QAM-Q-113

Responsibilities of the Laboratory Quality Assurance Officer

Rev. 9

Approval:

_____ 6-13-22
Laboratory Manager Date

_____ 6/13/2022
LQAO Date

Effective Date: 6-13-22

Renewal Date: 6-22-23 for 6-12-23 Initials: JPM

Texas Institute for Applied Environmental Research

1.0 Applicability and Purpose

This procedure applies to responsibilities of the Laboratory Quality Assurance Officer (LQAO) at the Texas Institute for Applied Environmental Research (TIAER), Tarleton State University, Stephenville, Texas. The purpose of this procedure is to ensure proper performance of duties assigned to the LQAO in compliance with the National Environmental Laboratory Accreditation Conference (NELAC) Standard, project requirements, and TIAER procedures.

2.0 Definitions

Refer to the TIAER Quality Assurance Manual (QAM-Q-100) and chapter QAM-Q-101 for definitions.

3.0 Equipment, Reagents, and Standards

None

4.0 Procedure

4.1 Review and approve all SOPs and QAMs in accordance with QAM-A-104, “Preparation and Control of Laboratory Procedures”.

4.2 The LM maintains the Lab SOP Control Log (A-104-3) on the TIAER intranet. The LQAO will review periodically.

4.3 The LM maintains the Lab SOP Control Log to document any reference to needed revisions of TIAER SOPs. Each time Lab Notes, Quality Management System Meeting Notes, or notes from any other quality-related meeting are distributed, review them to identify any discussion of the need for SOP revisions. Other quality-related emails, discussions, or documents may also prompt an entry in the Lab SOP Control Log (A-104-3) . The LQAO makes entries into the log as needed.

4.4 Laboratory Personnel Training Records

4.4.1 Maintain the Master Training ***Elog*** (Q-107-2) file in the QA/QC folder on the TIAER intranet monthly.

4.4.2 For each SOP# check if the SOP trained on is the most recent revision, that a DOC has been performed, and that if the SOP has more than one matrix, a separate DOC has been done for each listed matrix.

4.4.3 If any of the above conditions are not in compliance, notify the Laboratory Manager.

4.5 Internal Laboratory Audits

4.5.1 Perform laboratory audits, using NELAP and other audit forms according to the Internal Audit Schedule (Attachment 1)

4.5.2 Consult the Internal Audit Schedule at the beginning of each month to determine which areas of laboratory operation need to be inspected.

4.5.3 For analytical audits, compare the pertinent SOPs to the published methods, as previously outlined. Observe the actual performance of the procedure in comparison to the SOP. Include applicable instrument SOPs in the audit.

4.5.4 For other procedures, compare the laboratory practices to the NELAC Audit Checklist (Attachment 2), SOPs, and relevant documents, as applicable.

4.5.5 Review documentation associated with the audited procedure to ensure compliance with all requirements.

4.5.6 During the audit, document any positive or negative findings, as well as any comments or recommendations, for use in the audit report (below).

4.5.7 Write audit reports as soon as possible after completion of audit, and always within 30 days.

4.5.8 Organize information from audits into a formal audit report, using the form in Attachment 3.

4.5.9 Submit audit reports to the Laboratory Manager for response. Audit reports may be simple emails to the LM, if necessary information is provided.

4.5.10 Initiate corrective action for negative findings in accordance with QAM-Q-105, “Corrective Actions”.

4.5.11 Annually, one analytical procedure will be chosen for in-depth monitoring (recorded as such), where beginning-to-end or highly detailed reviews are performed.

4.5.12 Follow-up on responses to audits, as required by CARs. Maintain dates as scheduled. Review responses to make sure all findings are adequately addressed. The Follow-up is not complete until all findings have been adequately addressed. Note: any findings that contain serious non-conformances to Laboratory policies or the TNI standard

may justify additional internal audits to address these non-conformances.

4.6 PT Samples

4.6.1 The LQAO and Laboratory Manager establish a schedule for the ordering of PT samples, as required for programs and projects. When the TIAER Laboratory initiates new types of analysis for which PT samples are required, the Laboratory Manager adds those analytes to the schedule.

