Quality Assurance Manual

For the TIAER Laboratory

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SECTION 1 - TABLE OF CONTENTS

SECTION 1 - TABLE OF CONTENTS 3

SECTION 2 – INTRODUCTION AND SCOPE 5

2.1 Policy 5
2.2 Scope of Testing 5
2.3 Table of Contents, References and Appendices 5
2.4 Glossary and Acronyms or Abbreviations Used 5

Acronyms and Abbreviations 5

SECTION 3 – ORGANIZATIONAL ROLES AND RESPONSIBILITIES 7

3.1 Laboratory Organizational Structure 7
TIAER Management and Organization 8
Figure 1 Organizational Chart of Pertinent Personnel in TIAER 8
3.2 Responsibility and Authority 9

SECTION 4 – QUALITY SYSTEMS 10

4.1 Quality Policy 10
4.2 Quality Assurance Manual 10

SECTION 5 – DOCUMENT MANAGEMENT 11

5.1 Controlled Documents 11
5.1.1 Document Changes to Controlled Documents 12
5.2 Obsolete Documents 12
5.3 Standard Operating Procedures 13
5.3.1 Test Method SOPs 14

SECTION 6 – REVIEW OF REQUESTS, TENDERS AND CONTRACTS 15

6.1 Procedure for the Review of Work Requests 15
6.2 Documentation of Review 16

SECTION 7 – SUBCONTRACTING OF TESTS 16

SECTION 8 – PURCHASING SERVICES AND SUPPLIES 17

SECTION 9 – SERVICE TO THE CLIENT 17

9.1 Client Confidentiality 17

SECTION 10 – COMPLAINTS 18

SECTION 11 – CONTROL OF NON-CONFORMING WORK 18

SECTION 12 – CORRECTIVE ACTION 19

12.1 Selection and Implementation of Corrective Actions 20
12.2 Monitoring of Corrective Action 20
12.3 Technical Corrective Action 20
12.4 Policy for Exceptionally Permitting Departures from Documented Policies and Procedures 21

SECTION 13 – PREVENTIVE ACTION 21

SECTION 14 – CONTROL OF RECORDS 21

14.1 Records Management and Storage 24
14.2 Legal Chain of Custody Records 25

SECTION 15 – AUDITS AND MANAGEMENT REVIEW 25

15.1 Internal Audits 25
15.2 External Audits 26
15.3 Performance Audits 26
15.4 Quality Management System and Laboratory Meetings 26

SECTION 16 – PERSONNEL, TRAINING, AND DATA INTEGRITY 27

16.1 Job Descriptions 27
16.2 EMPLOYEE TRAINING NEEDS AND TRAINING RECORDS 27
16.3 PERSONNEL RESPONSIBILITIES 28

16.3.1 Laboratory Manager (NELAP Technical Director) 28
16.3.2 Laboratory Quality Assurance Officer (NELAP Quality Manager) 28
16.3.3 Other Personnel 29
16.4 Data Integrity 31
16.5 Data Integrity and Ethics Training 32
16.6 General Training 32

SECTION 17 – ACCOMMODATIONS & ENVIRONMENTAL CONDITIONS 33

SECTION 18 – TEST METHODS AND METHOD VALIDATION 34

18.1 Demonstration of Capability (DOC) 34
18.2 On-Going (or Continued) Proficiency 35
18.3 Initial Test Method Evaluation 35
18.3.1 LOD (formerly MDL) and MAL 35
18.3.2 PQL & LOQ 35
18.3.3 Precision and Bias 36
18.3.4 Selectivity 36
18.4 Estimation of Uncertainty 36
18.5 Laboratory-Developed or Non-Standard Method Validation 37
18.6 Control of Data 37

SECTION 19 – EQUIPMENT 39

19.1 General Equipment Requirements 39
19.2 Support Equipment 40
19.2.1 Support Equipment Maintenance 41
19.2.2 Support Equipment Calibration 41
19.3 Analytical Equipment 41
19.3.1 Maintenance for Analytical Equipment 41
19.3.2 Initial Instrument Calibration 42
19.3.3 Continuing Instrument Calibration 43
19.3.4 Unacceptable Continuing Instrument Calibration Verifications 44

SECTION 20 – MEASUREMENT TRACEABILITY 44

20.1 Reference Standards 45
20.2 Reference Materials 46
20.3 Transport and Storage of Reference Standards and Materials 46
20.4 Labeling of Reference Standards, Reagents, and Materials 47

SECTION 21 – SAMPLE MANAGEMENT 48

21.1 Sample Receipt 48
21.2 Sample Acceptance 48
21.3 Sample Identification 49
21.4 Sample Storage 49
21.5 Sample Disposal 49
21.6 Sample Transport 50
21.7 Sampling Records 50

SECTION 22 – QUALITY OF TEST RESULTS 50

22.1 Essential Quality Control Procedures 50
22.2 Internal Quality Control Practices 51
22.3 Method Blanks 53
22.4 Laboratory Control Samples 53
22.5 Matrix Spikes and Matrix Spike Duplicates 54
22.6 Surrogate Spikes 54
22.7 Proficiency Test Samples or Interlaboratory Comparisons 54
22.8 Data Review 55

SECTION 23 – REPORTING OF RESULTS 55

23.1 Test Reports 55
23.2 Supplemental Test Report Information 56
23.3 Environmental Testing Obtained from Subcontractors 56
23.4 Electronic Transmission of Results 56
23.5 Amendments to Test Reports 56

SECTION 24 – APPENDICES 57

Appendix 24.1 Fields of NELAP Accreditation 57

Appendix 24.2 TIAER Laboratory and QA Employees, Qualifications and Job Descriptions 58
Appendix 24.3 TIAER Laboratory Equipment List 59
Appendix 24.4 TIAER Demonstration of Capability Certification Statement 60
Appendix 24.5 List of Approved TIAER Laboratory Subcontractors and Vendors 61
Appendix 24.6 Data Integrity and Ethics 62
Code of Ethics Statement 62
Personal Quality Assurance Responsibilities 62
Quality Policy Statement 63
Appendix 24.7 Standard Operating Procedures 64
Appendix 24.8 List of Approved Reference Materials 67

SECTION 2 – INTRODUCTION AND SCOPE

The purpose of this *Quality Assurance Manual* is to outline the quality system of the Texas Institute for Applied Environmental Research (TIAER) laboratory. The *Quality Assurance Manual* defines the policies, procedures, and documentation that assure analytical services continually meet a defined standard of quality that is designed to provide clients with data of known and documented quality and, where applicable, demonstrate regulatory compliance.

2.1 Policy

The *Quality Assurance Manual* sets the standard under which all laboratory operations are performed including the laboratory's organization, objectives, and operating philosophy.

2.2 Scope of Testing

The laboratory scope of analytical testing services includes those currently listed in Appendix 24.1, Fields of Accreditation.

2.3 Table of Contents, References and Appendices

The table of contents is in Section 1 of this Manual. This *Quality Assurance Manual* uses the references from the 2016 TNI (NELAP) Standard. Standard Operating Procedures/Quality Assurance Manual addenda (SOP/QAMs) are described in Appendix 24.7. Individual SOPs contain specific references to chemical and biological laboratory methods. All current TIAER SOPs related to laboratory activities are included in the SOP Index on the TIAER website. The SOP/QAM Table in the Appendix 24.7 is an example that is updated as this procedure is revised.

2.4 Glossary and Acronyms or Abbreviations Used

Quality control terms are generally defined in the TIAER's QAM addenda (QAMs) for laboratory quality control, QAM-Q-101. TIAER's QAMs deal with instrumentation, safety, administrative, waste, quality and management issues. SOPs are chemical and biological methods used in the laboratory to generate data. Additional terms and definitions may be found in the 2016 TNI (NELAP) Standard.

Acronyms and Abbreviations

A list of acronyms and abbreviations used in this document and their definitions are:

AA – atomic absorption spectrometry
ASTM – American Society for Testing and Materials
AWRL – Ambient Water Reporting Level
°C – degrees Celsius
Cal – calibration
CCB – continuing calibration blank

CCV – continuing calibration verification
COA – certificate of analysis
COC/SIF–Chain of Custody/Sample Information Form
DO – dissolved oxygen
DOC – Demonstration of Capability
DOP – Demonstration of Performance
DSHS - The Texas Department of State Health Services
EPA – Environmental Protection Agency
ESDMS- Environmental Sample Data Management System
GC - Gas chromatography
ICP – Inductively coupled plasma spectrometry
ICB – initial calibration blank
ICV – initial calibration verification
INELA – Institute for National Environmental Laboratory Accreditation
ISO/IEC–International Organization for Standardization/International Electrochemical Commission
LCS - laboratory control sample
LCSD - laboratory control sample duplicate
LFB – laboratory fortified blank
LM - Laboratory Manager
LOD - Limit of Detection (formerly MDL)
LOQ - Limit of Quantitation (formerly RL)
LQAO – Laboratory Quality Assurance Officer
MAL - Minimum Activity Limit
MDA - Minimum Detectable Activity
MDL – Method Detection Limit, also known as the Limit of Detection (LOD)
mg/Kg– milligrams per kilogram
mg/L – milligrams per liter
MS – matrix spike
MSD – matrix spike duplicate
NELAC– National Environmental Laboratory Accreditation Conference
NELAP– National Environmental Laboratory Accreditation Program
NIST – National Institute of Standards and Technology
PQL - Practical Quantitation Limit (not necessarily equal to the LOQ)
PT – proficiency test(ing)
QA – Quality Assurance
QAM – Quality Assurance Manual and addenda or sections thereof
QAO - TIAER Quality Assurance Officer (projects only)
QAPP - Quality Assurance Project Plan
QC – Quality Control
QMT - Quality Management Team (Lab Manager with upper management)
RAD - Radiation Absorbed Dose
Rem - Roentgen Equivalent Man
RL – Reporting Level (now is LOQ)
R - Roentgen
RPD – Relative Percent Difference
RSO - Radiation Safety Officer
SOP – Standard Operating Procedure
S - spike
Std – standard
TAMUS- Texas A&M University System
TCEQ - Texas Commission on Environmental Quality
TIAER - Texas Institute for Applied Environmental Research
TNI - The NELAC Institute
TSU - Tarleton State University
µCi/g - microcuries per gram
µCi/L - microcuries per liter
µg/L – micrograms per liter
USDOE- United States Department of Energy
USEPA- United States Environmental Protection Agency
USNRC- United States Nuclear Regulatory Commission
UVvis – ultraviolet/visible light

SECTION 3 – ORGANIZATIONAL ROLES AND RESPONSIBILITIES

Policy

The TIAER analytical laboratory, through Tarleton State University, is a legally identifiable organization. Through application of the policies and procedures outlined in this chapter, the laboratory assures that it is impartial and that personnel are free from undue commercial, financial, or other undue pressures that might influence their technical judgment. The laboratory is responsible for carrying out testing activities that meet the requirements of the TNI/NELAP Standard and that meet the needs of the client.

3.1 Laboratory Organizational Structure

Policy

The organizational structure described below minimizes the potential for conflicting or undue interests that might influence the technical judgment of analytical personnel. TIAER is not aware of existing situations in which conflicts of interest or undue pressures influence the technical judgment of analytical personnel. TIAER's work for clients does not depend on the values resulting from analytical measurements.

TIAER is a unique multidisciplinary research center in Stephenville, Texas, housed at Tarleton State University, which is part of the Texas A&M University System. TIAER, a non-profit organization, conducts environmental research projects funded by private, state and federal entities. For over three decades, TIAER has worked with industry and governmental agencies to shape workable solutions to environmental problems in agriculture. As a proponent of industry-led solutions to nonpoint source pollution, TIAER brings together the distinct concerns of entrepreneurs and environmentalists to develop effective public policies and cooperative science-based solutions. Addressing emerging environmental issues, particularly those related to land management, is a matter of understanding the interfaces among policy, science, constituency, and economics. Researchers at TIAER include policy analysts, economists, mathematical modelers, data analysts, chemists, biologists, hydrologists and field operations staff.

TIAER has offices in Ferguson, the Athletics Administrative Building and the Hydrology Annex, all of which are located on the main campus of Tarleton State University. Computer facilities maintained in the three buildings by the TIAER computer resources division include personal computers for employees, internet access provided by Texas A&M University T-1 lines, SAS™ and Microsoft Access™ capabilities for TIAER's water quality databases and other databases, and a variety of other computer services and software.

TIAER also has two mobile laboratories, which are typically located outside the main lab on the Tarleton campus, but may be deployed to remote locations for measurement of analytes with short holding times. The same personnel, equipment, and QA/QC procedures that apply to the main laboratory also apply to the mobile laboratories, extensions of the main laboratory. Work in the mobile labs is unaccredited.

TIAER employs approximately 20 staff members, plus student workers, graduate assistants and part-time technicians. The analytical laboratory employs a team of analysts including chemists and microbiologists, technicians, and student interns. Two non-lab staff members work exclusively in field operations, while several other staff members participate in field operations along with other duties. TIAER employees generally adhere to the Tarleton State University schedule, working Monday through Friday from 8:00 a.m. until 5:00 p.m. Because many of TIAER's sample collection activities are based on rainfall runoff, the field

operations staff, laboratory staff, and others as needed, frequently work outside of normal working hours, especially on week-ends and holidays.

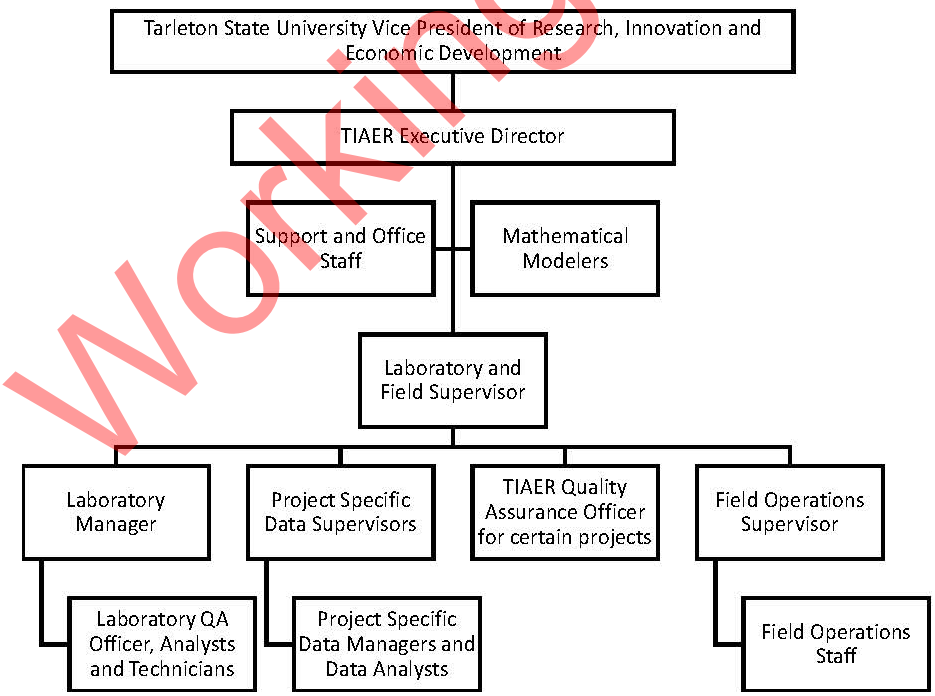
TIAER uses the Tarleton State University tax ID number, which is available upon request.

TIAER Management and Organization

TIAER's Director, reports directly to the Vice President of Research, Innovation and Economic Development. TIAER's Lead Scientist and Project Managers coordinate all TIAER projects for which environmental data are gathered. Staff members are independent of one another, yet communicate with each other and coordinate their efforts in the implementation of TIAER's quality system. Figure 1 presents the organizational hierarchy of those involved in the production and quality assurance of environmental data.

The TIAER Laboratory Manager is responsible for all activities in the TIAER Analytical Laboratory. All analysts, technicians, and student workers who work in the TIAER Analytical Laboratory report directly to the TIAER Laboratory Manager. The Laboratory Manager and Lead Scientist work together in coordinating the quality assurance aspects of the TIAER laboratory. TIAER Project Managers report directly to the TIAER Director, but may coordinate directly with the Laboratory Manager. Project managers who are not part of the TIAER staff coordinate directly with the Laboratory Manager. The Radiation Safety Officer is responsible for the radiochemistry aspect of the program, with QC oversight by the Laboratory Manager.

Figure 1 **Organizational Chart of Pertinent Personnel in TIAER***



* Appendix 24.2 provides a list of all TIAER laboratory employees, with qualifications, the position description title used by the Texas A&M University System and the TIAER designation that more appropriately describes job functions. Figure 1 uses TIAER designations. NELAP designations are in bold.

