


QAM-A-102

Laboratory Document and Data Control

Revision 14

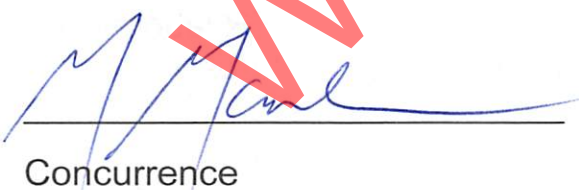
Approval:



Laboratory Manager

7-28-20

Date



Concurrence

7/28/2020

Date

Effective date: 7-31-20
A-30-21 For

Renewal date: 7-31-21 Initials: JM
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Texas Institute for Applied Environmental Research

1.0 Applicability and Purpose

This procedure applies to all quality related documents and data that are generated, calculated or reproduced in the laboratory at the Texas Institute for Applied Environmental Research (TIAER), Tarleton State University, Stephenville, Texas. The purpose of this procedure is to provide a method for control and maintenance of hard copies of data, data files, and all documents that pertain to the output of quality-related laboratory data. This SOP describes tracking and storage mechanisms for hard copy and electronic data. For specific information regarding procedure control, refer to SOP-A-101, "Preparation and Control of Procedures".

2.0 Definitions

Logbooks- bound and sequentially numbered notebooks that contain chronological entries and records. A logbook may be the personal logbook of an analyst containing his/her own data observations, an instrument specific or maintenance log, or other recorded information required for laboratory operations. May also be an electronic log secured on the TIAER server. E-logs are not bound or sequentially numbered.

3.0 Equipment, Reagents and Standards

None

4.0 Procedure

4.1 General documentation requirements

4.1.1 All hand-written documentation used by the TIAER laboratory is completed in blue indelible ink, unless procedures specifically call for the documentation to be written in another color. The Laboratory Manager (LM) or other authorized reviewer may review and make notations in indelible red ink or other color ink to differentiate writing and data log entries.

4.1.2 Mistakes, changes, or errors are drawn through with one line, initialed by the person making the entry and dated. A short reason for the change is written and circled. The correction is entered in close proximity to the changed entry. If insufficient space is located near the entry to be changed, asterisks may

QAM-A-102

Laboratory Document and Data Control

be used to indicate revisions made in available locations on the page.

- 4.1.3 Logbooks are maintained for all analytical procedures, records pertaining to ongoing laboratory maintenance activities, issuance of laboratory-related documents, and many other activities associated with laboratory procedures.
 - 4.1.4 Issuances of all logbooks for analytical procedures are recorded in the Master Logbook (See Attachment 1, A-102-1) and controlled by the Laboratory Manager.
 - 4.1.5 All forms used as part of a laboratory procedure are given a unique identification number, as described in QAM-A-104, "Preparation and Control of Laboratory Procedures."
 - 4.1.6 Logbooks created from forms may have an additional number added to indicate sequence, e.g., Q-102-1-15 represents the 15th logbook issued of form 1, which is an attachment to SOP-Q-102.
 - 4.1.7 Most logbooks are now electronic. The numbering is the same configuration as paper logs, but the LM controls E-logs by locking and unlocking cells and MS Excel workbook pages. E-logs are password protected from changing entered data once the LM has reviewed them.
 - 4.1.8 When supplies, reagents or standards are received, the receiver searches for any necessary Certificates of Analysis (COA) from the manufacturer. If the receiver cannot procure a COA, they inform the LM. COAs are be labeled with the TIAER inventory number and routed to the Laboratory Quality Assurance Officer (LQAO) to be filed.
- 4.2 Analytical Logbooks
- 4.2.1 All raw data, in the form of charts, graphs and other instrument or computer generated information, are kept in controlled logbooks or files, paper and/or electronic.
 - 4.2.2 Every analytical logbook entry has at a minimum the date, initials of the person making the entry and, if appropriate, the time of entry.
 - 4.2.3 Any entry not made in chronological order is initialed, dated and labeled as "Late Entry".
 - 4.2.4 All hand written data observations and instrument readouts without printed copies are entered into a pertinent logbook.

