QAM-A-104

Preparation and Control of Laboratory Procedures

Revision 7

Approval:

Laboratory Manager	Date 9-4-20
Concurrence	Date 9/4/2020

Effective Date 9-5-20

Renewal Date _____ Initials: _____

Texas Institute for Applied Environmental Research

1.0 Applicability and Purpose

This procedure establishes guidelines for the preparation and control of all Quality Assurance Manual chapters (QAM) and analytical Standard Operating Procedures (SOPs) prepared and used by the laboratory at the Texas Institute for Applied Environmental Research (TIAER), Tarleton State University, Stephenville, Texas. The QAMs/SOPs at TIAER shall be used to assure the quality and integrity of environmental data produced and managed by TIAER, ensure the safety of laboratory and field personnel, and protect the environment through proper waste control. **All laboratory SOPs and QAMs are considered part of the TIAER Laboratory Quality Assurance Manual.**

2.0 Definitions

2.1 Draft – clearly marked preliminary version or revision of existing standard operating procedure prior to management approval of the procedure.

2.2 Original – the first approved version of a revision of an analytical standard operating procedure (SOP) or Quality Assurance Manual chapter (QAM), which has original signatures by designated signers. Each approved revision of an SOP/QAM requires a signed original.

2.3 eSOP – electronic copy of an original SOP or QAM.

2.4 Working Copy – a copy designated in red as "Working Copy" on the pages, which is used for performance of procedures and is issued to staff members or work areas in which the procedures are performed. A working copy may be an eSOP.

2.5 NELAC/NELAP – National Environmental Laboratory Accreditation Conference/Program. TNI = The NELAP Institute

2.6 SOP/QAM Control eLogbook – a paper or electronic logbook (Attachment 3, A-101-3) used to track issuance of approved revisions of SOPs/QAMs.

2.7 SOP/QAM description & use designations – Chapters of the TIAER Laboratory QAM include A (Administrative), I (Instrument), Q (Quality), S (Safety), R (Radiochemistry I & C)

and W (Waste). SOPs are TIAER laboratory analytical methods only, designated C (Chemistry). Some A & Q chapter of the QAM may be called SOPs and shared by other TIAER sections such as the field or data groups. *These shared documents are not controlled by this procedure.*

3.0 Equipment, Reagents and Standards

Not Applicable

4.0 Procedure

4.1 All approved TIAER SOPs referencing a published analytical method comply with all requirements of the published method(s). Any deviations from the published method are specified in the SOP and included in all references to performance of the procedure by TIAER.

4.2 All official documents, including, but not limited to, standard operating procedures, forms, log books, and reports, include pagination, issuing authority, revision number (or issue date) and unique identification.

4.3 The Laboratory Manager (LM) or designee reviews the latest dated and approved Standard Methods and 40 CFR 136 to include changes each time an analytical SOP is written or updated. For procedures referencing published analytical methods not in Standard Methods, the latest approved version of the method being used is reviewed for changes.

4.4 The LM or designee reviews pertinent sections of the currently used version TNI Standards to ensure all requirements for the method are being met.

4.5 The Laboratory QA Officer and Concurring laboratory staff review SOP/QAMs on which they are signatories and compare them to the most current promulgated methods, where applicable, to ensure procedural compliance. The Radiation Safety Officer (RSO) reviews radiochemistry procedures.

4.6 SOPs for all TNI-accredited analyses lists the method included in the NELAP accreditation. SOPs for non-accredited work generally follow the same guidelines as accredited methods.

4.7 Signature of approval indicates that this review has been performed.

4.8 New SOP/QAM initiation and requirements:

4.8.1 When new methods or instruments are required to be used or developed, the LM initiates the writing of new standard operating procedures and assigns the writing of draft SOP/QAMs to appropriate personnel.

4.8.2 The format for authoring A, Q, S, I, R or W series QAM chapters includes, generally, the format listed in Attachment 1. All C and RC series SOPs follow the TNI formatting listed in Attachment 1.