3.2 Responsibility and Authority

The term "MANAGEMENT" includes the Laboratory Manager (NELAP Technical Director), Laboratory Quality Assurance Officer (NELAP Quality Manager), TIAER Data Supervisor, TIAER Laboratory and Field Supervisor, and Lead Scientist. The TIAER Director may also be involved in decisions affecting data quality. These individuals are also referred to as the TIAER Quality Management Team.

Policy

Management has overall responsibility for the technical operations and authority needed to generate the required quality of laboratory operations.

Management's commitment to quality and to the Quality System is stated in the Quality Policy, which is upheld through the application of related policies and procedures.

Management ensures technical competence of personnel operating equipment, performing tests, evaluating results, or signing reports, and limits authority to perform laboratory functions to those appropriately trained and/or supervised.

Procedure

The responsibilities, authorities, and interrelationships of the personnel who manage, perform, or verify work affecting the quality of environmental tests are documented in Appendix 24.2, which lists all TIAER laboratory and quality assurance employees and position description titles designated by the Texas A&M University System.

Management bears specific responsibility for maintenance of the Quality System. This includes defining roles and responsibilities to personnel, approving documents, providing required training, providing a procedure for confidential reporting of data integrity issues, and periodically reviewing data, procedures, and documentation.

Management ensures that audit findings and corrective actions are completed within required time frames.

A designated alternate is appointed by management during the absence of the Laboratory Manager, and always if the absence is more than 15 days. Potential designated alternates are found in Appendix 24.2. The TCEQ will be notified if the absence of the LM exceeds 35 calendar days.

The Laboratory Manager is responsible for defining the minimal level of education, qualifications, experience, and skills necessary for all positions in the laboratory and assuring that technical staff have demonstrated capabilities in their tasks. The Laboratory Manager formulates the goals with respect to the education, training, and skills of the laboratory personnel. The laboratory has a policy and procedures for identifying training needs and provide training of laboratory personnel. The training program is relevant to the present and anticipated tasks of the laboratory.

TIAER QAM Q-107, "Laboratory Personnel Training" describes the procedural requirements and training needs of laboratory personnel within the Quality System. Demonstrations of capability, annual retraining, analyst certification and corrective actions are covered in this document. Personnel are not allowed to perform any procedure affecting data generation in the laboratory until they are trained and have demonstration of capability (DOC)

documented in accordance with this QAM. Training forms with authorized signatures constitute the annual or new certification for the individual analyst on the specific analyte or suite of analytes, and management's authorization for the analyst to perform the analysis.

Training is kept up to date as described in Section 16.4 by periodic review of training records and through employee performance review. TIAER QAM-Q-107 contains specifics of TIAER's training program.

SECTION 4 – QUALITY SYSTEMS

The laboratory's Quality System is documented in this *Quality Assurance Manual* and referenced quality system documents, including SOP/QAMs. Cumulatively they describe TIAER's policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan for ensuring quality in its work processes, products, and services.

4.1 Quality Policy

The quality policy is signed and dated, and is issued under the authority of the TIAER management, which demonstrates management's commitment to integrity, ethics, the quality system and associated standards. A copy of TIAER's Quality Policy Statement is also found as Appendix 24.6. The policy is reprinted below.

Texas Institute for Applied Environmental Research
Quality Policy Statement

The objective of TIAER's quality system, and the commitment of management, is to consistently provide our customers with data of known and documented quality that meet their requirements. Our policy is to use good professional practices, to uphold and maintain the highest quality of service, continually improve the effectiveness of the management system, and to comply with the current National Environmental Laboratory Accreditation Conference Institute (TNI) international 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 also maintains a strict policy of client confidentiality except where prohibited by law.

4.2 Quality Assurance Manual

Policy

Management ensures that the laboratory's policies and objectives for quality are documented by reference or by inclusion in the *Quality Assurance Manual*, and that the *Quality Assurance Manual* is communicated to, understood by, and implemented by all personnel concerned. Where the *Quality Assurance Manual* inherently documents laboratory requirements, a separate SOP or policy is not required.

Procedure

All employees sign a Personnel Training Form, kept with their training records, that states that they have read and understood the *Quality Assurance Manual*, and forms for the Quality Policy and Code of Ethics Statement. These forms are attachments to QAM-Q-107 and this document.

The *Quality Assurance Manual* is maintained current and up-to-date by the Quality Management team.

SECTION 5 – DOCUMENT MANAGEMENT

QAM-A-102 "Laboratory Document and Data Control"
QAM-A-104 "Preparation and Control of Laboratory Procedures"

This Section provides an overview of procedures for document management, which includes controlling, distributing, reviewing, and accepting modifications. The purpose of document management is to preclude the use of invalid and/or obsolete documents. The entire procedure is found in TIAER QAM-A-102.

The laboratory manages two types of documents, 1) controlled and 2) obsolete.

A CONTROLLED DOCUMENT is an approved, current document, electronic or paper, that is uniquely identified, issued, tracked, and kept current as part of the quality system. Controlled document versions may be internally or externally controlled. The most current and approved versions of controlled documents are used.

OBSOLETE DOCUMENTS are previously approved documents, including procedures, forms and logbooks, either electronic or paper, that have been superseded by more recent versions, sent to permanent storage, or have been retired due to non-use.

Policy

All documents that affect the quality of laboratory data are managed appropriately according to the scope and depth required.

5.1 Controlled Documents

TIAER QAM-A-102 and QAM-A-104 describe the procedures for control and maintenance of documentation. These procedures clearly indicate the time period during which the procedure or document is in effect. Controlled Working Copies are used in the laboratory online manuals. Other controlled documents include paper and electronic forms and tables which are described in various SOP/QAMs. Forms are controlled by use of Master and Document Control Logbooks described in QAM-A-102 and maintained by the Laboratory Manager.

Policy

Documents, including reports, procedures and forms are reviewed and approved for use by appropriate personnel prior to issue. The Laboratory Manager, Lab Quality Assurance Officer, TIAER Project QAO, and/or any other pertinent section supervisors will review and approve SOP/ QAMs for their quality and administrative procedures. The Laboratory Manager, LQAO, and others as appropriate, review and approve SOP/QAMs for analytical

procedures, instrument calibration and operation, safety, waste, maintenance, and other laboratory procedures. Examples of external documents may include USEPA/USNRC/USDOE methods manuals, Standard Methods, pertinent journal articles used in certain SOP/QAM references, and QAPPs.

Procedure

Documents and forms are reviewed and approved at least annually by signatories to ensure their contents are suitable and in compliance with the current quality systems requirements, and accurately describe current operations. Various laboratory logbooks are pre-numbered pages of approved forms from SOP/QAMs. Overall procedure updating and approval processes are part of the Quality Management Review done on at least an annual basis. Approved copies of documents and forms are available at all locations where operations are essential to the effective functions of the laboratory; and are found or described in the various SOPs addressing them.

The main text of this QAM is not necessarily updated when SOP/QAMs are revised, except on an annual basis, though the appendices may be updated as necessary and appropriate. This modular approach lends itself to more timely and dynamic updating.

All SOP/QAMs are uniquely identified with 1) date of issue and effective dates, 2) revision identification, 3) page number, 4) total number of pages, or a mark to indicate the end of the document, and 5) copy of signatures of the issuing authority (i.e. management). Controlled copies of SOP/QAMs are issued by the Lab Manager. This master list includes the SOP/QAM identification, revision number, and name, the name of the recipient, and the date on which the SOP/QAM was issued to them. The Table of Contents for Controlled Manuals is updated each time a SOP/QAM is revised with the new revision number and date of approval (date of last signature on the approval sheet). Further information is provided in QAM-A-104.

The Master List of Documents (E-log) contains a list of external documents and reference material that includes title, revision or date of publication, and location. This document list is maintained by the Laboratory Manager. The logbook is updated periodically as needed.

5.1.1 Document Changes to Controlled Documents

TIAER procedures for changes to controlled documents are specified in QAM-A-102 and QAM-A-104. Both SOPs are included in the SOP Manuals.

Procedure
QAM-A-104 contains details of the procedures for making changes to both paper and electronic controlled documents. Electronic working copies of TIAER SOP/QAMs are scanned copies of the original, controlled hard copy with the words "Working Copy" in red. Approved new or revised SOP/QAMs are then scanned. The previous scanned version is deleted and the newly approved scanned version becomes the official electronic working copy for the laboratory. Electronic versions of forms, QC worksheets, and laboratory templates are also controlled and maintained by the Laboratory Manager and updated when the SOP/QAM is updated.

5.2 Obsolete Documents

Policy

All invalid or obsolete documents are removed, or otherwise prevented from unintended use.

Procedure

Obsolete SOP/QAMs retained for legal use or historical knowledge preservation are appropriately marked "Retired" on the cover and retained by the Laboratory Manager/LQAO in a locked area. The Laboratory Manager is responsible for ensuring that all retired copies of SOP/QAMs are removed when a new revision is issued. The Laboratory Manager is responsible for removing and filing retired forms and ensuring current, approved controlled documents for the laboratory are in use.

5.3 Standard Operating Procedures

STANDARD OPERATING PROCEDURES (SOPs) are used to ensure consistent application of common methods and are written procedures that describe in detail how to accurately reproduce laboratory processes. QUALITY ASSURANCE MANUAL ADDENDA (QAMs) are general use texts which document organizational procedures and instrumentation. The SOP/QAMs and SOP/QAM Table of Contents are located in Appendix 24.7.

SOPs are formal documents with predefined section headings and contents. Some general policy statements may be less formal descriptions of procedures described in the *Quality Assurance Manual* or other documents, but do not supersede formal and approved SOP/QAMs or QAPPs.

Policy

Copies of all SOP/QAMs are readily accessible to all personnel who use them.

Procedure

For each accredited analyte or test method, the TIAER laboratory develops chemical, radiochemical and biological Standard Operating Procedures (SOPs) based on specific, approved methods from Standard Methods for the Examination of Water and Wastewater (latest online edition) and of the USEPA/NRC/DOE, where such standards exist. In cases where the agencies have not approved methods for an analysis, or more appropriate methods are necessary for program purposes, the best available industry standard is used in developing TIAER SOPs. Examples of such references are Methods of Soil Analysis, published by the Soil Science Society of America, Inc., et al., for various extractable levels of phosphorus or nitrogen (e.g. Mehlich III, bioavailable P) and Standard Methods for the Examination of Water and Wastewater, published by the American Public Health Association, et al., for chlorophyll-a and pheophytin-a. Other references include articles from peer-reviewed journals, such as the Journal of Environmental Quality, for anaerobic absorption of soil phosphorus, and United States Department of Agriculture methods for estimated soil organic carbon and calcium carbonate determinations. In all cases, only the best available technology concept is used when determining sources for writing or revising SOPs.

TIAER SOP designations consist of the SOP acronym, hyphen, letter designating the usage/functional group with which the SOP is identified, hyphen, and a three digit number, followed by the procedure name. Example: SOP-C-106, "Determination of Orthophosphate Phosphorus". For TIAER's analytical laboratory, chemical and biological analytical SOPs are designated as the "C" series. Instrument operation and calibration procedures are derived from specific vendor instrument manuals and EPA or other approved Standard Methods, and are designated as the "I" series. "Q" series QAMs are quality related, "S" are safety related,

"W" are waste and pollution control, "A" are administrative and "R" are for radiochemistry methods (RI & RC). SOP/QAMs are written and reviewed by laboratory staff, followed by review and approval of the Laboratory Manager or LQAO and one other concurring staff member. Some SOP/QAMs shared within TIAER are also reviewed and approved by other managers outside the laboratory.

Each SOP/QAM indicates the effective date, the revision number, and the signature(s) of the Laboratory Manager and other concurrence as appropriate. TIAER QAM-A-104, which is included in Appendix 24.7, describes required inclusions in SOP/QAMs and the procedures for development and revision of SOP/QAMs.

5.3.1 Test Method SOPs

Policy

The laboratory has SOPs for all test methods within its scope and for procedures that are part of the Quality System that accurately reflect how the analytical process is performed. Appendix 24.7 has the SOP revisions in effect at the time of this revision of this QAM. A modular approach to review and revision of these SOP/QAMs allows for their issuance and control without having to necessarily revise the text of the QAM proper. Where certain equipment manuals or published methods accurately reflect exact laboratory procedures in detail, a separate SOP is not required. Examples of this are certain TCEQ methods used by TIAER exactly as written.

Any deviation from a test method is documented, including both a description of the change made and a technical justification. The deviation from a test method is reported to the client. For projects having a quality assurance project plan (QAPP), modifications to methods are specified in footnotes to the table listing measurement performance specifications.

Procedure

Each Test Method SOP includes or references (as applicable) the following:

Identification of the test method;
Applicable matrix or matrices;
Detection limit;
Scope and application, including components to be analyzed;
Summary of the test method;
Definitions;
Interferences;
Safety;
Equipment and supplies;
Reagents and standards;
Sample collection, preservation, shipment and storage;
Quality control;
Calibration and standardization;
Procedure;
Data analysis and calculations;
Method performance;
Pollution prevention;
Data assessment, including acceptance criteria for quality control measures;
Corrective actions for out-of-control;
Contingencies for handling out-of-control or unacceptable data;

Waste management;
References; and,
Any tables, diagrams, flowcharts and validation data.

SECTION 6 – REVIEW OF REQUESTS, TENDERS AND CONTRACTS

Policy

The review of all new work assures that oversight is provided so that requirements are clearly defined, the laboratory has adequate resources and capability, and the test method is applicable to the customer's needs. This process assures that all work will be given adequate attention without shortcuts that may compromise data quality.

Contracts or Cooperative Agreements for new work must be signed documents, except for those with Texas A&M University entities, which may also be verbal agreements.

Procedure

6.1 Procedure for the Review of Work Requests

The laboratory determines whether it has the necessary accreditations and resources to meet the work request, including schedules, equipment, deliverables, and personnel. The TIAER Laboratory Manager has the opportunity to review contracts involving the production of environmental data by the TIAER laboratory prior to the formal signing of the contract. The purposes of the review are to ensure the requirements and methods are adequately defined, documented, and understood, to establish that the laboratory has the necessary resources, equipment, and trained personnel to perform the test with the expected quality, and to ensure selection of appropriate analytical methods that are capable of meeting the clients' requirements.

Any differences between the contract and the Laboratory Manager's assessment of the contract are resolved before the contract is signed and work commences.

The laboratory informs the TIAER project manager of the results of the review if it indicates any potential conflict, deficiency, lack of accreditation, or inability of the lab to the complete the work satisfactorily. The TIAER project manager is responsible for ensuring the issues are resolved or for negotiating with the client concerning the reported problem areas.

The client is informed of any deviation from the contract including the test method or sample handling processes. All differences between the request and the final contract are resolved and recorded before any work begins. It is necessary that the contract be acceptable to both the laboratory and the client. For projects requiring a QAPP, the details are established prior to the initiation of data collection and all parties indicate approval by signing the QAPP.

TIAER project managers, typically external to the laboratory, are responsible for submitting bids and negotiating contracts with clients. The project managers and the Operations Manager maintain copies of all contracts.

The review and approval process is repeated when there are amendments to the original contract or QAPP that affect project activities related to laboratory methods and procedures. The participating personnel are given copies of the amendments and, where applicable, annual revisions to the QAPP.

6.2 Documentation of Review

Records are maintained for every contract or work request, when appropriate. Pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract will result, where appropriate, in written documentation in the contract, monitoring plan, or quality assurance project plan.

SECTION 7 – SUBCONTRACTING OF TESTS

A SUBCONTRACT LABORATORY is defined as a laboratory external to this laboratory, or at a different location than the address indicated on the front cover of this manual, that performs analyses for the *laboratory* on TIAER projects. TIAER's mobile laboratory, which does not have a constant address, is considered a section of the TIAER laboratory, not a subcontract laboratory. Other laboratories selected by clients or TIAER non-laboratory divisions to perform work during the development and completion of some TIAER contracts, monitoring plans, and QAPPs are not the responsibility of the TIAER laboratory and are not included as part of TIAER's NELAP accreditation efforts.

Policy

When subcontracting analytical services, the TIAER laboratory and project managers or designees assure that work requiring accreditation is placed with a NELAP-accredited laboratory or one that meets applicable statutory and regulatory requirements for performing the tests, *where applicable*. For some projects, subcontracted work may include analytes for which NELAP accreditation does not exist. The client is informed concerning the status of all analytical work subcontracted to another laboratory.

Procedure

A list of approved subcontractors used by the TIAER laboratory is maintained. A copy of this list is included as Appendix 24.5.

