that are stored only on electronic media shall be supported by the hardware and software necessary for their retrieval.

e) Access to archived information shall be documented with an access log.

f) All information necessary for the historical reconstruction of data shall be maintained by the laboratory.

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

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

iii) laboratory sample ID code;

iv) date of analysis;

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

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

vii) all manual calculations;

viii) analyst's or operator's 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) quality control 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 quality control requirements;

xvii) proficiency test results;

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

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

g) All generated data, except those that are generated by automated data collection systems, shall be recorded legibly in permanent ink.

i) An individual making corrections to records shall date and initial the correction.

ii) Corrections due to reasons other than transcription errors shall specify the reason for the correction.

h) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business. In addition, appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

4.14 Internal Audits *(ISO/IEC 17025:2005(E), Clause 4.14)*

4.14.5 Additional Items

a) The laboratory shall have a policy that specifies the time frame for notifying a client of events that cast doubt on the validity of the results.

b) The laboratory management shall ensure that these actions are discharged within the agreed time frame.

c) The Internal audit schedule shall be completed annually,

4.15 Management Reviews *(ISO/IEC 17025:2005(E), Clause 4.15)*

4.15.3 Management review shall be completed on an annual basis.

4.16 Data Integrity Investigations

All investigations resulting from data integrity issues should be conducted in a confidential manner until they are completed. These investigations shall be documented, as well as any notifications made to clients receiving any affected data.

5.0 TECHNICAL REQUIREMENTS

5.1 General *(ISO/IEC 17025:2005(E), Clause 5.1)*

5.2 Personnel *(ISO/IEC 17025:2005(E), Clause 5.2)*

NOTE: All references to Calibration Certificates in *ISO/IEC 17025:2005(E)* are not applicable to environmental testing.

5.2.6 Additional Personnel Requirements

5.2.6.1 Technical Manager Qualifications

The applicable requirements for technical managers are given below.

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.

d) Any technical manager of an accredited environmental laboratory engaged in radiological analysis shall be a person with a bachelor's degree in chemistry, environmental, biological sciences, physical sciences or engineering with twenty-four (24) college semester credit hours of chemistry with two (2) or more years of experience in the radiological analysis of environmental samples. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year experience.

e) The technical manager(s) of an accredited environmental laboratory engaged in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements:

i. For procedures requiring the use of a transmission electron microscope, a bachelor's degree, successful completion of courses in the use of the instrument, and one (1) year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.

ii. For procedures requiring the use of a polarized light microscope, an associate's degree or two (2) years of college study, successful completion of formal coursework in polarized light microscopy, and one (1) year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.

iii. For procedures requiring the use of a phase contrast microscope, as in the determination of airborne fibers, an associate's degree or two (2) years of college study, documentation of successful completion of formal coursework in phase contrast microscopy, and one (1) year of experience, under supervision, in the use of the instrument.

f) Any technical manager of an accredited environmental laboratory engaged in the examination of radon in air shall have at least an associate's degree or two (2) years of college and one (1) year of experience in radiation measurements, including at least one (1) year of experience in the measurement of radon and/or radon progeny.

5.2.6.2 Technical Manager Qualification Exceptions

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

b) A full-time employee of an industrial waste treatment facility with a minimum of two (2) years of experience under supervision in testing of environmental samples taken within such facility for the scope of that facility's regulatory permit shall be deemed to meet the requirements for

serving as the technical manager of an accredited laboratory. Such accreditation for an industrial waste treatment facility shall be limited to the scope of that facility's regulatory permit.

c) Persons who do not meet the education credential requirements but possess the requisite experience of Section 5.2.6.1 shall qualify as technical manager(s) subject to the following conditions.

i) The person shall be a technical manager of the laboratory on the date the laboratory applies for accreditation and/or becomes subject to accreditation under this Standard, and shall have been a technical manager in that laboratory continuously for the previous twelve (12) months or more.

ii) The person will be approved as a technical manager for only those fields of accreditation for which he/she has been technical manager in that laboratory for the previous twelve (12) months or more.

iii) A person who is admitted as a technical manager under these conditions, and leaves the laboratory, will be eligible for hire as a technical manager for the same fields of accreditation in another accredited laboratory.

5.2.7 Data Integrity Training

Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis for all current employees. Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution. The initial data integrity training and the annual refresher training shall have a signature attendance sheet or other form of documentation that demonstrates all staff have participated and understand their obligations related to data integrity.

Data integrity training requires emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient. The topics covered in such training shall be documented in writing (such as an agenda) and provided to all trainees. At a minimum, the following topics and activities shall be included:

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

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

c) data integrity training documentation;

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

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

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

5.3 Accommodation and Environmental Conditions *(ISO/IEC 17025:2005(E), Clause 5.3)*

5.4 Environmental Methods and Method Validation

NOTE: All references to Calibration Laboratories and Calibration Methods in *ISO/IEC 17025:2005(E)* in these Clauses are not applicable to environmental testing.