4.8.3 All forms used as part of the procedure, which are not described and numbered in another TIAER SOP/QAM, are attachments to the SOP/QAM. Each form is given a unique identification number.

4.8.3.1 The number begins with the letter and number of the SOP/QAM, e.g., A-101.

4.8.3.2 After is followed by a dash and a numeral designating the form's position in the SOP/QAM. The first form that is an attachment to the SOP/QAM is -1, regardless of which attachment number it is assigned.

4.8.3.3 The SOP/QAM revision number is included in the form's unique identification number. The first form in revision 4 of QAM-Q-102, for example, would be Q-102-1, Rev. 4.

4.8.3.4 Logbooks that are not changed when the SOP/QAM is revised are not required to update the revision number part of their form ID until the logbook is full or otherwise removed from service.

4.8.3.5 A date stamp *may* be added after the revision number to serve as part of the unique ID number if a form is changed between revisions. For example, a revision to the first form in QAM-Q-102 made after Revision 8 of the QAM chapter has been approved would be Q-102, Rev. 8 7/4/15. Note: This generally applies only to forms listed in the reference section of the SOP as "an example."

4.8.3.6 All copies of each form should have the identification number included in the footer.

4.8.3.7 After the SOP/QAM is approved, if the form has changed, all unused copies of the previous form are replaced with copies of the new form.

4.8.3.8 Some attachment forms may become pages in uniquely identified controlled paper logbooks or eLogs. Each time paper logbooks are issued, the LM ensures that the current form revision is used. Uncompleted logbooks do not necessarily need to include a copy of the new form, unless significant changes warrant use of the new form. The eLogs are not necessarily updated with new numbers, but should be restarted as new if significant format or information requirements are changed.

4.8.3.9 An attachment form labeled as an example may be modified at the direction of the LM.

4.8.4 Initial versions of new SOP/QAMs are designated as Revision 0. The revision number for the drafts remains 0 throughout the approval process.

4.8.5 SOPs for analytical procedures include, where applicable, the elements required by TNI/NELAP or other appropriate agency (see Attachment 1).

4.8.6 Draft procedures are labeled in a color other than black on the title page as “Draft.”

4.9 Approval procedure for initial drafts of SOP/QAMs.

4.9.1 Review by independent reviewer

4.9.2 An independent review by someone other than the author is then performed. The independent reviewer is a person who has used the procedure and/or is knowledgeable in the subject matter, whenever possible.

4.9.3 The independent reviewer initials and dates the reviewed draft and submits it to the LM. One or more reviewers may be consulted. Any other reviewers also initial and date the draft.

4.9.4 Review and approval by the LM

4.9.4.1 The LM reviews the draft SOP/QAM specific to the lab containing the comments made by the independent reviewer(s) and makes changes to the draft, as appropriate. If revisions are

minimal, a revised document does not need to be printed out before being routed. Revisions to drafts may be routed electronically, as appropriate.

4.9.4.2 The LM may initial and date the draft and give it and the draft reviewed by the independent reviewer to the LQAO, RSO or Concurring staff member for review.

4.9.4.3 The LM may choose to require approval by additional staff, as appropriate for the particular SOP/QAM, but some form of concurrence by other TIAER staff is required.

4.9.4.4 The LM, LQAO and/or concurring staff review and approve the SOP/QAM on the cover page.

4.9.5 The LM writes the effective date on the cover sheet of the original SOP/QAM prior to copying or scanning. The new effective date should allow sufficient time for staff training, if necessary, on the revision prior to the revised SOP/QAM going into effect.

4.9.6 The LM may issue Working copies from exact reproductions of the original, and the reproductions shall be labeled, preferably in red, as “Working Copy”. Working copies are generally in Adobe Acrobat PDF format made from the Microsoft Word file, with a scanned approval page added to the PDF file.