A copy of the certificate and analyte list for NELAP laboratory subcontractors may be maintained as evidence of compliance, where applicable.

The TIAER project manager or designee notifies the client of the intent to subcontract the work in writing, upon consultation with the TIAER Laboratory Manager. Subcontracting of analytical work may be required in events such as equipment failure or resource shortages. The project manager gains the written approval of the client to subcontract their work prior to implementation, unless an unexpected situation arises for which loss of data could result due to inability to obtain prior written approval.

Requirements for production of data that will be subcontracted to outside entities may not always be reviewed prior to finalization of the contract or QAPP. Subcontracted laboratories are informed of their responsibilities in the production of quality data and are either signatories to the QAPP, or they sign a verification letter that they have received a copy of the QAPP and will adhere to its requirements. Verification letters are always used when subcontracted laboratories have not been selected prior to QAPP finalization. Some documentation of competency for the subcontract laboratory that is agreeable to the client is obtained. Where applicable, a copy of certification by a regulatory or accrediting body fulfills the documentation requirement. The client may set additional requirements for use of a subcontract laboratory.

The laboratory performing the subcontracted work and all non-NELAP accredited work is identified in the final project report. The laboratory assumes responsibility to the client for the subcontractor's work, except in the case where a client or a regulating authority specified which subcontractor is to be used.

When the TIAER lab subcontracts other laboratories to perform analyses, TIAER will inform the sub-contract lab in writing of all sample receipt requirements (e.g. temperature) and request that TIAER be informed as soon as possible if excursions are noted so that TIAER can determine whether to proceed with the analyses.

SECTION 8 – PURCHASING SERVICES AND SUPPLIES

Policy

The TIAER laboratory ensures that purchased supplies and services that affect the quality of environmental tests are of the required or specified quality by using approved suppliers and products.

Procedure

TIAER is required to follow the Texas A&M University System (State of Texas) purchasing guidelines for acquiring services and supplies. TIAER Management submits requests to purchase services and supplies to the Tarleton State University Purchasing Department. The Laboratory Manager approves technical content of purchasing documents prior to ordering.

Evaluation of suppliers is accomplished by ensuring the supplier ships the product or material ordered and that the material is of the appropriate quality by signing packing slips or other supply receipt documents. The purchasing documents contain the data that adequately describe the services and supplies ordered.

TIAER purchasing keeps a list of approved suppliers for the laboratory, though others may be used at the discretion of the Laboratory Manager.

TIAER QAM-Q-102, "Laboratory Material Acceptance Criteria," describes TIAER's procedures for purchasing, receiving, and storage of supplies that affect the quality of environmental tests, in addition to TAMUS requirements. This QAM also describes the use of unique identifiers for all reagents and standards, and dilutions or solutions made from them. The identifier codes are recorded in all logbooks or electronic data records where they are used in data collection activities for traceability back to the manufacturer.

SECTION 9 – SERVICE TO THE CLIENT

TIAER Management and project managers collaborate with clients and/or their representatives in clarifying their requests and in monitoring of the laboratory performance related to their work. Each request is reviewed to determine the nature of the request and the laboratory's ability to comply with the request within the confines of prevailing statutes and/or regulations without risk to the confidentiality of other clients.

9.1 Client Confidentiality

Policy

The laboratory confidentiality policy is to not divulge or release any information to a third party without proper authorization.

All electronic data (storage or transmissions) are kept confidential, based on technology and laboratory limits, as required by client or regulation unless otherwise specified by law.

Procedure

The following statement is included on electronic data transferals, where appropriate or required.

This message is intended exclusively for the individual or entity to which it is addressed. This communication may contain information that is proprietary, privileged or confidential or otherwise legally exempt from disclosure. If you are not the named addressee, you are not authorized to read, print, retain, copy, or disseminate this message or any part of it. If you have received this message in error, please notify the sender immediately by e-mail and delete all copies of the message.

SECTION 10 – COMPLAINTS

The purpose of this section is to assure that customer complaints are addressed and corrected. This includes requests to verify results or analytical data.

Policy

The pertinent project manager reviews all complaints and determines appropriate action.

Procedure

All customer complaints are documented by the person receiving the complaint. Complaints are addressed by the pertinent project manager, who works with appropriate personnel, as necessary to resolve the issue. If it is determined that a complaint is without merit, it is documented, and the client is contacted. If it is determined that the complaint has merit, a corrective action is initiated. See Section 12 for corrective action procedures. Resolutions to complaints with merit are documented.

In the event that a client has questions, concerns or complaints about data production or laboratory services, they are directed to the Laboratory Manager for resolution at the discretion of the TIAER project manager. The Laboratory Manager will investigate the situation, in consultation with the Lead Scientist or others, and determine if corrective action is warranted. Every attempt is made to satisfy the client's wishes or concerns without compromising the data quality. All telephone conversations regarding complaints that concern laboratory issues are documented in the Laboratory Manager's personal logbook or electronic phone log. Emails and correspondence regarding complaints and concerns are maintained as electronic records for a minimum of five years.

SECTION 11 – CONTROL OF NON-CONFORMING WORK

NON-CONFORMING WORK is work that does not meet acceptance criteria or requirements. Non-conformances can include unacceptable quality control results (see Section 23, Reporting of Results) or departures from standard operating procedures or test methods. Requests for departures from laboratory procedures are approved by the client and documented.

Policy

The policy for control of non-conforming work is to identify the non-conformance, determine if it will be permitted, and take appropriate action. All employees have the authority to stop work on samples when any aspect of the process does not conform to laboratory requirements. Documentation of the situation on a corrective action report is required.

Procedure

The responsibilities and authorities for the management of non-conforming work are designated in TIAER QAM-Q-105, "Corrective Actions." The procedure for investigating and taking associated corrective actions of non-conforming work are also described in Section 12.

The laboratory evaluates the significance of the nonconforming work, and takes corrective action immediately. The client is notified by the project manager or designee if their data have been impacted. Resumption of work after non-conformance is authorized by the Laboratory Manager.

Laboratory staff or others involved in production or management of environmental data immediately notify the appropriate Management member or project manager of any non-conformance that may require resampling and analysis. The Management member or project manager reviews the significance of non-conformance, confers with others as necessary, and develops a course of action. Nonconformances that involve normal QC failures or mishandling of a limited number of samples (e.g., spilling of the contents of two sample containers) will be reported during project data submissions. Situations that are determined to substantively affect the overall project objectives are communicated to the TIAER project manager within 24 hours. After ascertaining details of the situation affecting overall project objectives, determining corrective actions, and developing preventive actions, the TIAER project manager notifies the client according to project requirements. Audits or events discovered that cast doubt on the validity of any results reported by the laboratory are reported to the client in writing within 30 days of the discovery.

SECTION 12 – CORRECTIVE ACTION

CORRECTIVE ACTION is the action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence (TNI/NELAP, 2016).

Policy

Deficiencies cited in external assessments, internal quality audits, data reviews, complaints, or managerial reviews are documented and require corrective action. Corrective actions taken are appropriate for the nature and magnitude of the problem and the degree of risk.

Procedure

Anyone who deals with laboratory data is responsible for initiating corrective action if they recognize a problem in data production or management. The initial step is to complete a corrective action report and route it to the appropriate section supervisor. TIAER QAM-Q-105 contains details of the procedures by which situations requiring corrective actions are documented, monitored, and resolved.

For deficiencies identified during internal or external audits, Management shall coordinate in formulating responses. All deficiencies are investigated and a corrective action plan developed and implemented if determined necessary. The implementation is monitored for

effectiveness by quality management reviews. Section 15.4 describes TIAER's quality management system reviews. Documentation of findings and corrective actions resulting from audit reports are in the form of written audit reports and written responses.

Specific corrective action protocols specified in test methods may over-ride general corrective action procedures specified in this manual.

12.1 Selection and Implementation of Corrective Actions

ROOT CAUSE is the condition or event that, if corrected or eliminated, would prevent the recurrence of a deficiency.

Once an exceedance or nonconformance is noted, the first action is an investigation to determine the root cause. Records are maintained of nonconformances requiring corrective action to show that the root cause(s) was investigated, and include the results of the investigation.

Where uncertainty arises regarding the best approach for analysis of the cause of exceedances that require corrective action, appropriate personnel will recommend corrective actions to be initiated by the analyst.

The pertinent section supervisor and/or QAO ensures that corrective actions are discharged within the agreed upon time frame. It should be noted that the root causes of some nonconformances may not be determined, while other root causes may not be remediated.

12.2 Monitoring of Corrective Action

Policy

Appropriate section managers will monitor implementation and documentation of the corrective action to assure that the corrective actions were effective. Section managers include the Laboratory Manager, LQAO, Field Operations Supervisor, Data Supervisor, and TIAER Project Quality Assurance Officer.

Procedure

TIAER QAM-Q-105 contains details of the procedure for monitoring corrective actions.

12.3 Technical Corrective Action

CAUSE ANALYSIS in corrective action investigates the root cause of the problem.

Policy

Sample data associated with failed quality control is evaluated for the need to be reanalyzed or qualified.

Procedure

Unacceptable quality control results are documented, and if the evaluation requires cause analysis, the cause and solution are recorded.

The analyst is responsible for initiating or recommending corrective actions and ensuring that exceedances of quality control acceptance criteria are documented.

Analysts routinely implement corrective actions for data with unacceptable QC measures. First level correction may include re-analysis without further assessment. If the test method SOPs addresses the specific actions to take, they are followed. Otherwise, corrective actions start with assessment of the cause of the problem.

Section supervisors review corrective action reports and suggest improvements, alternative approaches, and procedures where needed. If the reported data are adversely affected by the nonconformance, the client is notified in writing.

The discovery of a non-conformance for results that have already been reported to the client must be immediately evaluated for significance of the non-conformance, its acceptability to the client, and determination of the appropriate corrective action.

12.4 Policy for Exceptionally Permitting Departures from Documented Policies and Procedures

Policy

The laboratory allows the release of non-conforming data only with approval on a case-by-case basis by the Laboratory Manager, LQAO, TIAER Project QAO and pertinent project manager. Planned departures from procedures or policies do not require audits or investigations. The client is always informed when nonconforming data are released.

Procedure

Permitted departures for non-conformances, such as QC failures, are fully documented and include the reason for the departure, the affected analysis, the impact of the departure on the data, and the data. Identified and defined data flagging mechanisms are described in QAM-A-103, "Data Reporting by the Laboratory Manager".

SECTION 13 – PREVENTIVE ACTION

PREVENTIVE ACTION, rather than corrective action, aims at minimizing or eliminating inferior data quality or other non-conformance through scheduled maintenance and review, before the non-conformance occurs.

Preventive action includes, but is not limited to, review of QC data to identify quality trends, regularly scheduled staff quality meetings, annual managerial reviews, scheduled column adjustments, evaluating a new program or process in tandem with the old one to assure at least one working system, equipment maintenance, and other actions taken to prevent problems.

All employees have the authority to recommend preventive action procedures; however, management is responsible for selecting and implementing preventive action.

SECTION 14 – CONTROL OF RECORDS

RECORDS are a subset of documents, usually data recordings that include annotations, such as daily refrigerator temperatures posted to a laboratory form, lists, templates, tables, spreadsheets, or analyst notes on a chromatogram. Records may be on any form of media, including electronic and hard copy. Records allow for the historical reconstruction of laboratory activities related to sample-handling and analysis.

Policy

The laboratory maintains a record system appropriate to its needs, records all laboratory activities, and complies with applicable standards or regulations as required.

Procedure

The laboratory retains all original observations, calculations and derived data, calibration records, and a copy of the test report for a minimum of five years after the end of a project.

Retained records must contain the following information:

Identity of personnel involved in sampling, sample receipt, preparation, or testing;

Information related to equipment, test methods, sample receipt, sample preparation, and data verification;

Record-keeping system that facilitates retrieval of information for verification or inspection; Changes to records are initialed and dated by TIAER staff;

Records, except those generated by automated systems, are generated directly, promptly, and legibly in permanent ink;

Entries are not obliterated by methods such as erasures, over-writings, or markings. All changes are made by one line marked through the entry with the entry signed or initialed and dated by the individual making the change; and

Changes to electronic records are tracked through the data system audit tracking system or by notations made in the electronic system.

Records of all procedures to which a sample is subjected while in the possession of the laboratory are kept, including the following:

Sample preservation, including appropriateness of sample container and compliance with holding time requirement;

Sample identification, receipt, acceptance and log-in;

Sample storage and tracking including shipping receipts, sample transmittal forms (chain of custody form);

Documented procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples;

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

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

Copies of final reports;

Archived SOP/QAMs;

Correspondence relating to laboratory activities for a specific project;

All corrective action reports, audits and audit responses;

Proficiency test results and raw data; and

Results of data review, verification, and cross-checking procedures.

Analytical records (such as calibrations, tabular printouts, computer data files, analytical notebooks, and run logs) include the following:

Laboratory sample ID numbers;

Date and time of analysis;

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

Analysis type;

All manual calculations, e.g., manual integrations; analyst's or operator's initials/signature;

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

Sample analysis;

Standard and reagent origin, receipt, preparation, and use;

Calibration criteria, frequency and acceptance criteria;

Data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;

Quality control protocols and assessment;

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

Method performance criteria including expected quality control requirements;

Administrative records;

Personnel qualifications, experience and training records;

Records of demonstration of capability for each analyst;

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

Quality control records, including spikes, duplicates and check standards;

Internal audit reports;

Management reviews; and

Corrective and preventive actions.

14.1 Records Management and Storage

Policy

Records, including electronic records, are relatively easy to retrieve, legible, and protected from deterioration or damage; held secure and in confidence; and are available to accrediting authorities for a minimum of five years, unless otherwise stated by a project QAPP or overriding guidance document.

The laboratory maintains a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage and reporting.

Archived information and access logs are protected against fire, theft, loss, environmental deterioration, vermin, and in the case of electronic records, electronic or magnetic sources.

In the event that the laboratory transfers ownership or goes out of business, all electronic and paper data records will be transferred to the Dick Smith Library at Tarleton State University. The library will maintain the records in storage for a minimum of five years and will make them available to the client.

Procedure

Access to protected records is limited to Management or their designees to prevent unauthorized access or amendment. Only authorized personnel are allowed into the TIAER laboratory. Visitors may be escorted by laboratory or TIAER personnel. Student technicians are not generally allowed unescorted access or keys unless expressly approved by the TIAER Laboratory Manager and Director. The laboratory is locked at all times when approved personnel are not present. The sample login area contains sample records, COC/SIFs, and temporary storage of samples prior to receipt and is kept locked and closed at all times when approved personnel are not present. Key access to all areas is controlled by the university Physical Facilities. Any key issuance must be approved and signed by the TIAER Director. University police monitor activities of the buildings after hours.

Procedures for identification, collection, access, filing, storage, and disposal of records are found in TIAER QAM-A-104, "Preparation and Control of Laboratory Procedures", QAM-Q-104, "Laboratory Data Entry and Review", and QAM-A-102, "Laboratory Document and Data Control" (Appendix 24.7).

Observations, data and calculations are recorded at the time they are made. When mistakes are made in technical records, each mistake is crossed out with a single line (not erased, made illegible, or deleted) and the correct value entered alongside. Corrections are signed or initialed by the person making the correction. For electronic systems, all changes are tracked by the audit trail or by added notes. When changes are made to technical records for reasons other than for correction of transcription errors, the reason for the change is recorded on the document.

All records stored on electronic media are supported by the hardware and software required for retrieval and have hard-copy or write-protected backup copies. Records are filed promptly and in an organized fashion.

The TIAER database for environmental data resides on a server in the TIAER local area network. This database, termed the Environmental Sample Data Management System (ESDMS), is a Microsoft Access® database file. All sample records are stored in this file. A tape back-up of all files on the server is performed each night. A DOS batch file is executed each night that copies the database file (ESDMS.MDB) to a folder on a different TIAER server (dbmgr).

14.2 Legal Chain of Custody Records

EVIDENTIARY SAMPLE DATA are used as legal evidence, including chain of custody records.

TIAER does not currently analyze data for the purpose of providing legal evidence. If any previously collected TIAER data are requested to be used as legal evidence, the quality of the data have been assured and documented. If future contracts include the production of data for use as evidentiary samples, all required procedures will be clearly specified in the QAPP for the project.

SECTION 15 – AUDITS AND MANAGEMENT REVIEW

AUDITS measure laboratory performance and verify compliance with accreditation/ certification and project requirements. Audits specifically provide management with an on-going assessment of the quality system. They are also instrumental in identifying areas where improvement in the quality system will increase the reliability of data. Audits are of three main types: internal, external, and performance.