5.4.1 General (*ISO/IEC 17025:2005(E), Clause 5.4.1)*

5.4.2 Selection of Methods (*ISO/IEC 17025:2005(E), Clause 5.4.2)*

5.4.3 Laboratory-Developed Methods *(ISO/IEC 17025:2005(E), Clause 5.4.3)*

5.4.4 Non-Standard Methods *(ISO/IEC 17025:2005(E), Clause 5.4.4*) ~~is not applicable to this module and is addressed in specific technical modules based on technology.~~

5.4.5 Validation of Methods *(ISO/IEC 17025:2005(E), Clause 5.4.5)* ~~is not applicable to this module and is addressed in specific technical modules based on technology.~~

5.4.5.4 See 1.5.1 of each of the technical modules for discipline-specific requirements. Except when specified, an initial demonstration of capability (see 1.6 of the technical modules) is adequate to validate reference methods.

5.4.6 Estimation of Analytical Uncertainty

Clause 5.4.6 of the *ISO/IEC/IEC 17025:2005(E)* concerning calibration testing does not apply. The following requirement replaces the *ISO/IEC Clause*. Environmental testing laboratories shall have a procedure(s) for estimating analytical uncertainty. Quality control measurement data may be used to determine analytical uncertainty.

5.4.7 Control of Data *(ISO/IEC 17025:2005(E), Clause 5.4.7)*

5.5 Calibration Requirements (ISO/IEC 17025:2005(E), Clause 5.5)

NOTE: *ISO/IEC Clauses 5.5.1 to 5.5.12* apply with respect to equipment in environmental testing laboratories.

5.5.13 Additional Requirements and Clarifications

Calibration requirements for analytical support equipment are included in this Section while requirements for instrument (testing) calibration are included in technical modules (i.e., Asbestos, Chemistry, Microbiology, Radiochemistry and Toxicology).

5.5.13.1 Support Equipment

This Standard applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices), if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume.

a) All support equipment shall be maintained in proper working order. The records of all repair and maintenance activities, including service calls, shall be kept.

b) All support equipment shall be calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use. The results of such calibration or verification shall be within the specifications required of the application for which this equipment is used or:

i) the equipment shall be removed from service until repaired; or

ii) the laboratory shall maintain records of established correction factors to correct all measurements.

c) Raw data records shall be retained to document equipment performance.

d) On each day the equipment is used, balances, ovens, refrigerators, freezers and water baths shall be checked and documented. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.

e) Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis.

5.6 Measurement Traceability

5.6.1 General *(ISO/IEC 17025:2005(E), Clause 5.6.1)* is not applicable to environmental testing.

5.6.2 Specific Requirements (*ISO/IEC 17025:2005(E), Clause 5.6.2)* is not applicable to environmental testing.

5.6.3 Reference Standards and Reference Materials *(ISO/IEC 17025:2005(E), Clause 5.6.3)*

5.6.4 Additional Requirements and Clarifications

5.6.4.1 Reference Standards and Reference Materials

The laboratory shall provide satisfactory evidence of correlation of results, for example, by participation in a suitable program of inter-laboratory comparisons, proficiency testing, or independent analysis.

a) Reference Standards

Where commercially available, this traceability shall be to a national standard of measurement.

b) Reference Materials

Where possible, traceability shall be to national or international standards of measurement or to national or international standard reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

5.6.4.2 Documentation and Labeling of Standards, Reagents, and Reference Materials

Documented procedures shall exist for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory.

a) The laboratory shall retain records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, and recommended storage conditions.

b) For original containers, if an expiration date is provided by the manufacturer or vendor it shall be recorded on the container. If an expiration date is not provided by the manufacturer or vendor it is not required.

c) Records shall be maintained on standard, reference material, and reagent preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

d) All containers of prepared standards, reference materials, and reagents shall bear a unique identifier and expiration date.

e) Procedures shall be in place to ensure prepared reagents meet the requirements of the method.

f) Standards, reference materials, and reagents shall not be used after their expiration dates unless their reliability is verified by the laboratory.

5.7 Collection of Samples *(ISO/IEC 17025:2005(E), Clause 5.7)*

5.7.4 Additional Requirements

a) Documentation shall include the date and time of sampling.

b) Any deviations from sampling procedures shall be documented.

5.8 Handling Samples and Test Items *(ISO/IEC 17025:2005(E), Clause 5.8)*

5.8.5 Additional Requirements – Documentation

The following are essential to ensure the validity of the laboratory's data.

a) The laboratory shall have a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates.

b) This laboratory code shall maintain an unequivocal link with the unique field ID code assigned to each sample.

c) The laboratory ID code shall be placed as a durable mark on the sample container.

d) The laboratory ID code shall be entered into the laboratory records and shall be the link that associates the sample with related laboratory activities such as sample preparation.

e) In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the laboratory ID code may be the same as the field ID code.

5.8.6 Additional Requirements – Sample Acceptance Policy

The laboratory shall have a written sample acceptance policy that includes the following:

a) proper, full, and complete documentation, which shall include sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample;

b) proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink;

c) use of appropriate sample containers;

d) adherence to specified holding times;

e) sufficient sample volume to perform the necessary tests;

f) procedures to be used when samples show signs of damage, contamination or inadequate preservation; and

g) qualification of any data that do not meet the above requirements.