4.9.7 Initials are not required on Information copies or drafts, except as evidence of review previously discussed.

4.9.8 The new SOP/QAMs then replace old ones in bench and other SOP/QAM compilations, electronic manuals, and work areas. It is the responsibility of the LM to ensure that all copies of retired SOP/QAMs have been replaced with updated versions and that their staff have access to the most current revision of each SOP/QAM. It is also the responsibility of the LM to ensure that no unauthorized copies are in use, and that authorized copies are properly labeled with the correct designation for use.

4.9.9 In the laboratory, ***unauthorized*** **SOP/QAMs include hand-written notes or printouts that are not the official SOP/QAM.** Certain documents for clarification and reference (such as instrument manuals, Lab meeting notes, etc.) may be referenced with permission of the LM, but do not ever override or replace the SOP/QAM without proper revision.

4.10 Revisions to SOP/QAMs

4.10.1 SOP/QAMs are reviewed annually by the LM and concurring staff.

4.10.2 If changes to a procedure are required, the LM assigns an appropriate person to revise the SOP/QAM. The revised SOP/QAM is completed by the same approval and distribution process as new SOP/QAMs described above.

4.10.3 If no changes have been made or need to be made to the procedure, the LM and concurring staff change the final effective date on the front cover to extend the effective period by one year. They initial and date the cover sheet of the original SOP/QAM. A copy of the initialed original cover sheet replaces the original cover sheet in all authorized and controlled copies issued within TIAER, including electronic copies. Any Table of Contents is updated with the new effective period.

4.10.4 If changes to a procedure are extensive enough to require a revision to the SOP/QAM between annual reviews, the LM assigns an appropriate person to revise the SOP/QAM. The revised SOP/QAM is completed by the same approval and distribution process as new SOP/QAMs described above.

4.10.5 If the procedure is not undergoing a major revision, the revised sections are marked with a change bar or line "|" in the left-hand margin beside the sentence or section being changed. Additions to the text are also underlined.

4.10.6 If the procedure is undergoing a major revision, the procedure is identified on the cover page with "**MAJOR REVISION – Changes Not Indicated**." Change bars are not required.

4.10.7 All SOP/QAM revisions are designated with sequential revision numbers. The revision number changes only with each approved and issued SOP/QAM revision, not with each draft. Both those SOP/QAMs undergoing major revisions and those requiring only change bars require new revision numbers. SOP/QAMs that are extended for another year, but not changed, do not require new revision numbers.

4.10.8 After a new or revised SOP/QAM involving data collection activities is issued, all personnel who use the SOP/QAM are trained in accordance with QAM-Q-107, "Laboratory Personnel Training" before collecting data using the newly approved version of the SOP/QAM.

4.10.9 Minor or temporary changes to an SOP/QAM may be made between annual updates by the LM and concurring staff.

4.11 The TNI format in Attachment 1 lists the requirements for analytical SOPs. QAM-Q-101 describes general QC in detail.

4.12 The LM updates the following tables in accordance with QAM-Q-101, as appropriate:

4.12.1 Holding Times, Preservations and Sample Requirements (see Attachment 1, QAM-Q-101).

4.12.2 Manager Set Limits for Acceptance of Duplicates, Spikes and Standard Recovery (if applicable; see Attachment 2, QAM-Q-101)

4.12.3 Suggested Standard and Spiking Levels (if applicable; see Attachment 4, QAM-Q-101)

5.0 Quality Control and Safety Aspects

5.1 An example of the format for the cover page is shown in Attachment 2. All approved SOP/QAMs are signed and dated

for approval on the cover page by the LM and the concurring staff.

5.2 No one is allowed to perform a procedure without documentation that they have been trained on the most recent version of the SOP/QAM.

5.3 The LM keeps original copies of approved laboratory procedures in a locked file. Distribution of paper copies of SOP/QAMs is documented in the SOP/QAM Control Logbook or E-Log. The LM keeps electronic copies in secured electronic format. An assigned staff member will perform and document secondary reviews of QAM/SOP due dates on the log.

5.3.1 The LM keeps archived revisions of retired SOP/QAMs for at least five years.

5.4 Copies of approved SOP/QAMs in the possession of TIAER personnel are considered controlled documents. TIAER SOP/QAMs in the possession of non-TIAER personnel are not considered controlled documents.