Notification of clients for events that cast doubt on the validity of the results associated with their project data is completed in accordance with project requirements after determination of the potential invalid data.

15.1 Internal Audits

Policy

The laboratory conducts internal audits of its quality systems activities, including data integrity, using trained and qualified personnel at least annually. Personnel may not audit their own activities except when it can be demonstrated that an effective audit will be carried out.

Procedure

Annually, Management prepares a schedule of internal audits to be performed during the year. These audits verify compliance with the requirements of the quality system, including analytical methods, SOPs, ethics policies, other laboratory policies, and the TNI/NELAP Standard.

It is the responsibility of the LQAO to plan and organize internal audits as required by the schedule and requested by management.

The area audited, the audit findings, and audit responses, including documentation of corrective actions, are recorded.

All investigations that result in findings of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients.

Clients must be notified promptly, in writing, when audit findings cast doubt on the validity of their project data.

Audits are reviewed after completion to assure that corrective actions were implemented and effective. Responses to all internal audits will require follow-up documentation by the internal auditor to indicate whether all findings have been appropriately addressed, to be completed within three months of the auditee's response and completion of corrective actions. Any findings not satisfactorily addressed will be reviewed on a monthly basis through completion.

15.2 External Audits

Policy

It is the laboratory's policy to cooperate and assist with all external audits, whether performed by clients or an accrediting authority.

All external audits are fully documented and tracked to closure.

Procedure

Management ensures that all areas of the laboratory are accessible to auditors as applicable and that appropriate personnel are available to assist in conducting the audit.

Any findings related to an external audit follow corrective action procedures.

Management ensures that corrective actions are carried out within the timeframe specified by the auditor(s).

15.3 Performance Audits

Performance audits may be Proficiency Test Samples, internal single blind samples, double blind samples through a provider or client, or anything that tests the performance of the analyst and method.

The policy and procedures for Proficiency Test Samples are discussed in Section 22.7

15.4 Quality Management System and Laboratory Meetings

Policy

Top level management meets as needed to discuss new and ongoing issues related to the TIAER Laboratory Quality System.

Procedure

Quality Management System (QMS) meetings are held informally throughout the year. Attendees may include top management such as the TIAER Director, Lead Scientist, Project Managers, Data Supervisors, Data Managers, Laboratory Manager, LQAO, and the TIAER

Project Quality Assurance Officer. Issues dealing with maintaining and improving quality assurance are discussed at these meetings. The reviews may be documented by a memo, email, or Corrective Action Report, noting any items that require follow-up or documentation, the responsible party, and the expected time frame for completion. If all items are considered complete, the record will indicate such.

Members of the laboratory staff have frequent meetings, informally at the beginning of each work day, and periodically in a formal setting, which may be documented by written notes emailed to lab staff and filed. Lab meeting notes are reviewed the Laboratory Manager and LQAO to determine whether any items requiring action have been completed or if procedures need to be clarified.

The Laboratory Manager will submit an Annual Management Review to upper management by March 1st of each year. The LM will document the required follow-up responses from upper management. Management Review will include the current Quality Policy Statement.

SECTION 16 – PERSONNEL, TRAINING, AND DATA INTEGRITY

16.1 Job Descriptions

Policy

Job Descriptions (JDs) are prepared for each position, as specified by the Texas A&M University System. The JDs specify job descriptions, job functions, the percentage of time devoted to each job function, physical and environmental demands and hazards, cognitive skills, oral and written communication requirements, and other job-related knowledge and skills. The Human Resources Department of Tarleton State University maintains JDs for project staff and TIAER retains copies of the JDs.

Project personnel have the appropriate education and experience to be qualified to perform their assigned work. Initial and ongoing personnel qualifications are determined, training needs are identified, access to appropriate training opportunities are provided, and the acquisition of needed knowledge and skills are verified through the annual Tarleton State University personnel evaluations system, and annual training and/or demonstrations of capability for the laboratory staff.

Procedure

Personnel qualification requirements are determined by job class and on a position-specific basis. Personnel qualifications for job classes are determined by the Tarleton Human Resources staff as part of the position classification system. Job descriptions specify educational requirements, technical and non-technical knowledge and skills, certifications, time-in-grade, and other requirements for all positions (e.g., Associate Research Scientist, Research Assistant). Job descriptions include the specific tasks, minimum education and qualifications, skills, and experience required for each position.

Education and experience for laboratory personnel are included in Appendix 25.2 of this document.

16.2 EMPLOYEE TRAINING NEEDS AND TRAINING RECORDS

Training needs are determined annually on an individual basis by supervisors in consultation with employees, as part of the Tarleton annual review process. Training determinations for laboratory staff may be based on statutory requirements, TNI/NELAP requirements, management directives, SOPs, QAM addenda, and quality assurance project plans.

TIAER Management and Tarleton Human Resources maintains a record of all staff training through the annual performance review process and internal staff training records. The TIAER Project Quality Assurance Officer (QAO) maintains training records for TIAER field staff. The Laboratory QAO maintains electronic and paper copies of training and demonstration-of-capability records for laboratory staff.

16.3 PERSONNEL RESPONSIBILITIES

16.3.1 Laboratory Manager (NELAP Technical Director)

The TIAER Laboratory Manager is responsible for:

Supervision of laboratory personnel involved in generating analytical data for each project, ensuring that laboratory personnel involved in generating analytical data have adequate training and a thorough knowledge of quality assurance project plans (QAPPs) and all SOP/QAMs specific to the analyses or task performed and/or supervised and maintaining records of such training,

Overseeing all laboratory operations to ensure that all quality assurance/quality control (QA/QC) requirements are met, all documentation related to the analysis is complete and adequately maintained, and that results are recorded accurately in the database,

Writing or overseeing the writing of SOP/QAMs for all analytical procedures and instrument calibration and maintenance;

Updating all analytical and instrument SOPs in a timely manner, including annual reviews of SOPs,

Ensuring that laboratory corrective actions are documented, reported, and implemented,

verifying that all data entered for each sample are correct according to the information on the Chain-of-Custody/Sample Information Form (COC/SIF) and analytical logbooks prior to transfer from ESDMS to the appropriate table for export to the client,

Data reporting to specified clients, and

Notifying pertinent TIAER Project Managers of particular circumstances that may adversely affect the quality of data.

16.3.2 Laboratory Quality Assurance Officer (NELAP Quality Manager)

The Laboratory Quality Assurance Officer is responsible for:

Conducting in-house audits of laboratory procedures to ensure compliance with written SOP/QAMs and to identify potential problems,

Auditing training records and demonstrations-of-capability for laboratory analysts to ensure that all analyses are performed by trained personnel,

Ordering Performance Testing (PT) samples, documenting dilutions and preparations of PT samples, and maintaining records of PT results onsite to ensure that TIAER complies with requirements for demonstrating analytical proficiency for all analytes measured by TIAER for which PT samples are available,

Conducting reviews of TIAER's quality system to ensure its continuing suitability and effectiveness and to introduce improvements to the system as part of internal audits and for documenting QMS meetings,

Training and documentation of data integrity and ethics issues,

Investigating corrective actions and outcomes associated with analytical activities, as necessary,

Reviewing quality control spreadsheets for correctness of formulas, documentation and appropriate corrective actions for failed QC samples, and appropriate frequency of QC sample analysis, and

Reviewing and approving SOPs for analytical procedures and instrument maintenance and calibration.

16.3.3 Other Personnel

Laboratory Analysts are responsible for:

Collection of analytical results from automated analyzers and analytical procedures, following the established SOP/QAMs,

Correctly recording those data in personal logbooks,

Reporting and documenting situations requiring corrective action, and

Transferring data to analytical logbooks or the electronic database.

The TIAER Project Quality Assurance Officer is responsible for:

Coordinating development and implementation of the TIAER's QA program for certain projects only,

Writing or overseeing the writing of QAPPs and maintaining QAPPs,

Maintaining or overseeing maintenance of records of QAPP distribution, including amendments,

Ensuring the data collected for the project is of known and acceptable quality and adheres to the specifications of the QAPP,

Maintaining written records of sub-tier commitment to requirements specified in this QAPP,

Maintaining copies of all original SOPs shared between various TIAER groups and ensuring the distribution of controlled copies of shared SOPs,

Identifying, receiving, and maintaining project quality assurance records for certain projects only,

Coordinating with contractor QA specialists to resolve QA-related issues for certain projects only,

Notifying pertinent TIAER Project Managers of particular circumstances that may adversely affect the quality of data,

Conducting assessments of participating sub-tier laboratories or obtaining documentation of competence during the life of the certain projects,

Overseeing the audits of field personnel and site installations for certain projects, and

Performing validation and verification of data for submissions described in QAPPs.

The TIAER Data Supervisor is responsible for:

Ensuring that TIAER databases are appropriate for the types of data to be stored,

Supervising or working with personnel who maintain TIAER databases,

Ensuring the integrity of data shared with external and internal database users, and

Ensuring that corrective actions associated with data management are implemented, documented, reported and verified.

The TIAER Data Manager is responsible for:

Ensuring the integrity of data storage in TIAER SAS™ databases,

Maintaining TIAER's SAS™ databases, which contain environmental data for use by data analysts in statistical analysis and report generation,

Assisting in maintaining completeness of data records in TIAER's SAS™ databases,

Maintaining TIAER-generated application programs that use SAS™, and

Importing new data into TIAER's SAS™ databases.

The TIAER Database Manager is responsible for:

Ensuring the integrity of data storage in TIAER's laboratory information management system, which is a user-produced database interface titled Environmental Sample Data Management System (ESDMS),

Maintaining ESDMS, which contains sample identification information and analytical data input by laboratory staff members, prior to data transfer to the SAS™ databases, and

Assisting in maintaining completeness of data records in ESDMS.

The Radiation Safety Officer (RSO) is responsible for:

Supervision of the overall radiochemistry program at TIAER, including procedure approval,

Performance of area and personnel monitoring for exposure and contamination,

Maintenance of personnel exposure records, waste and source logs,

Ordering radioactive standards, materials and dosimetry, and

Coordination with Tarleton, Texas A&M, DSHS and TCEQ for radiation issues in the lab.

16.4 Data Integrity

DATA INTEGRITY is the result of the processes that together assure valid data of known and documented quality.

Data integrity and ethics procedures in the laboratory include training, signed and dated integrity documentation for all laboratory employees, periodic monitoring of data integrity, and documented data integrity procedures.

Policy

Managers uphold the spirit and intent by supporting integrity procedures, by enforcing data integrity procedures, and by signing and dating the data integrity procedure training forms.

Data integrity procedures and evidence of inappropriate actions are reviewed annually or through regularly scheduled internal audits, and are updated by management. The Laboratory QAO is responsible for ensuring that new employees receive training in data integrity and ethics. The Laboratory QAO maintains the signed training documentation, which are kept with other laboratory personnel training documentation. Appendix 24.6 lists the items covered by the data integrity and ethic training sessions. An ethics statement is included in QAM-Q-107, "Laboratory Personnel Training" in Appendix 24.7.

The mechanisms for confidential reporting of ethics and data integrity issues include (1) unrestricted access to senior management, (2) an assurance that personnel will not be treated unfairly for reporting instances of ethics and data integrity breaches, and (3) reporting by personnel kept anonymous to the suspected violator.

Employees are required to understand, through training and review of quality systems documents, that any infractions of the laboratory data integrity procedures will result in a detailed investigation that could lead to very serious consequences such as immediate termination, or civil/criminal prosecution.

Any potential data integrity issue is handled confidentially until a follow-up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified. Inappropriate activities are documented, including disciplinary actions, corrective actions, and notifications of clients, if applicable. These documents are maintained for a minimum of 5 years unless otherwise required by project QAPPs or overriding documents.

Procedure

Any determination for detailed investigation of data integrity issues must be communicated to senior management. Allegations are investigated and remain confidential to the extent necessary.

Documentation for all investigations that result in findings of inappropriate activity include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients.

Data integrity procedures are reviewed annually by the Laboratory Manager and the Laboratory QAO and are periodically monitored through in-depth data review, records review, or other thorough check processes.

16.5 Data Integrity and Ethics Training

Policy

Data integrity and ethics training is provided by the Laboratory QAO initially upon hire and annually thereafter for all employees associated with production of laboratory data. All Tarleton employees receive general integrity training, with records maintained by Tarleton Employee Services.

Procedure

Attendance at an initial data integrity training (part of new employee orientation) and the annual refresher training is recorded with a signature attendance sheet or other form of documentation that demonstrates all staff have participated and understand their obligations related to data integrity.

Training records regarding data integrity and ethics are signed and dated by laboratory staff and the Laboratory Manager.

When contracted technical or support personnel are used, management is responsible for ensuring that they are trained to the pertinent laboratory's quality system and data integrity procedures, competent to perform the assigned tasks, and appropriately supervised.

Topics covered are provided in writing and provided to all trainees. Training is documented in an electronic log, on a training form (QAM-Q-107-1) and on a DOC Certification Statement (Appendix 24.4)

16.6 General Training

Policy

All personnel are appropriately trained and competent in their assigned tasks before they contribute to functions that can affect data quality. It is the Laboratory Manager's responsibility to assure laboratory personnel are trained. All analysts in the TIAER laboratory shall be properly trained prior to initially performing analyses and at least annually thereafter. A training log is maintained by the Laboratory QAO by recording data from individual personnel training forms in accordance with QAM-Q-107. These forms contain information on demonstration of capability and how it is met for each analyte or procedure. Ongoing and annual DOC may be satisfied by one of the following:

Acceptable performance on a Proficiency Testing double blind sample for the analyte of interest,

Acceptable analyses of four Laboratory Control Standards made from a source other than the one for standards used in calibration,

Successful analyses of a single blind submitted by the Laboratory Manager or QA Officers Acceptable performance on a sample that has been analyzed by other analysts for precision and accuracy as described by QAM-Q-107.

Only trained personnel are authorized to perform specific tasks.

Training records are kept on individual training forms by the Laboratory QAO.

Procedure

New staff members are given introductory training and orientation upon arrival. Various forms are used depending on the use of the training. Group training is documented by signature sheets of all who attended. Laboratory training related to data quality is documented in accordance with QAM-Q-107 on a Personnel Training Form.

The initial laboratory training for a new task will contain the following steps:

All documentation and SOP/QAMs involved with a new and unfamiliar task will be read and understood by the trainee. Training will be under the direct supervision of a qualified senior analyst. During the time the analyst is training, the trainee may sign laboratory notebooks or logbooks, but laboratory notebooks must be cosigned by the senior analyst, who is responsible for the data generated.

The trainee will demonstrate competency in the new task before they can operate independently. The competency for a test method is accomplished by a demonstration of capability as indicated in the Policy section above. Approval of competency is noted by the initials or signature of the qualified senior analyst on the Personnel Training Record and by the analyst, Laboratory Manager and Laboratory QAO on the DOC Certification Statement. Each step of the training process is documented on the Personnel Training Record.

The initial DOC for all analyses will consist of four aliquots, prepared and analyzed according to the method, either concurrently or over a period of days. Initial DOC for microbiology shall include 4 LCS aliquots with or without a PT sample.

Ongoing training will consist of the following:

The analyst attests, through signature, that they have read, understood and agreed to perform the latest version of the *Quality Assurance Manual* and any method SOPs that the analyst performs.

Annually, the analyst will show continued proficiency in each method they perform. Other training as determined by management.

Proof of acceptable on-going training is documented by the annual demonstrations of capability for each analyst and each method with updated training forms and DOC Certification Statements.

SECTION 17 – ACCOMMODATIONS & ENVIRONMENTAL CONDITIONS

Policy

TIAER laboratory facilities are designed and organized to facilitate testing of environmental samples. Environmental conditions are monitored to ensure that conditions do not invalidate results or adversely affect the required quality of any measurement.

Environmental tests are stopped when the environmental conditions jeopardize the results.

Access to and use of areas affecting the quality of the environmental tests are controlled by restriction of areas to authorized personnel only.

The laboratory work spaces are adequate and appropriately clean to support environmental testing and ensure an unencumbered work area.

Procedure

Laboratory space is arranged to minimize cross-contamination between incompatible areas of the laboratory. Aisles and walkways are kept clear for safety purposes. Electrical panels are kept accessible with no obstructions. Alarmed doors remain locked during nonworking hours and the area outside is routinely patrolled by Tarleton Police. The laboratory has a motion activated camera system to record during off hours. All laboratory areas are air-conditioned with humidity controls. Ventilation hoods are constantly operating and periodically checked in accordance with Tarleton Risk Management procedure, which also details safety inspections and training. Should power be disrupted, a backup diesel generator automatically engages to provide electricity to certain equipment including sample storage refrigerators and emergency lighting. During power outages, hood sashes are lowered and the laboratory is evacuated, if noxious fumes are present in the hoods. If water supply is disrupted, all analyses and laboratory activities are stopped due to the lack of safety shower and eyewash. Bench space and work areas are cleaned immediately after use. Spills and breakages are cleaned up immediately. Radiochemistry work areas are separate from stable chemistry area. Equipment and consumables are segregated.