5.8.7 Additional Requirements – Sample Receipt Protocols

5.8.7.1 The laboratory shall implement procedures for verifying and documenting preservation.

5.8.7.2 If the sample does not meet the sample receipt acceptance criteria listed in this Standard, the laboratory shall either:

a) retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or

b) fully document any decision to proceed with the analysis of samples not meeting acceptance criteria.

i) The condition of these samples shall be noted on the chain of custody or transmittal form and laboratory receipt documents.

ii) The analysis data shall be appropriately qualified on the final report.

5.8.7.3 The laboratory shall utilize a permanent chronological record such as a logbook or electronic database to document receipt of all sample containers.

a) This sample receipt log shall record the following:

i) client/project name,
ii) date and time of laboratory receipt,
iii) unique laboratory ID code (see Section 5.12.1.b)i.), and
iv) signature or initials of the person making the entries.

b) During the login process, the following information shall be unequivocally linked to the log record or included as a part of the log. If such information is recorded/documented elsewhere, the records shall be part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample.

NOTE: The placement of the laboratory ID number on the sample container is not considered a permanent record.

i) The field ID code, which identifies each sample, shall be linked to the laboratory ID code in the sample receipt log.

ii) The date and time of sample collection shall be linked to the sample and to the date and time of receipt in the laboratory.

iii) The requested analyses (including applicable approved method numbers) shall be linked to the laboratory ID code.

iv) Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.

5.8.7.4 All documentation, such as memos, chain of custody, or transmittal forms that are transmitted to the laboratory by the sample transmitter, shall be retained.

5.8.7.5 A complete chain of custody record form, if utilized, shall be maintained.

5.8.8 Additional Requirements – Legal Chain of Custody Protocols

Legal chain of custody procedures are used for evidentiary or legal purposes. If a client specifies that a sample is to be used for evidentiary purposes, then a laboratory shall have a written SOP for how that laboratory will carry out legal chain of custody.

5.8.9 Additional Requirements – Sample Storage and Disposal

a) Samples shall be stored according to the conditions specified by preservation protocols.

i) Samples that require thermal preservation shall be stored under refrigeration that is +/- 2°C of the specified preservation temperature unless regulatory or method specific criteria exist. For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C shall be acceptable.

ii) Samples shall be stored away from all standards, reagents, and food. Samples shall be stored in such a manner to prevent cross contamination.

b) Sample fractions, extracts, leachates and other sample preparation products shall be stored according to Section 5.8.9 a) above or according to specifications in the method.

c) The laboratory shall have SOPs for the disposal of samples, digestates, leachates and extracts or other sample preparation products.

5.9 Quality Assurance for Environmental Testing *(ISO/IEC 17025:2005(E), Clause 5.9)*

5.9.3 Essential Quality Control Procedures

These general quality control principles shall apply, where applicable, to all testing laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (i.e., asbestos, chemical, microbiological, radiological, toxicity) and are further described in Technical Modules. The standards for any given test type shall assure that the applicable principles are addressed:

a) All laboratories shall have detailed written protocols in place to monitor the following quality controls:

i) positive and negative controls (see technical modules), chemical or microbiological as applicable to the test type, to monitor tests such as blanks, matrix spikes, reference toxicants;

ii) tests to define the variability and/or repeatability of the laboratory results such as replicates;

iii) measures to assure the accuracy of the method including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures;

iv) measures to evaluate method capability, such as limit of detection and limit of quantitation 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/external standard calculations, and statistical analyses;

vi) selection and use of reagents and standards of appropriate quality;

vii) measures to assure the selectivity of the test for its intended purpose; and

viii) measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the method such as temperature, humidity, light or specific instrument conditions.

b) All quality control measures shall be assessed and evaluated on an on-going basis and quality control acceptance criteria shall be used.

c) The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist.

The quality control protocols specified by the laboratory's SOP shall be followed (see Section 4.2.8.5 in this Standard). The laboratory shall ensure that the essential standards outlined in Technical Modules or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent, the QC in the mandated method or regulations is to be followed.

5.10 Reporting the Results ~~*(ISO/IEC 17025:2005(E), Clause 5,10)*~~

NOTE: All references to Calibration Certificates in *ISO/IEC 17025:2005* are not applicable to environmental testing.

~~*ISO/IEC 17025:2005(E), Clause 5.10.4* does not apply to environmental testing activities.~~

5.10.1 General *(ISO/IEC 17025:2005(E), Clause 5.10.1)*

5.10.2 Test Reports and Calibration Certificates *(ISO/IEC 17025:2005(E), Clause 5.10.2)*

5.10.3 Test Reports *(ISO/IEC 17025:2005(E), Clause 5.10.3)*

5.10.4 Calibration Certificates *(ISO/IEC 17025:2005(E), Clause 5.10.4)* does not apply to environmental testing activities.

5.10.10 Exceptions

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

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

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

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

c) see Section 5.10.1, paragraph 3.

5.10.11 Additional Requirements

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

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

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

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