5.4.1 Paper copies of SOP/QAMs being replaced are destroyed by the person receiving the new version. Replaced electronic copies are archived.

5.4.2 Copies of non-original procedures are labeled on the cover page (Attachment 2) as “Working Copy”, or “Draft”. Working copies may be used to perform analyses or procedures and may be sent to project partners, auditing and regulatory bodies, or other entities as designated by TIAER staff.

5.4.2.1 Laboratory working copies may be maintained electronically by the LM for computer access by personnel, but are in a secure format so that text cannot be altered (generally a PDF document).

5.4.2.2 All aspects of this procedure pertaining to the laboratory shall comply with QAM-Q-101, “Laboratory Quality Control” and QAM-S -101, “Laboratory Safety”.

5.4.3 The review process which SOP/QAMs undergo prior to approval provides assurance that all requirements in the published method(s) are followed.

6.0 References

6.1 Standard Methods for the Examination of Water and Wastewater, latest online Edition (EPA Approved), APHA, AWWA, Washington, D.C.

6.2 2016 TNI Standard, The NELAC Institute.

7.0 Attachments

7.1 Example of QAM Format and SOP Format

7.2 Example of SOP/QAM Cover Sheet

7.3 Example of SOP/QAM Control Logbook Format

Attachment 1
Example of QAM chapter format

1.0 Applicability and Purpose
This section describes how these instructions apply to activities and equipment associated with the generation and management of data at TIAER and what should be accomplished.

2.0 Definitions

Any technical words, phrases and acronyms used to describe the instructions.

3.0 Equipment
Lists any equipment needed to perform the activities.

4.0 Procedure
Step-by-step description of actions required to accomplish the purpose. These instruction may be divided into several sections, which will change the numbering of subsequent sections, in QAM chapter sections.

5.0 Quality Control and Safety Aspects
Any special criteria of the procedure, plus those which are needed to comply with safety and quality requirements, described in QAM-Q-101, “Laboratory Quality Control”, QAM-S-101, “Laboratory Safety” or the Quality Manual proper, QAM-Q-100. Generally individual analytical SOPs provide specific aspects or refer to the QAM chapter that does. Corrective action requirements may also be described in this section.

6.0 References
All references (bibliography), manuals and sources used in the preparation of the instruction.

7.0 Attachments
Additional tables, examples of forms or logbook pages, or other information used to document the procedural requirements or to be used in completing the procedure.

Attachment 1 (cont.)
TNI Analytical SOP format

i. Identification of the method; (includes date of method approval)
ii. Applicable matrix or matrices;
iii. Limits of detection and quantitation;
iv. Scope and application, including parameters to be analyzed;
v. Summary of the method;
vi. Definitions;
vii. Interferences;
viii. Safety;
ix. Equipment and supplies;
x. Reagents and standards;
xi. Sample collection, preservation, shipment and storage;
xii. Quality control;
xiii. Calibration and standardization;
xiv. Procedure;
xv. Data analysis and calculations;
xvi. Method performance;
xvii. Pollution prevention;
xviii. Data assessment and acceptance criteria for quality control measures;
xix. Corrective actions for out-of-control data;
xx. Contingencies for handling out-of-control or unacceptable data;
xxi. Waste management;
xxii. References; and
xxiii. Any tables, diagrams, flowcharts and validation data.

Example of SOP Cover Sheet

SOP/QAM-X-XXX

Procedure

Title
Revision X

Approval:

_____ _____
Laboratory Manager Date

_____ _____
Concurrence Date

Effective Date _____

Renewal Date: _____ Initials: _____

Texas Institute for Applied Environmental Research

QAM-A-104
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Attachment 3
Example of SOP/QAM Control Logbook Format

QAM/SOP #	Rev	Approval Date	Effective Date	Title	Method	Status	Comments	Secondary review of due date

A-104-3, Rev. 7