SECTION 18 – TEST METHODS AND METHOD VALIDATION

A method is validated before being put into use. All methods used by the laboratory are industry-accepted, published or well documented by TIAER, if newly developed.

18.1 Demonstration of Capability (DOC)

A DEMONSTRATION OF CAPABILITY (DOC) is a procedure to establish the ability of the analyst to generate data of acceptable accuracy and precision.

WORK AREAS consist of analysts with specifically defined tasks who together perform the method. Work areas together meet specified acceptance criteria and demonstrations of capability for their individual responsibilities within a method.

Policy

The laboratory confirms that it is capable of generating data of acceptable accuracy and precision on all methods before employing them.

Procedure

The DOC is documented on the form from the TNI/NELAP 2016 standard, and these completed forms are kept in the training files for each analyst.

A new DOC is performed for each analyte whenever the method, analysts, analytes, or instrument type is changed.

The Laboratory Manager certifies that technical staff members in their area of expertise are trained and authorized to perform all tests for which TIAER is accredited by signing the DOC form.

The process for DOC is documented in QAM-Q-107 (Appendix 24.7).

18.2 On-Going (or Continued) Proficiency

After the demonstration of capability is completed, on-going proficiency is maintained and demonstrated at least annually through the analysis of either single-blind samples, performing another DOC, or use of four consecutive laboratory control samples compared to pre-determined acceptance limits for precision and accuracy. This is documented in the training file of each analyst.

18.3 Initial Test Method Evaluation

For chemical analyses, the INITIAL TEST METHOD EVALUATION involves the determination of the Limit of Detection (LOD), confirmation of the Limit of Quantitation (LOQ), an evaluation of precision and bias, and an evaluation of the selectivity of the method.

18.3.1 LOD (formerly MDL) and MAL

The LOD is an estimate of the minimum amount of a substance that an analytical process can reliably detect at a level different from zero. The LOD may be analyte and matrix-specific and may be laboratory-dependent. The MAL is essentially an LOD for radiochemical analyses.

18.3.2 PQL & LOQ

According to Standard Methods, the PQL is an estimate of the minimum amount of a substance that can be reported with a specified degree of confidence, generally 95% confidence or better. The PQL is used by the TIAER laboratory to determine certain matrix spike bias or precision limits of sample duplicates for information purposes.

Policy

If an LOD study is not performed, concentrations less than the LOQ are not reported. If results are not reported outside of the calibration range (low), the LOD determination is not required and the lowest calibration standard becomes the LOD.

For some QAPPs, the lowest calibration standard may be equal to the Limit of Quantitation (LOQ, formerly RL or Reporting Limit) for those analyses with calibrations. For those analyses without calibrations and in some other cases, project specific QAPPs or contracts specify the required LOQ.

The PQL will always be greater than the LOD, and is defined as 5 times the LOD. The LOQ will always be greater than or equal to the LOD.

Procedure

LODs are determined from a quality system matrix using all sample processing steps, and are verified about annually or when there is a change in the test method or instruments affects sensitivity.

TIAER's method for determination of the LOD is equivalent to the determination of method detection limit in 40 Code of Federal Regulations part 136. The procedure for LOD determination is found in QAM-Q-101, "Laboratory Quality Control".

The LOQ is verified using a quality systems matrix sample of deionized water spiked at a level determined by the project QAPP or TCEQ AWRL list. The LOQ returns a concentration

within the acceptance criteria for accuracy, according to the requirements of the method or client data quality objectives.

18.3.3 Precision and Bias

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

BIAS is the systematic error that contributes to the difference between the mean of a significant number of test results and the accepted reference value.

Policy

Precision and bias are determined for standard and non-standard methods.

Procedure

Precision and bias are determined for standard methods through the performance of a new or annual DOC by the analyst. As time is available, ongoing precision and accuracy may be monitored for overall analytical performance through the use of graphs or mathematical control charts to assist in tracking and trending.

Precision and bias using non-standard, modified standard or laboratory-developed methods are compared to the criteria established by the client (when requested), the method, or the laboratory.

Replicate spikes in a quality system matrix are analyzed according to the outline in the TNI/NELAP 2016 standard, where applicable.

The procedure for monitoring ongoing precision and accuracy, spikes and tracking and trending of blanks is found in QAM-Q-101.

18.3.4 Selectivity

SELECTIVITY is the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances.

The laboratory evaluates selectivity through procedures defined in the test method SOPs found in Appendix 24.7

18.4 Estimation of Uncertainty

ESTIMATION OF UNCERTAINTY consists of the sum (combining the components) of the uncertainties of the numerous steps of the analytical process, including, but not limited to, sample plan variability, spatial and temporal sample variation, sample heterogeneity, calibration/calibration check variability, extraction variability, and weighing variability.

Procedure

The laboratory estimates uncertainty due to analytical processes using the standard deviation calculated from routine quality control samples. A series of independent measurements of a standard are made. The arithmetic mean and the experimental standard deviation of the mean are determined. The experimental standard deviation of the

mean is used as the standard uncertainty. Documentation of TIAER's estimation of uncertainty is maintained and evaluated by the Laboratory Manager, and is documented in the QC Module. For radiochemistry, all results are reported with the combined standard uncertainty of one standard deviation from the mean of 20 measurement points of a laboratory fortified matrix.

18.5 Laboratory-Developed or Non-Standard Method Validation

Laboratory-developed methods, modified standard methods, and non-standard methods require method validation.

Procedure

Laboratory SOP/QAMs are created and controlled in accordance with QAM-A-104, "Preparation and Control of Laboratory Procedures" (Appendix 24.7). New and nonstandard methods may be evaluated and developed from time to time. No data produced by such procedures shall be used until such time as the SOP/QAM is approved by the Laboratory Manager and Laboratory Quality Assurance Officer in writing, and the SOP/QAM has been through a successful Demonstration of Performance for new methods or instruments in accordance with QAM-Q-101. TIAER SOP/QAMs are written in the standard format and issued by the same review and approval process prior to producing any useable data. Analyst training shall be documented for such modifications on a Personnel Training Form and standard DOC may apply.

METHOD VALIDATION is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled (TNI/NELAP 2016 standard).

Policy

Where applicable, the laboratory validates non-standard methods, laboratory-designed/developed methods, standard methods used outside their published scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The Laboratory Manager is responsible for validation of non-standard methods and maintains documentation of that validation.

The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), is assessed for the intended use and whether it is relevant to the clients' needs.

Procedure

The laboratory's method validation procedures include, at a minimum, the steps described in the TNI/NELAP 2016 standard. The laboratory records method validation results, the procedure used for the validation, and a statement as to whether the method is fit for the intended use (DOP).

18.6 Control of Data

Policy

All calculations and all relevant data are subject to appropriate checks in a systematic manner.

Commercial off-the-shelf software (e. g. word processing, database and statistical programs) used within the designed application range is considered sufficiently validated when in-house programming is not used.

Procedure

The TIAER laboratory assures that computers and software are protected, maintained, and secure through measures such as documentation, locked access, and control of the laboratory environment. The ESDMS QC Module uses formulas that have been confirmed by the Laboratory QAO. The QC Module formulas, criteria, and other set values are locked by the Database Manager and cannot be changed by analysts, who input the QC sample results. The Laboratory QAO periodically reviews the module to reconfirm the formulas. QC Module is a part of the ESDMS LIMS. Any new formulas in the QC Module in ESDMS will be verified by the LQAO prior to use in the QC Module and can be changed only by the TIAER Database Manager with documented approval from the LQAO. Changes in formulas are tracked by the ESDMS Change Log. The laboratory database is backed up daily to a second, secured server located in a separate building.

TIAER's ESDMS database is locked so as not to allow changes to basic structure. Only new analyte data values are permitted to be added. Ability to revise analytical data is restricted to the Laboratory Manager. Revisions are automatically tracked to provide documentation concerning changed data. Further details of data entry security are found in Section 14.

The laboratory has procedures to ensure that transcription and calculation errors are minimized in reported data. QAM-Q-104, "Laboratory Data Entry and Review" details these procedures.

The laboratory has procedures ensuring that all quality control measures are reviewed and evaluated before data are reported. This is also addressed and documented in accordance with QAM-Q-104.

The laboratory uses the following procedures to address manual calculations, including manual integrations:

Transcription and calculation errors are minimized through data review and through periodic review of data reduction processes, which are described in QAM-Q-104.

Quality control results are reviewed by the analyst and by the Laboratory Manager or other chemist. The results are evaluated to determine whether they meet acceptance criteria by the Laboratory Manager and Project Manager before data are released to the client or transferred to the SAS™ database.

Manual integrations and any analytical notes are reviewed by the Laboratory Manager for integrity and justification prior to the release of data or transfer to the SAS™ database.

The laboratory assures that computers, user-developed computer software, automated equipment, or microprocessors used for the acquisition, processing, recording, reporting, storage, or retrieval of environmental test data are:

Documented in sufficient detail and validated as being adequate for use; Protected for integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of environmental test data; and

Held secure including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

SECTION 19 – EQUIPMENT

19.1 General Equipment Requirements

Policy

The laboratory provides all the necessary equipment required for the correct performance of the scope of environmental testing presented in this *Quality Assurance Manual*.

All equipment and software used for testing and sampling are capable of achieving the accuracy required and comply with the specifications of the environmental test method as specified in the laboratory SOP.

QAM-Q-103, "Laboratory Equipment Maintenance", describes the safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

Procedure

Equipment is operated only by authorized and trained personnel.

Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available for use by laboratory personnel and maintained by the Laboratory Manager.

All equipment is calibrated or checked before being placed into use to ensure that it meets laboratory specifications and the relevant standard specifications. No equipment may be repaired or altered without the consent and approval of the Laboratory Manager. Generally, only minor adjustments and repairs are performed by laboratory personnel in accordance with instrument manuals and documentation. More complex repairs are performed by contracted instrument service technicians. Instruments are normally repaired by contractors on site, but some instruments may be shipped off to the manufacturer or contractor for repair. All instrument repairs are documented in an electronic maintenance logbook.

Test equipment, including hardware and software, are safeguarded from adjustments which would invalidate the test results measures by limiting access to the equipment and using password protection where possible.

Equipment that has been subject to overloading or mishandling, giving suspect results, or has been shown to be defective or outside specifications, is taken out of service, isolated to prevent its use, or clearly labeled as being out of service until it has been shown to function properly. If it is shown that previous tests are affected, then procedures for non-conforming work are followed.

When equipment is needed for a test that is outside of permanent control of the laboratory, the lab ensures the equipment meets the requirements of this manual prior to its use by inspecting or otherwise testing it.

Each item of equipment and the software used for testing significant to the results is uniquely identified and records of equipment and software are maintained. This information includes the following:

Identity of the equipment and its software;

Manufacturer's name, type identification, serial number or other unique identifier;

Checks that equipment complies with specifications of applicable tests;

Current location;

Manufacturer's instructions, if available, or a reference to their location;

Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

Maintenance plan where appropriate, and maintenance carried out to date; Documentation on all routine and non-routine maintenance activities and reference material verifications;

Any damage, malfunction, modification or repair to the equipment;

Date received and date placed into service (if available); and

Condition when received, if available (new, used, reconditioned).

The equipment list for the TIAER laboratory is found in Appendix 24.3. Maintenance schedules are found in QAM-Q-103 (Appendix 24.7).

19.2 Support Equipment

SUPPORT EQUIPMENT includes, but is not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices, volumetric dispensing devices, and thermal/pressure sample preparation devices.

Policy

All support equipment is maintained in proper working order and records are kept of all repair and maintenance activities, including service calls.

Procedure

All raw data records are retained to document equipment performance. These records include logbooks, data sheets, and equipment computer files.

All support equipment is calibrated or verified annually using NIST traceable references where available. The results of the calibration of support equipment must be within specifications required in the SOP/QAMs or (1) the equipment is removed from service until repaired, or (2) records are maintained of correction factors to correct all measurements.

Support equipment such as balances, ovens, refrigerators, freezers, and water baths are checked for temperature with an NIST traceable reference thermometer, if available, each day prior to use, to ensure they are operating within the expected range for the application for which the equipment is to be used as described in the SOP. If an NIST traceable thermometer is not used, the thermometer used is at least calibration checked against the main NIST thermometer in the lab to bracket range of use or within the range of use if the expected range is less than 10°C. Temperatures are also checked daily when the laboratory is operating, or maximum/minimum readings are recorded when equipment is in use while the laboratory is closed.

Mechanical volumetric dispensing equipment are checked for accuracy at least quarterly.

For use of the autoclave, the temperature, cycle time, and pressure are documented by temperature and pressure gauges. These data are documented in accordance with QAM-I-110, "Operation and Calibration of the Autoclave". Generally, sterilized equipment and reagents are purchased certified pre-sterilized and tested for sterility at TIAER with the use of non-selective growth media. Documentation of acceptable temperature, pressure and sterility efficiency is performed on each use. Maximum registering thermometers are used. Pressure and temperature are calibrated annually by an outside contractor who provides a calibration certificate.

19.2.1 Support Equipment Maintenance

Regular maintenance of support equipment, such as balances, is conducted at least annually.

Maintenance on other support equipment, such as ovens, refrigerators, and thermometers, is conducted on an as-needed basis.

Required maintenance frequency and records of maintenance to support equipment are documented in Instrument Maintenance Logs. Each piece of support equipment does not necessarily have its own logbook. Maintenance logbooks may be shared with equipment that is housed in the same laboratory area.

19.2.2 Support Equipment Calibration

Calibration requirements for analytical support equipment and instrumentation are found in the individual analytical SOPs (Appendix 24.7). All equipment that is calibrated or calibration checked and used in data collection activities shall be designated with a unique code. This code shall be used to identify use of the equipment on all logbooks and electronic data records associated with the data produced with this equipment.

All support equipment is labeled with a unique ID, the date of calibration, the date of expiration, and the correction factor, if applicable.

19.3 Analytical Equipment

19.3.1 Maintenance for Analytical Equipment

Policy

All equipment is properly maintained, inspected, and cleaned.

Procedure

Maintenance of analytical instruments and other equipment may include regularly scheduled preventive maintenance or maintenance on an as-needed basis due to instrument malfunction and is documented in Instrument Maintenance Logs, which become part of the laboratory's permanent records. Analytical equipment maintenance is described in the individual instrument or analytical SOPs.

19.3.2 Initial Instrument Calibration

Initial instrument calibration and continuing instrument calibration verification are an important part of ensuring data of known and documented quality. If more stringent calibration requirements are included in a mandated method or by regulation, those calibration requirements override any requirements outlined here or in laboratory SOPs. Generally, instrument calibrations are provided in test methods.

Policy

All initial instrument calibrations are verified with a standard obtained from a second source traceable to a national standard when commercially available. If a second source is not available, a standard prepared from a separate lot may be used as long as the manufacturer can demonstrate the lot was prepared independently from other lots purchased.

If the reference or mandated method does not specify the number of calibration standards to use, the minimum number is four, not including blanks or a zero standard, except as noted below.

After an unacceptable initial calibration, the cause is determined and standards are re-analyzed, appropriate to the scope of the unacceptable condition. In cases where calibration cannot be redone, data may be reported to the client with qualifiers explaining the reasons and questionable results, appropriate to the situation.

Quantitation is always determined from the initial successful calibration unless the test method or applicable regulations require quantitation from the continuing calibration or do not have calibration requirements.

The lowest calibration standard is the lowest concentration for which quantitative results can be reported without qualification. The lowest calibration standard may be equal to the LOQ (per QAPP) and is greater than the limit of detection. All standards used in a calibration curve are within 25% of their calculated values from the curve. For some projects the actual LOD, not the LOQ, is used for reporting.

The highest calibration standard is the highest concentration for which quantitative results can be reported without flagging the data as suspect.

Data reported that are greater than the highest calibration standard without dilution are considered to be an estimate and are reported with a qualifier code and explained in the case narrative.

Procedure

Initial instrument calibration includes calculations, integrations, acceptance criteria, and associated statistics referenced in the test method SOP.

Sufficient raw data records are collected to allow reconstruction of the initial instrument calibration. These include, at a minimum, calibration date, test method, instrument, analysis date, analyte names, analysts signature or initials, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument responses to concentration.