4.6.2 The LQAO orders PT samples at least semi-annually (5-7 months apart) or as needed for each accredited analyte.

4.6.3 Routine ordering of PT Samples.

4.6.3.1 Approved PT provider websites are used to set up orders.

4.6.3.2 Currently Phenova and ERA are approved PT providers of choice.

4.6.3.3 Determine which PT standards are required for the current Fields of Accreditation under NELAP.

4.6.3.4 Complete an Intent to Purchase (TIAER form) and submit to supervisors for the appropriate signatures.

4.6.4 Quik/Rapid Response PT Sample(s). A PT sample may be ordered outside the established schedule if the previous PT result did not pass, if a new type of analyte is added, if an analytical method or instrument changes, or for other reasons. The LQAO orders a Quik Response PT Sample, as requested by the Laboratory Manager, for such situations.

4.6.4.1 If the PT is used for corrective action on another PT failure, the PT provider is notified.

4.6.4.2 If the order is a Quik/Rapid Response for an analyte previously analyzed by the TIAER Laboratory, check that the ship date for the past order was not within the last seven (7) calendar days.

4.6.4.3 If needed, call the toll-free contact number on the ERA, Phenova or other approved PT provider website.

4.6.4.4 To request a quote for the PT sample(s) needed, or refer to the online catalog. If necessary,

arrange for the sample to be shipped no sooner than seven (7) calendar days from the previous shipment when ordering.

4.6.4.5 PT provider will email a quote. Use this quote form to fill out an "Intent to Purchase" form.

4.6.4.6 As needed, attach the quote to the completed Intent to Purchase form and submit to supervisors for the proper signatures.

4.6.5 The LQAO (or LM when necessary) reports PT results per online instructions of the PT provider. The LQAO maintains records of all PT results and reports from the provider.

4.7 NELAP Related Activities

4.7.1 Annually review and update TIAER's Quality Assurance Manual, including all sub-chapters (QAM-Q-100 thru 113).

4.7.2 Request draft revision of the QAM from Laboratory Manager approximately 6 weeks before the approval due date.

4.7.3 Ensure the draft QAM follows all requirements set forth in the TNI Standard.

4.7.4 Also review the draft QAM in accordance with QAM-A-104, "Preparation and Control of Laboratory Procedures", QAM-Q-101, "Laboratory Quality Control", and other TIAER QAMs/SOPs, as applicable.

4.7.5 When review is complete, marked draft QAM as reviewed, initial and date return, and return to the Laboratory Manager.

4.7.6 Ensure compliance with TNI requirements for laboratory (on-going)

4.7.7 With the LM, review the TNI Standard periodically.

4.7.8 Note any deficiencies in the QAM or specific SOPs, as related to the standard, and initiate corrective action in accordance with QAM-Q-105, "Corrective Actions". Report any deficiencies to the LM.

4.7.9 Corrective actions may be in conjunction with laboratory audits or may be performed separately.

4.8 Provide ethics and data integrity training (annually and for new laboratory employees)
- 4.8.1 Reserve the conference room or other area for a training session, or set up online training.
- 4.8.2 Review ethics training PowerPoint presentation for needed updates and edit as necessary, including changing the presentation date.
- 4.8.3 Go over the details of ethics training with employees as required by the TNI Standard.
- 4.8.4 Obtain the following for attendees to read, sign, and date:
  - 4.8.4.1 the TIAER Code of Ethics Statement
  - 4.8.4.2 the TIAER Quality Policy Statement
  - 4.8.4.3 a Personnel Training Record Form
- 4.8.5 Answer any questions attendees may have about the above forms prior to signing, and collect signed forms.

4.9 Other Responsibilities
- 4.9.1 Review at least 10% of lab data against lab notebooks (monthly)
  - 4.9.1.1 Open and log into the ESDMS QC Module.
  - 4.9.1.2 Under “Sample Management” click on “LQAO Review”.
  - 4.9.1.3 Select the analyte, month, and year for the results to be reviewed, and click “OK”. The analytical run summaries for that analyte during the selected month will then be displayed.
  - 4.9.1.4 Determine which runs, or combination of runs, contain a sufficient number of samples to review to cover at least 10% of the data. For large runs, review 10% of the total or one QC set, whichever is larger. Smaller analytical runs may be combined for review.
  - 4.9.1.5 Select the run(s) you wish to review by clicking on the line for that analytical run and clicking the “Review” button.
  - 4.9.1.6 Scroll to the right side of the screen to view the logbook ID and page number for the run in question.