Calibration date and expiration date (when recalibration is due) are recorded for equipment requiring calibration, where practicable.

Acceptance criteria are listed in individual method SOPs (Appendix 24.7) and project specific QAPPs.

Corrective actions are performed when the initial calibration results are outside acceptance criteria. Calibration points are not dropped from the middle of the curve unless the cause is determined and documented. If the cause cannot be determined, the calibration curve is re-prepared. If the low or high calibration point is dropped from the curve, the working curve is adjusted and sample results outside the curve are qualified.

Results that are less than the lower calibration standard are considered to have increased uncertainty, and are either reported with a qualifier code or explained in the case narrative.

Results that are greater than the highest calibration standard are either diluted to within the calibration range or considered to be an estimate; and if estimated, these are reported with a qualifier code and explained in the case narrative.

For instrumentation where single point calibration is recommended by manufacturer's instructions, such as with some ICP and ICP/MS technologies (with a zero and single point calibration), the following apply:

For single point plus zero blank calibrations, the zero point and the single point standard are analyzed prior to the analysis of samples, and the linear range of the instrument established by analyzing a series of standards, one of which is at the lowest quantitation level.

Zero blank and single point calibration standards are analyzed with each analytical batch for methods where they are specified.

A standard corresponding to the limit of quantitation is analyzed for each day of analysis and must meet established acceptance criteria when using single point plus zero blank calibrations.

The linearity of single point plus zero blank calibrations is verified at a frequency established by the method or the manufacturer.

19.3.3 Continuing Instrument Calibration

Policy

The validity of the initial calibration is verified prior to sample analysis by use of an initial instrument calibration verification (ICV) standard with subsequent calibration verification performed with a continuing calibration verification standard (CCV) at the end of each quality control batch.

Corrective action is initiated for continuing instrument calibration verification results that are outside of acceptance criteria.

Procedure

Instrument calibration verification is performed at the beginning and end of each quality control batch for those analyses requiring calibration. TIAER does not employ the use of internal standards.

Continuing instrument calibration verification is also performed whenever it is expected that the analytical system may be out of calibration or might not meet verification acceptance criteria.

Continuing instrument calibration verification is performed when the time period for calibration or the most recent calibration verification has expired.

Instrument calibration verification is performed for all analytical systems that have a calibration verification requirement.

Calibration is verified for each compound, element, or other discrete chemical species.

The calculations and associated statistics for continuing instrument calibration are included or referenced in the test method SOP.

Sufficient raw data records are retained to allow reconstruction of the continuing instrument calibration verification. Continuing instrument calibration verification records connect the continuing verification data to the initial instrument calibration.

Acceptance criteria for CCVs are listed in QAM-Q-101, "Laboratory Quality Control".

19.3.4 Unacceptable Continuing Instrument Calibration Verifications

If routine corrective action for continuing instrument calibration verification fails to produce a second consecutive (immediate) calibration verification within acceptance criteria, then a new calibration is performed or acceptable performance is demonstrated after corrective action with two consecutive calibration verifications.

For any samples analyzed on a system with an unacceptable calibration, some results may be useable if qualified and under the following conditions:

If the acceptance criteria are exceeded high (high bias) and the associated samples are below detection, then those sample results that are non-detects may be reported as non-detects.

If the acceptance criteria are exceeded low (low bias) and there are samples that exceed the maximum regulatory limit, then those exceeding the regulatory limit may be reported.

SECTION 20 – MEASUREMENT TRACEABILITY

Measurement quality assurance comes in part from traceability of standards to certified materials.

Policy

All equipment used that affects the quality of test results are calibrated prior being put into service and on a continuing basis. These calibrations are traceable to national standards of measurement where available.

Measurements from laboratory equipment provide the certainty required by test method or client.

If traceability of measurements to international standard units is not possible or not relevant, evidence for correlation of results through interlaboratory comparisons, proficiency testing, or independent analysis is provided.

Procedure

All equipment that affects the quality of test results are calibrated according to the minimum frequency suggested by the manufacturer, by regulation, by method, or as needed.

Traceability of measurements is assured by compliance with approved laboratory SOPs. The SOP/QAMs require documentation and labeling of all equipment, standards and reagents used in generation of data within the laboratory. All use of these elements is recorded in bound, numbered logbooks or electronic logs, including receipt, storage, disposal and audit trail of any containers of chemicals used in the laboratory for data generation. Manufacturer, lot number, grade, unique container identifications, with dates of receipt, opening, emptying and expiration all logged into the Chemical Inventory by laboratory personnel. Manufacturer, receipt date and lot number are used in tracing required standards back to the National Institute for Standard and Testing (NIST) where required. Standard balance weights, thermometers and other equipment have associated vendor certifications on file by the Laboratory Manager. Collected samples are uniquely identified by numbers that are traceable to a specific site, date, time and Chain of Custody. Samples are also logged and maintained in a Laboratory Information Management System (TIAER ESMDS).

The following procedures (Appendix 24.7) describe traceability for chemicals and samples:
- QAM-Q-101, "Laboratory Quality Control"
- QAM-Q-102, "Laboratory Material Acceptance Criteria"
- QAM-Q-103, "Laboratory Equipment Maintenance"
- QAM-Q-104, "Laboratory Data Entry and Review"
- QAM -Q-110, "Sample Receipt and Login" (shared)

Clients can verify that required amount of certainty is achieved by reviewing the internal quality control data any time they request it.

When supplies, reagents or standards are received, lab staff will attempt to obtain a Certificate of Analysis, if one is not included in the shipment. If a COA cannot be obtained the Laboratory Manager will be notified so they may obtain any necessary COAs from the manufacturer. COAs are maintained by the LQAO.

20.1 Reference Standards

REFERENCE STANDARDS are standards of the highest quality available at a given location, from which measurements are derived.

Policy

Reference Standards, such as ASTM Class 1 weights, are used for calibration only and for no other purpose unless it is shown that their performance as reference standards will not be invalidated.

Procedure

Reference standards, such as ASTM Class 1 weights or better, are calibrated by an entity that can provide traceability to national or international standards.

The following reference standards are sent out to be calibrated to a national standard:

Class 1 weights are sent out for calibration or purchased new with certificates at least annually.

The NIST reference thermometer, if not damaged or separated, is good for up to five years with a calibration certificate of five points. The thermometer must be accompanied by a certificate that matches the 5-year acceptance time. The Laboratory Manager or designee will notify the Laboratory Quality Assurance Manager so they may obtain any necessary certificates from the manufacturer if not properly received. Other thermometers are calibrated to bracket range of use, within the range of use if less than 10°C, or purchased new with such NIST traceable calibration certificates at least annually. The NIST thermometer is mercury filled only and not spirit filled. Vendor certificates and in-house logs show calibration points that bracket the range of use or are within the range of use for the equipment in which they are in service. NIST traceable clocks are not used. The barometer is sent out for calibration or purchased with NIST traceable certificate.

20.2 Reference Materials

REFERENCE MATERIALS are substances that have concentrations that are sufficiently well established to use for calibration or as a frame of reference.

Policy

Reference materials, where commercially available, are traceable to national standards of measurement, or to Certified Reference Materials, usually by a Certificate of Analysis.

Internal reference materials, such as working standards or intermediate stock solutions, are checked as far as technically and economically possible.

Procedure

Purchased Reference Materials require a Certificate of Analysis, where available. Otherwise, purchased reference materials are verified by application to a certified reference material, interlaboratory comparison, and/or demonstration of capability.

Internal Reference Materials, such as working standards and intermediate stock solutions, are checked against existing, proven standards.

Internal thermometers are checked annually against the NIST certified reference thermometer.

Working class weights are Class 1 weights or better.

20.3 Transport and Storage of Reference Standards and Materials

Policy

The laboratory handles and transports reference standards and materials in a way that protects their integrity.

Procedure

Reference standard and material integrity is protected by separation from incompatible materials and/or minimizing exposure to degrading environments or materials.

Standards, reagents and media must be stored separately from samples.

Reference standards and materials are stored according to manufacturer's recommendations and separately from working standards or samples.

20.4 Labeling of Reference Standards, Reagents, and Materials

Policy

Reference standards and materials are tracked from purchase, receipt, and storage through disposal.

Expiration dates are not extended.

Reagent quality is verified during routine blank and check standard analysis. Only approved vendors are chosen to supply these materials.

Procedure

Records for all standards, reagents, reference materials, and media include:

The manufacturer/vendor name (or traceability to purchased stocks or neat compounds);

The manufacturer's Certificate of Analysis or purity (if supplied);

The date of receipt;

Reference to the method of preparation;

Date of preparation;

Recommended storage conditions;

An expiration date after which the material shall not be used unless its reliability is verified by the laboratory. It may be documented elsewhere if referenced; and

Preparer's initials (if prepared)

In methods where the purity of reagents is not specified, analytical reagent grade is used. If the purity is specified, that is the minimum acceptable grade. Purity is verified and documented according to Section 8, Purchasing, Services, and Supplies.

All containers of standards, reagents, or materials prepared in the lab are labeled with an expiration date. Some purchased materials may not have an expiration date.

All containers of prepared standards and reference materials have a preparation date and unique identifier. This laboratory uses expiration periods specified in analytical SOPs where they exist. Where they are not specified, stock standards have expiration dates of 6 months, and working standards have expiration dates of 3 months.

Standard preparation records are kept in the Standard Logbook and indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date, and preparer's initials.

Prepared reagents are verified to meet the requirements of the test method through internal QC standards.

Standard and reagent component acceptance is described and documented in accordance with QAM-Q-102 (Appendix 24.7).

Vendors are approved by the Laboratory Manager and have established records of quality materials and service. In general, the TIAER Laboratory uses the following for scientific goods and services:

Fisher Scientific, Fox Scientific, HACH Corporation, Beckman Instruments, VWR Scientific, Aldinger Corporation, Water and Power Technologies.

SECTION 21 – SAMPLE MANAGEMENT

21.1 Sample Receipt

Procedure

When samples are received at the laboratory, their condition is documented, they are given unique identifiers, and they are logged into the sample tracking system.

21.2 Sample Acceptance

Policy

QAM-Q-110, "Sample Receipt and Login" describes TIAER's sample acceptance policy, which specifies the minimum conditions a sample must meet on receipt. If these conditions are not met, attempts are made to contact the client prior to any further processing. If the client is not immediately available, processing is initiated, when necessary to meet holding times in the event that the client requests completion of analysis. *This SOP is shared between the laboratory, field and data groups, but is not a laboratory analytical SOP.*

Procedure

The laboratory checks samples for the following qualities, where appropriate, to evaluate sample acceptance: temperature, pH, preservative type, bottle type, sample container integrity, station ID, location, date and time of collection, collector's name, preservation type, sample type, screening for radioactivity levels and comments.

The preservation checks are performed and documented upon receipt in accordance with QAM-Q-110. Samples are confirmed for thermal preservation, pH, container type and other requirements specified by the project or method.

The sample acceptance policy is available to sample collection personnel and clients, is part of the COC/SI form, and emphasizes adherence to holding times and acceptance requirements. The TIAER lab can provide guidance for the use of water-resistant ink, appropriate containers, sample volume requirements, and what to do with compromised samples as provided in SOPs, but it is up to the client or field personnel to assure collection and preservation requirements of samples prior to receipt by TIAER laboratory personnel. Any deviation from standard methods will be noted on analytical reports.

Field data sheets, which may be filled out at the time of sample collection by TIAER or client field personnel, are attached to the COC/SIF, where applicable, when samples are submitted to the laboratory. COC/SIFs, with attached field data sheets and other documentation, are kept in separate TIAER offices for at least five years after completion of the project. Other client COCs may be used and are attached to the TIAER COC/SIF.

If the checks performed upon sample receipt indicate the criteria are not met, then the sample is rejected unless a decision by the client to proceed is documented and agreed upon with the client. In either case, the condition is noted on the Chain of Custody form and subsequently in the database, and the data are qualified in the report to the client. A Corrective Action Report may be initiated to document the occurrence.

21.3 Sample Identification

Policy

Samples, including subsamples, extracts, and digestates, are uniquely identified in a permanent chronological record (in the sample logbook, aliquot preservation logbook and ESMDS database) to prevent mix-up and to document receipt of all sample containers.

Procedure

Samples are assigned sequential numbers, as described in QAM-Q-110 (Appendix 24.7).

The information recorded on the COC/SIF accompanying the sample, and later input into the ESDMS database is included in QAM-Q-110.

Each aliquot of the same sample (collected from the same site at the same time) that is submitted to the laboratory has a unique identification on the container to indicate the sample identification number and the type of analysis required.

21.4 Sample Storage

Storage conditions are monitored for any required criteria, verified, and the verification recorded in the Equipment Temperature logbook in accordance with QAM-Q-103. Holding times are flagged in the ESDMS database and printed out on the sample backlog.

Samples are held secure, as required. Samples are stored apart from standards, reagents, food or potentially contaminating sources, such that cross-contamination is minimized. All portions of samples, including extracts, digestates, leachates, or any product of the sample is maintained according to the required conditions and the bottles are uniquely identified.

21.5 Sample Disposal

Samples are disposed of according to Federal, State and local regulations. Procedures are available for the disposal of samples, digestates, leachates, and extracts. Details of TIAER's

waste disposal procedures are described in QAM-W-101, "Disposal of Laboratory Waste" (Appendix 24.7).

21.6 Sample Transport

Samples that are transported under the responsibility of TIAER, where necessary, are done so safely and according to storage conditions. This includes moving bottles within the laboratory. Specific safety operations for transport are addressed outside of this document.

21.7 Sampling Records

Policy

Sampling plans are based, whenever it is reasonable or requested by the client, on appropriate statistical sampling methods. Sampling plans are determined by project managers and clients according to project needs and are not determined by laboratory staff. Sampling plans are not addressed in this document.

Procedure

Sub-sampling within the laboratory is performed according to test method SOPs and documented in the Sample Preservation Logbook in accordance with QAM-Q-111, "Aliquot Preparation and Sample Preservation" and SOP-C-131 "Preparation of Soil Samples".

Relevant laboratory subsampling data are recorded, including the date, time, identification of the analyst dividing the sample into aliquots, what aliquots are made, laboratory preservations and storage requirements, and preparation descriptions.

SECTION 22 – QUALITY OF TEST RESULTS

22.1 Essential Quality Control Procedures

Policy

All essential quality control elements are collected and assessed on a continuing basis.

The qualities of test results are recorded in such a way that trends are detectable, and where practicable, are statistically evaluated.

For test methods that do not provide acceptance criteria for an essential quality control element or where no regulatory criteria exist, acceptance criteria may be developed using quality control tables, forms or charts. Control limits are monitored using the mean, plus or minus 3 standard deviations, or static limits such as +/- 15 percent. These limits can be found in QAM-Q-101 or project QAPPs.

The quality control procedures specified in test methods are followed by laboratory personnel. The most stringent of control procedures is used in cases where multiple controls apply. If it is not clear which is the most stringent, that mandated by test method or regulation is followed.

Procedure

To monitor the validity of environmental tests performed, review includes any one or a combination of the techniques below:

Use of certified reference materials or cultures and/or internal quality control using secondary reference materials,

Participation in proficiency testing programs,

Replicate testing using the same or different methods,

Retesting of retained samples, and/or

Correlation of results for different characteristics of a sample.

Written procedures to monitor quality controls, including acceptance criteria, are located in the test method SOPs, except where noted, and include such procedures as:

Use of laboratory control samples and blanks to serve as positive and negative controls for chemistry methods;

Use of laboratory control samples to monitor test variability of laboratory results;

Use of calibrations, continuing calibrations, certified reference materials and/or PT samples to monitor accuracy of the test method;

Measures to monitor test method capability, such as method detection limit, practical quantitation limit, and/or range of test applicability, such as linearity;

Use of regression analysis, internal/external standards, or statistical analysis to reduce raw data to final results;

Use of reagents and standards of appropriate quality;

Procedures to ensure the selectivity of the test method;

Measures to assure constant and consistent test conditions, such as temperature, humidity, rotation speed, etc., when required by test method;

Use of sterility checks for equipment, media and dilution water for microbiology; and

Use of positive and negative culture controls for microbiology.

22.2 Internal Quality Control Practices

Analytical data generated with QC samples that fall within prescribed acceptance limits indicate the test method is IN CONTROL.

QC samples that fall outside QC limits indicate the test method is OUT OF CONTROL (non-conforming) and that corrective action is required or that the data are qualified in accordance with QAM-Q-105 "Corrective Actions" (shared) or project requirements.

Policy

Detailed QC procedures and QC limits are included in test method standard operating procedures (SOPs), or where unspecified in the SOPs, are detailed elsewhere.

All QC measures are assessed and evaluated on an on-going basis, so that trends are detected.

Procedure

The following general controls are used:

Positive and Negative Controls such as:

Blanks (negative),

Laboratory control sample (positive), and

Sterility checks and control cultures (positive and negative).

Selectivity is assured through:

Absolute and relative retention times in chromatographic analyses,

Use of appropriate wavelengths and reagents for colorimetric analyses,

Use of the correct method according to its scope assessed during method validation, and

Use of reference cultures (positive and negative) from a recognized manufacturer (where applicable).

Consistency, Variability, Repeatability, and Accuracy are assured through:

Proper installation and operation of instruments according to manufacturer's recommendations or according to the processes used during method validation;

Monitoring and controlling environmental conditions (temperature, access, proximity to potential contaminants);

Selection and use of reagents and standards of appropriate quality;

Cleaning glassware appropriate to the level required by the analysis. Cleaning procedures not provided in test method SOPs are provided in QAM-I-116, "Preparation of Labware" (Appendix 24.7). For microbiology, glassware care includes use of borosilicate glassware, use of detergents designed for laboratory use, deionized water rinsing, and sterilization prior to use;

Following SOP/QAMs and documenting any deviation, assessing for impact, and treating data appropriately;

Testing to define the variability and/or repeatability of the laboratory results, such as replicates;

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

Acceptance or rejection criteria are created according to laboratory policy where no method or regulatory criteria exist. Acceptance criteria define the boundary for the appropriate

response from laboratory personnel, such as corrective action, reporting with qualifiers, reanalysis, review, and others.

Test Method Capability is assured through:

Establishment of the limit of detection where appropriate,

Establishment of the limit of quantitation or reporting level, and/or

Establishment of the range of applicability such as linearity.

Data reduction is assured to be accurate by:

Selection of appropriate formulae to reduce raw data to final results such as regression;

Periodic review of data reduction processes to assure applicability;

Microbiological calculations, data reduction, and statistical interpretations specified by each test method.

QAM-Q-101 and individual analytical SOPs summarize the key elements of a quality control system for a laboratory performing chemistry and microbiology testing.

22.3 Method Blanks

Policy

Contaminated blanks are identified according to the acceptance limits in the test method SOPs or laboratory documentation.

Samples associated with a contaminated blank are evaluated as to the appropriate corrective action for the samples (e.g. reprocessing or data qualifying codes).

Procedure

The TIAER laboratory identifies a blank as contaminated when analyte results are greater than the LOQ, or where the contamination affects the sample results according to test method requirements or client objectives. Corrective action is taken when either of these cases occurs. If the method blank exceeds the LOQ, the data are evaluated and the failure is documented. If the blank is less than 5% of the lowest analytical sample value in the batch, the data are evaluated only and do not need to be qualified. Some projects will use 10% as the screening level. Measures are taken to minimize or identify the problem, where possible, up to and including a reanalysis of the blank. If a method blank exceeds the LOQ upon reanalysis, the problem is evaluated, if possible, and the data are flagged as questionable, or are not reported.

Data that are unaffected by the blank contamination (non-detects or other analytes) are reported unqualified unless required by the project or client.

22.4 Laboratory Control Samples

LABORATORY CONTROL SAMPLES (LCS) are prepared from analyte free matrix, and spiked with verified and known amounts of analytes for the purpose of establishing precision or bias measurements.

Policy

Laboratory control samples are analyzed at a frequency mandated by method, regulation, or client request, whichever is most stringent.

Procedure

The results of laboratory control samples (LCS) are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria. The laboratory documents the calculation in the QC Module in accordance with QAM-Q-101.

The individual LCS is compared to the acceptance criteria as published in the mandated test method or project QAPP, or where there are no established criteria, the limits set by the Laboratory Manager.

22.5 Matrix Spikes and Matrix Spike Duplicates

MATRIX SPIKES (MS) are environmental samples fortified with a known amount of analyte to help assess the effect of the matrix on method performance.

TIAER analyzes matrix spike duplicates based on method requirements, but are not otherwise required by current project QAPPS.

Policy

The MS results are used to help assess the effect of the sample matrix on method performance.

Procedure

The laboratory procedure for MS includes spiking appropriate analytes at appropriate concentrations, calculating percent recoveries, and evaluating and reporting the results. Matrix spikes are analyzed at a minimum rate of 10 percent of samples processed, or at least one per QC batch.

Where there are no established criteria, the laboratory uses 75-125% recovery as the control limits for MS. For MS results outside the limits, a corrective action report is completed and the data are reported with the appropriate data qualifying code as required by project QAPPs.

22.6 Surrogate Spikes

The TIAER laboratory does not currently perform surrogate spiking for NELAC analyses.

22.7 Proficiency Test Samples or Interlaboratory Comparisons

Policy

The laboratory participates in proficiency test samples (PT) as required.

The laboratory institutes corrective action procedures for failed PT samples.

The laboratory does not share PT samples with other laboratories, does not communicate with other laboratories regarding current PT sample results, and does not attempt to obtain the assigned value of any PT sample from the PT provider.

Procedure

Proficiency Testing (PT) samples are treated as typical samples in the normal production process where possible, including the same preparation, calibration, quality control and acceptance criteria, sequence of analytical steps, number of replicates, and sample log-in. PT samples are not analyzed multiple times unless routine environmental samples are analyzed multiple times.

PT samples are analyzed at least semi-annually.

Corrective action procedures are followed for unacceptable PT results.

22.8 Data Review

Policy

The TIAER laboratory reviews all data generated in the laboratory for compliance with method, laboratory and, where appropriate, client requirements. Procedures for data review are described in QAM-Q-101, "Laboratory Quality Control" and QAM-Q-104, "Laboratory Data Entry and Review".

Procedure

Initially, the analyst reviews data for acceptability of quality control measures and accuracy of the final result(s).

After the initial review, the Laboratory Manager or a second reviewer considers all manual transfers and calculations of data in detail and spot checks all electronic transfers of data.

Final reports are compared to raw data either directly or through several reviewed steps.

All data review is documented, as noted in the QAMs referenced above, plus QAM-A-102, "Laboratory Document and Data Control".

SECTION 23 – REPORTING OF RESULTS

Policy

The result of each test carried out is reported accurately, clearly, unambiguously, and objectively and complies with all specific instructions contained in the test method.

Data are reported without qualification if they are greater than the lowest calibration standard, lower than the highest calibration standard, without compromised QC sample results or method integrity, and are reasonable when compared to corresponding analyses (e.g. TP>OPO4P). TIAER also follows data reporting guidelines of the clients to whom data are reported.

23.1 Test Reports

Policy

The report format has been designed to accommodate each type of test performed and to minimize the potential for misunderstanding or misuse. Different clients may require different reporting formats.

Procedure

Many data reports must follow highly formatted requirements of the client. Some data are submitted electronically by TIAER staff directly to the client and do not have a written report. Written data reports by the Laboratory Manager for clients follow the format listed in QAM-A-103, "Data Reporting by the Laboratory Manager", unless otherwise required, and will be signed by the Laboratory Manager with a secondary reviewer initialing the report. Electronic signatures and initials may be used for data reports, but hand-signed original reports are kept in paper form in any such case. Electronic signatures and initials are unique to the reviewer and are kept secured on the Laboratory Manager's computer.

23.2 Supplemental Test Report Information

When necessary for interpretation of the results or when requested by the client, test reports may include additional information. Such supplements are normally described in case narrative form and are delineated in QAM-Q-103.

23.3 Environmental Testing Obtained from Subcontractors

Test results obtained from analyses performed by subcontractors are clearly identified on the test report by subcontractor name and/or accreditation number. The test results from subcontractors are reported in writing or electronically. A copy of the subcontractor's report will be made available to the client if requested.

23.4 Electronic Transmission of Results

All test results transmitted by telephone, fax, telex, e-mail, or other electronic means comply with the requirements of this *Quality Assurance Manual* and associated procedures to protect the confidentiality and proprietary rights of the client.

23.5 Amendments to Test Reports

Policy

Material amendments to a test report after it has been issued are made only in the form of another document or data transfer. All supplemental reports meet all the requirements for the initial report and the requirements of this *Quality Assurance Manual*.

Procedure

Amended test reports are titled "Supplement", "Amendment", "Revised" or an equivalent form of wording to assure they can be differentiated from other test reports. These reports types are described in QAM-A-103.

When it is necessary to issue a complete new report, the new report is uniquely identified and contains a reference to the original that it replaces.

SECTION 24 – APPENDICES

Appendix 24.1 Example Fields of NELAP Accreditation

Matrix: NonPotable Water

Analyte	Method(s)	Analyte ID:	Method ID(s):
Escherchia coli (enumeration)	IDEXX Laboratories Colilert®	2525	60002600
Escherchia coli (enumeration)	EPA 1603 (mTEC mod)	2525	10236201
Enterococci	IDEXX Laboratories Enterolert ®	2520	60030208
Conductivity	SM 2510 B	1610	20048004
pH	SM 4500H+ B	1900	20104603
Residue-nonfilterable (TSS)	SM 2540 D	1960	20004802
Residue-volatile (VS)	EPA 160.4	1970	10010409
Residue-filterable (TDS)	SM 2540 C	1955	20049803
Ammonia as N	SM 4500-NH3 G	1515	20023205
Kjeldahl Nitrogen (Total Kjeldahl Nitrogen-TKN)	SM 4500-NH3 G	1795	20023205
Nitrate-nitrite	SM 4500-NO3 E	1820	20114209
Nitrate-nitrite	SM 4500-NO3 F	1820	20024402
Orthophosphate as P	SM 4500-P E	1870	20025803
Phosphorus (Total)	EPA 365.4	1910	10071202
Biochemical Oxygen Demand (BOD)	SM 5210 B	1530	20027401
Carbonaceous BOD, CBOD	SM 5210 B	1555	20027401
Chemical Oxygen Demand (COD)	Hach 8000	1565	60003001

Matrix: Drinking Water

Analyte	Method(s)	Analyte ID:	Method ID(s):
Total Coliforms and E. Coli (P/A)	SM 9223-IDEXX Laboratories Colilert® Test	2502	20212413
Escherichia coli (enumeration)	SM 9223-IDEXX Laboratories Colilert® Quaniti-Tray Test	2525	20211603
Total coliforms (enumeration)	SM 9223-IDEXX Laboratories Colilert® Quaniti-Tray Test	2500	20211603

Appendix 24.2 TIAER Laboratory and QA Employees, Qualifications and Job Descriptions

TIAER Employees, Qualifications and Job Descriptions

Name, Title, Phone	Qualifications	Job Description
James Hunter, Technical Director for NELAP, 254-968-9333, TAMUS title: Laboratory Manager (Radiation Safety Officer)	Over 20 years analytical experience working in an environmental testing laboratory. BS in Chemistry. 40 hr. HAZWOPER certification. 40 hr RSO certification.	Laboratory Manager. Responsible for overall implementation of the NELAP program at TIAER. Responsible for supervising TIAER chemistry laboratory personnel involved in generating analytical data for all projects. Responsible for ensuring that laboratory personnel involved in generating analytical data have adequate training and a thorough knowledge of the QAM, QAPPs, and SOP/QAMs specific to the analysis or task performed and/or supervised. Responsible for oversight and review of all stable and radiochemical laboratory operations and ensuring that all quality assurance-quality control requirements are met. Responsible for documentation related to laboratory analyses. Enforces corrective action and NELAP compliance, as required. Develops and facilitates laboratory system audits with TIAER Laboratory QA Officer. Prepares analytical reports and notifies clients of particular circumstances that may adversely affect the quality of data.
Michael Machen, Quality Manager /Deputy Technical Manager for NELAP, TIAER Laboratory QA Officer, 254-968-1928; TAMUS title: Lead Scientist	Over 30 years' experience as a professional working in public health, analytical chemistry and microbiology, and emergency response. BS in Chemistry. PhD in Toxicology.	Monitors and controls implementation of the QAM within the laboratory to ensure complete compliance with QA objectives as defined by contracts and project QAPPs. Conducts internal audits to identify potential problems and ensure compliance with written SOP/QAMs. Responsible for supervising and verifying all aspects of the QA/QC in the laboratory. Responsible for validation and verification of all data collected according to project specifications and acquired data procedures after each task is performed. Insures that all QA reviews are conducted in a timely manner from real-time review at the bench during analysis to final pass-off of data to the TIAER QA officer. Conducts laboratory inspections. Is responsible for maintaining the currency of the Quality Manual.
Rajita Bhuju, TAMUS title: Senior Research Associate, 254-968-9564	Over 3 years' experience working in an environmental testing laboratory. MS in Environmental Science.	Assists with the preparation and analysis of samples, performing quality control and assurance tasks, and reviewing data in accordance with approved SOP/QAMs.
Technicians	Varying levels of chemistry or laboratory science required, four semesters of chemistry including organic preferred.	Assist analysts and technicians in preparing samples and labware.

Appendix 24.3 Example TIAER Laboratory Equipment List

TIAER Equipment List														
Equipment	Equipment ID	Associated Software	Manufacturer/model	Serial #	Year purchased/ received	Date Placed in Service	Service status in/out	Location	Condition When Received	Condition	Equipment use	Maintenance frequency	Acceptance criteria	comments
Alpha spectrometer	Wolverine	n/a	Canberra Industries inc.,7200-04	13000091	2015	9/24/2015	In	Radlab	New	New	General	Annual	See SOP	"
Analytical Balance	S-1	none	Sartorius AC210P	10205066	1993	1993	in	125	new	good	weights	Daily	0.0999-0.1001	
Autoanalyzer	A-1	Omnion	Lachat Quickchem 8000	A83000-1666 TSU-83075	2000	2000	in	125	new	good	nh3, no3, TP, TKN	Monthly	NA	
Autoclave	AC-1	none	Market Forge Sterilmatic	100137	1985	1985	in	125	new	fair	Sterlization	annual	15psi, 121oC	
Block Digester	Digestor-6	none	Tecator Digester 40 Auto	91725654	2015	2015	in	125	new	excellent	TP, TKN	Monthly/Annual	NA/(+/-)10oC	
BOD incubator	I-18	na	Thermo PR505755R	300029992	2015	10/7/2015	In	130A	new	new	BOD/CBOD	daily in use	DOP done	
Conductivity Meter	C-1	internal	YSI Incorporated 3200	99F1258 AB	1987	1987	in	125	new	excellent	Conductivity	Daily	varies	
Data Logger	Batman	n/a	Ludlum, 2350-1	313152	2014	9/24/2015	In	Radlab	New	Good	General	Annual	±20%	Ck daily in use
Dissolved Oxygen meter	D-1	internal	YSI Incorporated 59E	93K11377	1994	1994	out	125	new	good	DO	when used	varies	
Dissolved Oxygen meter	D-2	internal	YSI Incorporated 5100	06G1684	2006	2006	in	125	new	good	DO	when used	varies	
Freezer	F-2	none	fisher Scientific	97-926-1	2012	2012	in	130a	new	good	storage	daily/in use	<0°C	
Hach COD Reactor	CR-1	none	Hach	930400	1994	1994	in	125	new	good	COD	NA	NA	
Incubator	I-12	none	binder, DD-53	06-08469	2011	2011	in	125	new	excellent	bacteria	daily/in use	24.5-35.5	
Mobile lab	Mobile Lab	none	Guthrie/Pace	NA	2004	2004	in	parking lot	new	excellent	general	Monthly	NA	
Oven	O-5	none	Fisher Isotemp		2012	2012	in	130A	Used	fair	dessicant	NA	103-105°C	used by field crew
pH meter	NA	none	Orion 611	34104-288	1993	1993	out	unk	new	poor	NA	NA	NA	out of service
portable UV light	UV-1	none	unk	unk	unk	unk	in	125	new	new	misc	NA	NA	
Reagent pump	RP-1	none	Lachat	A82000-396	2001	2001	in	125	new	good	nh3, no3, TP, TKN	Monthly	NA	
Refrigerator	R-7	none	Harford Duracool	ZWA015	2011	2011	in	130A	used	excellent	sample storage	Daily	0-6°C	
Sampler controller	scs	unk	hewlett packard, 18594B	3234A29651	2012	no	out	storage container	poor	poor	sampling	unk	unk	Not in service
Scintillation Detector	Cyclops	n/a	Canberra Industries inc.,2007P	92564	2014	na	Out	Radlab	Used	Fair	General	Annual	See SOP	"
Sealer	Q-1	none	IDEXX Quantitray	3293	2004	2004	in	125	new	excellent	MPN E. Coli	NA	NA	
Shaker- orbital	OS-2	none	Lab-line instruments, Inc	none	2010	2010	out	storage container	new	non-functional	ExtP, M3P, sINO3	NA	NA	lemon
Spectrophotometer, UV-vis	A-2	DU-640	Beckman Coulter DU-640	4325817	2001	2001	in	125	new	excellent	OPO4	Monthly	NA	
Stirrer	SP-1	none	VWR Scientific 205	890	2002	2002	in	125	new	fair	general	NA	NA	
stirring hot plate	HP-1	none	corning	410503	1995	1995	in	125	new	fair	general	NA	NA	
Survey meter	Clayface	n/a	Ludlum,3	90073	2014	9/24/2015	In	Login	Good	Good	Sample receipt	Annual	±20%	Ck daily in use
Vacuum pump	P-1	none	GE	TNJ190094	2002	2002	in	125	new	good	Sample Preparation	Monthly	NA	discarded
Water Bath	WB-2	None	Thermo-Fisher	176653-885	2014	2014	In	125	New	Good	MTEC E. coli	Monthly	NA	

For the complete list, see the Master List of Documents E-log.