4.9.1.7 Retrieve the identified logbook from the Laboratory Manager's office, or from the individual analyst, for review.

4.9.1.8 Compare the analytical run data in the laboratory notebook to the results entered in the QC Module, and click the box in the "qao_rev" column for each line reviewed.

4.9.1.9 If any discrepancies are found between ESDMS and the laboratory notebooks, initiate corrective action in accordance with QAM-Q-105, "Corrective Actions". Document the discrepancy by adding the CAR number to the QAO Comments column.

4.9.1.10 When all review for a specific run is completed, click "Complete" to save the review.

4.9.1.11 Initial and date the logbook page with "10% data review" or an equivalent designation and the CAR number from above, if necessary.

4.9.1.12 If review of further analytical runs of the same analyte is required, repeat the previous steps.

4.9.1.13 When all review of the specified analyte is completed, select a different analyte to review, if necessary, and repeat the steps listed above.

4.9.2 Once all analytes have been reviewed, review and/or print a Laboratory QAO Review Summary report for review:

4.9.2.1 Click on "Reports/Views" from the QC Module menu.

4.9.2.2 Select "Lab QAO Review Summary" from the drop-down menu.

4.9.2.3 Select the month and year of interest and click "OK".

4.9.2.4 Wait for the program to build the report view.

4.9.2.5 To print the report, click on the printer icon at the top left of the screen, and the click on the door icon to exit the report view.

4.9.2.6 Click "Cancel" to exit the Report generation screen.

4.9.2.7 Review each line of the generated report to determine if the percentage reviewed for each analyte is greater than or equal to 10% of the total data. If any deficiencies are apparent, review the analytes with less than 10% of the data reviewed again until 10% is reached.

4.9.2.8 Exit the QC Module, and return any laboratory notebooks used for review to the Laboratory Manager or to the individual analyst.

4.9.3 Periodically review and approve all spreadsheets, calculation logs and other data production forms for accuracy and completeness.

4.9.4 Sign and take responsibility as Quality Manager for NELAP accreditation (annually)

4.9.5 Sign documentation as the TIAER NELAC Quality Manager for annual renewal of NELAP accreditation.

4.10 Write or respond to Corrective Action Reports (CARs)

4.10.1 For writing CARs, see QAM-Q-105, “Corrective Actions”. Situations requiring a CAR to be written include, but are not limited to, the following:

4.10.1.1 Documentation of audit findings, both internal and external

4.10.1.2 Errors in data entry discovered during data review

4.10.1.3 Expired SOPs

4.10.1.4 Expired training

4.10.1.5 Failed PT samples

4.10.1.6 Respond to CARs as necessary.

4.11 Review and sign QAPPs (as required). Review all QA/QC requirements in the QAPP in comparison to TIAER QA/QC protocols, including QAM-Q-101, “Laboratory Quality Control”. Pay special attention to the following:

4.11.1 Table A7.1 Measurement Performance Specifications

4.11.2 Section B Sampling and Handling Table

4.11.3 Section B.5. Quality Control.

4.11.4 Review LQAO duties in sections A.4, C.1, and D.2.If corrections are required; note those corrections on the draft in the appropriate place(s). Once review is

complete, initial and date the draft QAPP as reviewed, and return to the Project QAO for further review.

4.11.5 Once the final draft is received, sign and date the draft and return to Quality Assurance Officer.

4.12 Preparation of report of activities for Quality Management System is a LM activity.

5.0 Quality Control and Safety Aspects

5.1 All aspects of this procedure are conducted in accordance with QAM-Q-101, “Laboratory Quality Control”.

5.2 Any discrepancies or nonconformances that affect data quality are addressed and documented in accordance with QAM-Q-105, “Corrective Actions”.