Appendix 24.4 TIAER Demonstration of Capability Certification Statement

Demonstration of Capability
Certification Statement

Analyst: _____ Date: _____

Laboratory Name: Texas Institute for Applied Environmental Research
Laboratory Address: Box T-0410, Stephenville, TX 76401

Matrix: _____ SOP: _____
Reference Method: _____

Comments or limitations:

Performance criteria described on the Personnel Training Form, Q-107-1, is attached.

We, the undersigned, CERTIFY that:

1. The analysts identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability and is hereby authorized by TIAER Laboratory Management to perform the procedures.

2. The test method(s) was performed by the analyst(s) identified on this certification.

3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.

4. The data associated with the demonstration capability are true, accurate, complete and self-explanatory.

5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized assessors.

Analyst Name	Signature	Date
Technical Director Name	Signature	Date
Quality Manager Name	Signature	Date

Q-100-1, rev. 15 TIAER

Appendix 24.5 Example List of Approved TIAER Laboratory Subcontractors and Vendors

Laboratory Subcontractors

Guadalupe-Blanco River Authority Regional Laboratory
933 East Court St., Seguin, TX 78155
830-379-5822, Fax 830-379-9178
Contact: Josephine Longoria

Trinity River Authority, Central Regional Laboratory
6500 W. Singleton Blvd., Dallas, TX 75212-3038
(972) 263-2251
Contact: Craig Harvey

Texas Commission on Environmental Quality Houston Laboratory
5144 E. Sam Houston Pkwy N, Houston, TX 77015-3225
281-457-5229, FAX: 281-457-9107

Sabine River Authority, Environmental Services Division Water Quality Laboratory
1895 Owens-Illinois Road, Orange, TX 77632
409-746-3284, fax 409-746-2249

Lower Colorado River Authority Environmental Laboratory Services
3505 Montopolis Drive, Austin, TX 78767
512-356-6022, fax 512-356-6021

A&L/ETC Laboratories
2790 Whitten Rd., Memphis, TN 38133-4753
901-213-2400

Angelina and Neches River Authority
2901 N John Redditt Dr.
Lufkin, TX 75904

Vendor	Products
Fisher Scientific	All laboratory items
VWR	All laboratory items
Thomas Scientific	All laboratory items
Midland Scientific	All laboratory items
Hach/LaChat	All laboratory items
Beckman	Instrumentation and parts
Aldinger	Balance calibrations
Accura	Autoclave calibration
Hardy	Sterile Water
IDEXX	Microbiology
Suez Water Technologies	DI water system
Phenova	PT samples
BioMerieux	Bacterial cultures
AirGas	Gases
UPS	Shipping
Fedex	Shipping
Amazon	General consumable items
Wal-Mart (local)	General consumable items
Smith Supply (local)	General consumable items
Ace Hardware (local)	General consumable items
McCoys (local)	General consumable items
Staples (local)	General consumable items

These lists are not exclusive and may be appended by the Laboratory Manager.

Appendix 24.6 Data Integrity and Ethics

TIAER Laboratory
Code of Ethics Statement

Laboratory staff members perform quality functions as a part of each analytical batch processed by the laboratory. They have the responsibility to know the requirements of their jobs and to continually improve the quality aspects of their tasks. Quality concepts are applied to monitor and measure conformance to criteria, as well as to recognize, solve, and prevent problems. Co-workers rely on each other to develop and express professional and interpersonal skills in a professional atmosphere that builds trust, respect, communication, and cooperation. With these needs in mind, the elements presented below are adopted from *Quality Assurance of Chemical Measurements, U.S. Environmental Protection Agency* for implementation by the TIAER Laboratory.

Personal Quality Assurance Responsibilities
(Analyst's Code of Ethics)

I have a commitment to quality testing. I understand that my work is important. I know that data produced by the TIAER laboratory is used by state and federal government agencies in making possible decisions for the environment.
I will strive to develop and enhance my technical expertise *whenever possible*.
I will understand special project analytical requirements prior to working on samples for the project (read and understand my role in QAPPs when they are given to me).
I will always discuss limitations of the measurements with my supervisor and immediately reveal any problems associated with a measurement when I discover it.
I understand that I must have completed a formal, documented Demonstration of Capability in any area or procedure to which I am assigned before performing unsupervised work on project samples.
I will demonstrate control of the measurement system via required quality control checks, calibration and verification with external standards, or quality control samples, wherever applicable. The results of quality control measurements and accompanying descriptive information will be documented promptly and completely.
I will use documented procedures (SOP/QAMs), will read, understand and follow them to the letter. Should I recognize errors in an SOP/QAM, or any directions contrary to project requirements, I will immediately bring them to the attention of my supervisor.
I will always keep detailed records to permit reconstruction of the analysis and follow all rules for data reporting and correction as described in TIAER SOP/QAMs.
I will always maintain the integrity of all samples, data, and documentary evidence to the best of my ability. Where needed, I will perform peer review of analytical data to help detect any potential fraudulent practices or transcription errors and to help verify correct operations of instrument software.
I understand that the penalties for not following the above ethical practices may result in disciplinary action up to and including my immediate termination, and that my supervisor may report any unethical action to the appropriate authorities for possible legal recourse up to and including prosecution, fines and prison sentences.
I hereby agree that the above statements are true, and that I will abide by them.

Printed Name: _____Signed: _____ Date: _____

Witness signature: _____ Date: _____

Q-100-2, rev. 15

Texas Institute for Applied Environmental Research
Quality Policy Statement

The objective of TIAER's quality system, and the commitment of management, is to consistently provide our customers with data of known and documented quality that meet their requirements. Our policy is to use good professional practices, to uphold and maintain the highest quality of service, continually improve the effectiveness of the management system, and to comply with the current National Environmental Laboratory Accreditation Conference Institute (TNI) international 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 also maintains a strict policy of client confidentiality except where prohibited by law.

I hereby agree that the above statements are true, and that I will abide by them.

Printed Name: _____Signed: _____ Date: _____

Witness signature: _____ Date:_____

Q-100-3, rev. 15

TIAER QAM Appendix 24.7 Standard Operating Procedures

Example Standard Operating Procedures/QAM Addenda
Table of Contents

(Table updated as procedures are revised)

Updated 7/21/22

Q = Quality Control S = Safety W = Waste *ob*=obsolete d=draft
A = Administrative C = Chemistry I = Instrument R=Radiochemistry

Procedure #	Rev	Procedure Title
QAM-Q-100	14	Quality Assurance Manual (copyright by TNI)
QAM-Q-101	14	Laboratory Quality Control
QAM-Q-102	15	Laboratory Material Acceptance Criteria
QAM-Q-103	17	Laboratory Equipment Maintenance
QAM-Q-104	13	Data Entry and Review
QAM-Q-105	15	Corrective Actions
SOP-Q-106	*ob*	*Preparation of Labware*
QAM-Q-107	17	Laboratory Personnel Training
SOP-Q-108	*ob*	*Pipette Calibration Verification*
SOP-Q-109	*ob*	*Thermometer Calibration Verification*
QAM-Q-110	16	Sample Receipt and Login
QAM-Q-111	15	Aliquot Preparation and Sample Preservation
QAM-Q-112	16	Sample Compositing
QAM-Q-113	9	Responsibilities of the Laboratory Quality Assurance Officer
QAM-S-101	13	Laboratory Safety
SOP-A-101	*ob*	*Preparation and Control of Procedures (not laboratory)*
QAM-A-102	14	Laboratory Document and Data Control
QAM-A-103	10	Data Reporting by the Laboratory Manager
QAM-A-104	7	Preparation and Control of Laboratory Procedures
QAM-W-101	12	Disposal of Laboratory Waste
QAM-I-101	11	Operation and Calibration of the Analytical Balance
QAM-I-102	15	Operation and Calibration of the Autoanalyzers
QAM-I-103	12	Operation and Calibration of the UV-Vis Spectrophotometer
QAM-I-104	10	Operation and Calibration of the Hach Portable Spectrophotometer
QAM-I-105	10	Operation and Calibration of the pH Meter
SOP-I-106	*ob*	*Operation and Calibration of the Gas Chromatograph*
QAM-I-107	11	Operation and Calibration of the Block Digester
SOP-I-108	ob	Operation and Calibration of the Ion Chromatograph
QAM-I-110	10	Operation and Calibration of the Autoclave
QAM-I-111	12	Operation and Calibration of the Conductivity Meter
SOP-I-112	*ob*	*Operation and Calibration of the AA*
QAM-I-113	7	Operation and Calibration of the D.O. Meter
SOP-I-114	*ob*	*Operation and Calibration of the Spectro Cirros Inductively Coupled Plasma Spectrophotometer*
QAM-I-115	8	Operation and Calibration of IR Thermometer
QAM-I-116	13	Preparation of Labware
QAM-I-117	14	Volumetric Equipment Calibration Verification
QAM-I-118	14	Thermometer Calibration Verification
QAM-I-119	1	Operation and Calibration of the Fluorometer
QAM-I-120	0	Operation and Calibration of the Seal AQ300 Autoanalyzer

Procedure #	Rev	Procedure Title
SOP-C-101	15	Determination of Biochemical Oxygen Demand
SOP-C-102	8	Determination of Chemical Oxygen Demand
SOP-C-103	15	Determination of Total Kjeldahl Nitrogen and Phosphorus
SOP-C-104	12	Determination of Ammonia as Nitrogen
SOP-C-105	15	Determination of Nitrate/Nitrite as Nitrogen
SOP-C-106	15	Determination of Orthophosphate as Phosphorus
SOP-C-107	17	Determination of Total Suspended Solids
SOP-C-108	13	Determination of Nonfilterable Volatile and Fixed Solids
SOP-C-109	13	Determination of Total Dissolved Solids
SOP-C-110	*ob*	*Determination of Turbidity*
SOP-C-111	*ob*	*Determination of Total Organic Carbon*
SOP-C-112	14	Determination of Chlorophyll-a and Pheophytin-a
SOP-C-113	11	Determination of Specific Conductance
SOP-C-114	14	Determination of Fecal Coliform and E. coli by Membrane Filtration
SOP-C-115	*ob*	*Determination of Alkalinity*
SOP-C-116	*ob*	*Determination of Anions by Ion Chromatograph*
SOP-C-117	*ob*	*Determination of Organohalide Pesticides*
SOP-C-118	*ob*	*Determination of Organophosphorus Pesticides*
SOP-C-119	*ob*	*Determination of Triazine Pesticides*
SOP-C-120	10	Determination of pH in the Laboratory
SOP-C-121	9	Determination of Residual Chlorine
SOP-C-122	*ob*	*Determination of Oil & Grease*
SOP-C-123	*ob*	*Determination of MBAS Surfactants*
SOP-C-124	17	Determination of Total Coliform, Escherichia coli & Enterococci by IDEXX Defined Substrate Analysis™
SOP-C-125	*ob*	*Hieltjes/Lijklema Fractionation of Phosphorus*
SOP-C-126	10	Determination of Temperature
SOP-C-130	13	Determination of Total and Percent Solids
SOP-C-131	*Ob*	*Preparation of Soil Samples*
SOP-C-132	0	Preparation of Soil Samples for Analysis on SEAL AQ300
SOP-C-135	*0*	*Determination of Tannin and Lignin*
SOP-C-136	0	Determination of Chlorophyll-a and Pheophytin-a by Fluoroscopy
SOP-C-137	0	Determination of Chlorophyll-a by Fluoroscopy (Special narrow-band method)
SOP-C-150	*ob*	*Determination of Soil Extractable Phosphorus*
SOP-C-151	*ob*	*Determination of Soil Estimated Organic Carbon*
SOP-C-152	*ob*	*Determination of Soil Nitrate/Nitrite as Nitrogen*
SOP-C-153	*ob*	*Determination of Acid Hydrolyzable Phosphorus*
SOP-C-154	*ob*	*Determination of Dissolved Silica (High Range)*
SOP-C-155	*ob*	*Determination of Soil Calcium Carbonate*
SOP-C-156	*ob*	*Determination of Sulfate*
SOP-C-157	*ob*	*Determination of Bioavailable Phosphorus*
SOP-C-158	*ob*	*Determination of Chloride*
SOP-C-160	*ob*	*Determination of Particle Size in Soils and Sediments*
SOP-C-161	*Ob*	*Determination of Phosphorus Sorption/Desorption*
SOP-C-162	0	Determination of Soil Phosphorus by Mehlich 3 Extraction
SOP-C-163	0	Determination of Ammonia Nitrogen in Soil
SOP-C-170	*ob*	*Determination of Metals by Inductively Coupled Plasma Spectroscopy*

Procedure #	Rev	Procedure Title
QAM-R-100	4	TIAER Laboratory Radiochemistry Program
QAM-RI-101	1	Operation and Calibration of the Ludlum Model 3 Survey Meter
QAM-RI-102	2	Operation and Calibration of the Ludlum Model 2350-1 Data Logger
QAM-RI-103	1	Operation and Calibration of the Ludlum Model 43-10 Alpha-Beta Sample Counter
QAM-RI-104	d	Operation and Calibration of the Canberra Gamma Spectrometer
QAM-RI-105	0	Operation and Calibration of the Direct Reading Dosimeter
QAM-RI-106	3	Operation and Calibration of the Packard Tri-Carb Liquid Scintillation Counter
QAM-RI-107	1	Operation and Calibration of the Canberra Alpha
QAM-RI-108	d	Spectrometer
QAM-RI-109	d	Operation and Calibration of the Eberline Area Monitors Operation and Calibration of the EG&G Ortec Portable Gamma Spectrometers
SOP-RC-101	1	Determination of Gross Alpha/Beta Activity
SOP-RC-102	0	Determination of Uranium by Alpha Spectrometry
SOP-RC-103	0	Determination of Tritium by Liquid Scintillation
SOP-RC-104	d	Determination of Low Level Alpha Emitting Radium Isotopes
SOP-RC-111	1	Determination of Radioactive Surface Contamination Using Swipe Surveys

Appendix 24.8 Example List of Approved Reference Materials

Master list of Documents			
Updated: 7/24/20	jrh		
Title	**Revision**	**Distribution**	**Storage**
Electonic Logs			
Autoanalyzer Maintenance eLogbook, I-102-1	13	Electronic Log Menu	na
Bacteria Worksheet C-114.124	0	Electronic Log Menu	na
Logbooks			
Radiation Safety and Survey Logbook	S-101-2-1	Counting Room	na
Hazardous Waste Shipping Logbook, W-101	11	Logbook Rack	na
Forms			
Demonstration of Capability	12	Mailboxes	na
Code of Ethics Statement, Q-100-2	12	Mailboxes	na
Procedures			
QAM-Q-100	12	See SOP Index via tarleton.edu/tiaer/laboratory-services.html	Fireproof Cabinet
QAM-Q-101	13	See SOP Index via tarleton.edu/tiaer/laboratory-services.html	Fireproof Cabinet
Equipment Manuals			
Foss Tecator Digestor Users Manual	4	Main Lab Bookshelf	na
MLA Pipette Operator's Manual	1	Main Lab Bookshelf	na
2016 TNI Standards	**Revision**	**Distribution**	
2016 TNI Standard	2016	Document List\2016 TNI STD-ELV1-2016-Rev2.1_LabRegs.pdf	
TNI Check List	2016	Document List\CSDP-Volume1Checklist-Master-2-15-18-v9 (1).xlsx	
Reference Procedure	**Revision**	**Distribution**	
EPA Quality Management Tools	na	https://www.epa.gov/quality	
Standard Methods 1020 QA	2017	Document List\SM 1020 QA.pdf	

For the complete list, see the Master List of Documents E-log.