5.3 The LQAO is responsible for documenting and monitoring effectiveness for corrective actions on failed PT samples.

5.4 No safety aspects are associated with this procedure.

5.5 All preparations and dilutions of PT samples are documented in the Standards Log (Q-102-2) by the LQAO or designee.

5.6 Records of LQAO completion of activities found and documented in ELog Maintenance LOGBOOK Q-103-1-10.

6.0 References

6.1 National Environmental Laboratory Accreditation Conference (NELAC) Standard, 2016, The NELAC Institute (TNI).

6.2 TIAER Quality Assurance Manual and chapters, most current version.

6.3 TIAER Quality Standard Operating Procedures.

6.4 TCEQ Surface Water Quality Monitoring Procedures, Volume 1: Physical and Chemical Monitoring Methods for Water, Sediment, and Tissue (RG-415), October 2008.

7.0 Attachments

7.1 Example Internal Audit Schedule

7.2 Excerpt from NELAC Audit Checklist

7.3 Example Audit Report

Attachment 1 Internal Audit Schedule Example

SOP#	SOP Title	Date Due	Date Done	Last Date Done	Tech Area	Findings/Corrective Actions
QAM-A-102	Laboratory Document and Data Control	5/11/2022		5/11/2021	QA/QC	
QAM-A-103	Data Reporting by the Laboratory Manager	5/11/2022		5/11/2021	QA/QC	
QAM-A-104	Preparation and Control of Laboratory Procedures	5/11/2022		5/11/2021	QA/QC	
QAM-Q-100	Quality Assurance Manual	5/11/2022		5/11/2021	QA/QC	
QAM-Q-100	Review of Tenders, Offers and Contracts	5/11/2022		5/11/2021	QA/QC	
QAM-Q-100	Review of Subcontracting, Complaints, etc	5/11/2022		5/11/2021	QA/QC	
QAM-Q-101	Laboratory Quality Control	5/11/2022		5/11/2021	QA/QC	
QAM-Q-102	Laboratory Material Acceptance Criteria	5/11/2022		5/11/2021	QA/QC	
QAM-Q-103	Laboratory Equipment Maintenance	5/11/2022		5/11/2021	QA/QC	
QAM-Q-104	Data Entry and Review	5/11/2022		5/11/2021	QA/QC	
QAM-Q-105	Corrective Actions	5/11/2022		5/11/2021	QA/QC	
QAM-Q-107	Laboratory Personnel Training	5/11/2022		5/11/2021	QA/QC	
QAM-Q-110	Sample Receipt and Login	5/11/2022		5/11/2021	QA/QC	
QAM-Q-111	Aliquot Preparation and Sample Preservation	5/11/2022		5/11/2021	QA/QC	
QAM-Q-112	Sample Compositing	5/11/2022		5/11/2021	QA/QC	
QAM-Q-113	Responsibilities of the LQAO	5/11/2022		5/11/2021	QA/QC	
QAM-S-101	Laboratory Safety	5/11/2022		5/11/2021	QA/QC	
QAM-W-101	Disposal of Laboratory Waste	5/11/2022		5/11/2021	QA/QC	
QAM-I-117	Volumetric Equipment Calibration Verification	5/11/2022		5/11/2021	QA/QC	
QAM-I-116	Preparation of Labware	5/11/2022		5/11/2021	QA/QC	
QAM-I-115	Operation and Calibration of IR Thermometer	5/11/2022		5/11/2021	QA/QC	
QAM-I-118, SOP-C-126	Thermometer Calibration Verification, Determination of Temperature	1/13/2023		1/13/2022	Wet	
QAM-I-111, SOP-C-113	Operation and Calibration of the Conductivity Meter, Determination of Specific Conductance	1/13/2023		1/13/2022	Wet	
QAM-I-105, SOP-C-120	Operation and Calibration of the pH Meter, Determination of pH in the Laboratory (liquid)	1/13/2023		1/13/2022	Wet	
SOP-C-101, QAM-I-113	Determination of Biochemical Oxygen Demand (BOD/CBOD), Operation and Calibration of the D.O. Meter	1/13/2023		1/13/2022	Wet	
QAM-I-104, SOP-C-102	Operation and Calibration of the Hach Portable Spectrophotometer, Determination of Chemical Oxygen Demand	1/13/2023		1/13/2022	Wet	
QAM-I-103, SOP-C-106	Operation and Calibration of the UV-Vis Spectrophotometer, Determination of Orthophosphate as Phosphorus	1/13/2023		1/13/2022	Wet	
SOP-C-121	Determination of Residual Chlorine	1/13/2023		1/13/2022	Wet	
SOP-C-108	Determination of Nonfilterable Volatile and Fixed Solids (TFS/VSS/NVSS)	8/12/2022		8/12/2021	Solids	
SOP-C-109	Determination of Total Dissolved Solids	8/12/2022		8/12/2021	Solids	
SOP-C-130	Determination of Total & %Solids (TS liquids)	8/12/2022		8/12/2021	Solids	
SOP-C-107, QAM-I-101	Determination of Total Suspended Solids, Operation and Calibration of the Analytical Balance	8/12/2022		8/12/2021	Solids	
SOP-C-105	Determination of Nitrate/Nitrite as Nitrogen	5/17/2023		5/17/2022	UV/vis	
SOP-C-112	Determination of Chlorophyll-a and Pheophytin-a (CHLA)	5/17/2023		5/17/2022	UV/vis	
SOP-C-104	Determination of Ammonia as Nitrogen	5/17/2023		5/17/2022	UV/vis	
SOP-C-103, QAM-I-107, QAM-I-102	Determination of Total Phosphorus and TKN, Operation and Calibration of the Block Digester, Operation and Calibration of the Autoanalyzers	5/17/2023		5/17/2022	UV/vis	
SOP-C-124	Determination of Total Coliform & E. coli	5/25/2023		5/25/2022	Micro	
SOP-C-114, QAM-I-110	Determination of Fecal Coliform and E. coli by Membrane Filtration-mTEC *E. coli, Operation and Calibration of the Autoclave*	5/25/2023		5/25/2022	Micro	
	2020 Report to Management			3/1/21		
		SEE PAPER DOCUMENTS FOR DETAILED NOTES AND TNI CHECKLISTS				

TNI 2016 Standard Checklist: Volume 1 Module 1 - Proficiency Testing

Citation Volume 1 Module 1 (V1M1 - PT)	Does the laboratory comply with this section?	Yes	No	N/A	Comments
V1M1 1	**PROFICIENCY TESTING**	N/A	N/A	N/A	
V1M1 1	**INTRODUCTION, SCOPE, AND APPLICABILITY**	N/A	N/A	N/A	
V1M1 1.1	**Introduction**	N/A	N/A	N/A	
V1M1 1.1	Volume 1, Module 1 provides the requirements for laboratory participation in the TNI Proficiency Testing (PT) program.	N/A	N/A	N/A	
V1M1 1.2	**Scope**	N/A	N/A	N/A	
V1M1 1.2	The purpose of the TNI PT program is to provide a means for an Accreditation Body (AB) to evaluate a laboratory's performance, under specified conditions relative to a given set of criteria in a specific area of testing, through analysis of PT samples provided by an external source.	N/A	N/A	N/A	
V1M1 1.3	**Applicability**	N/A	N/A	N/A	
V1M1 1.3.1	Volume 1, Module 1 is applicable to any laboratory attempting to gain or maintain accreditation from a Primary AB that uses this Standard as the basis for accreditation regardless of the number of personnel working in the laboratory or the scope of testing performed by the laboratory.	N/A	N/A	N/A	

Attachment 3 Example Audit Report

To: Laboratory Manager
Cc: TIAER Project Quality Assurance Officer, TIAER Lead Scientist, TIAER Data Supervisor
From: Laboratory Quality Assurance Officer
Date: Date of Memo
Re: Internal Audit of Laboratory Area of Operations

Purpose: A brief statement of the area of laboratory operations audited, including the date the assessment was conducted.

Scope: Information regarding which SOP(s) were audited; which documents, data, and logbooks were examined; and which published methods and/or checklists were used for reference.

Positive Findings: Description of all positive findings identified.

Negative Findings: Description of the all negative finding(s) and a reference.

Comments: Any issues noted that are not serious enough to qualify as a negative finding, but which the laboratory may want to address in order to improve operations and/or data quality.

Recommendations: Suggested corrective action to address negative findings and/or comments.

Please respond to these findings by 30 calendar days from the Date of Memo.