QAM-A-102

Laboratory Document and Data Control

- 4.2.5 Worksheets are normally affixed to a logbook prior to writing data on them. No loose worksheets are used for data collection, even if they are to be bound into book form later.
- 4.2.6 Instrument printouts, tabulated data, graphs and other paper information to be attached into personal or other logbooks are taped onto separate pages and do not cover over other data or information. Taped additions to a logbook are dated and initialed across the interface of the page and attachment, with tape covering the date and initials for an unequivocal record.
- 4.2.7 Unused areas of the logbook (when entries have been made to subsequent pages) are crossed out, initialed, and dated, "N/A" or blacked out cells in the case of E-logs.
- 4.2.8 Changes made after data has been reviewed and closed out must be approved in writing by the LM.
- 4.3 Documents, records, hard copies, and electronic copies of data are stored when completed in a manner that does not compromise the integrity or the ability to read or retrieve them.
 - 4.3.1 Raw data, logbooks, procedures, control charts and other laboratory information are maintained for at least 5 years after the end of the project for which the data are collected. A record of disposal of any expired data and laboratory information is kept by the Laboratory Manager.
 - 4.3.2 Hazardous waste disposal information, including manifest documents, is maintained for a minimum of 10 years after the close of the project.
 - 4.3.3 Electronic data and the program(s) enabling the data to be read are stored for at least five years after the close of the project. Electronic data are backed up by the laboratory manager and/or database supervisor in at least two separate locations.
 - 4.3.4 All records, logbooks, documents and data remain in a readily accessible working file for one year prior to being sent to permanent storage, which remains reasonably accessible upon request to the LM.
- 4.4 Project Quality Assurance Officer files
 - 4.4.1 Corrective Action Reports (CARs) are initiated, resolved and maintained in accordance with QAM-Q-105, "Corrective Actions". The Project QAO maintains and tracks CARs with the Laboratory QAO.

QAM-A-102

Laboratory Document and Data Control

- 4.5 Laboratory Quality Assurance Officer files
 - 4.5.1 The LQAO maintains records of performance testing samples analyzed by the TIAER laboratory as part of establishing and maintaining accreditation with NELAP and other organizations.
 - 4.5.2 The LQAO maintains paper and electronic copies of training files for laboratory staff, including Demonstrations of Capability for each analyte measured by individual analysts.
 - 4.5.3 The LQAO maintains Quality System audits and responses in a secure file.
 - 4.5.4 The LQAO maintains the electronic master training log for analysts.
- 4.6 Laboratory Manager files
 - 4.6.1 The LM is responsible for securing and maintaining other records, documents and data files associated with laboratory activities and procedures, including email and other forms of correspondence. Standard Operating Procedures are created, issued and maintained in accordance with QAM-A-101, "Preparation and Control of Procedures". The LM maintains control of issuance, revision, and archiving of SOPs & QAMs in the laboratory.
 - 4.6.2 He/she also maintains a file index system for reference by the LQAO, Program Manager, and TIAER Director.
 - 4.6.3 The LM maintains a separate, locked file for storage of client and proprietary information, and other information deemed necessary to be controlled for security purposes. He/she also maintains back-up copies of secured electronic data with help from the Database Supervisor.
 - 4.6.4 The LM may maintain an electronic record or log of telephone conversations relating to client or project activities.
 - 4.6.5 The LM maintains and controls instrument and vendor manuals for equipment in the laboratory and maintains an updated equipment list in accordance with QAM-Q-103, "Laboratory Equipment Maintenance".
 - 4.6.6 The LM controls and issues forms used exclusively in the laboratory. Each form issued is entered into the Laboratory Controlled Form Logbook (Attachment 2, A-

QAM-A-102

Laboratory Document and Data Control

102-2). This logbook may also be in electronic format. Forms are designated by the appropriate form number described in each SOP/QAM. Revisions to forms may be indicated by sequential letters or a date, following the form number. For example, the first revision to A-102-2, which is the second form in SOP-A-102, would be A-102-2a. The second revision to the form would be A-102-2b. If the SOP is revised, but the form is not changed, the form would maintain the same form number.

- 4.6.7 The LM maintains electronic copies of SOPs for laboratory use and ensures only the current versions are in place.
- 4.6.8 The LM maintains original copies of all Chain-of-Custody records for a minimum of 5 years after completion of a project.

5.0 Quality Control and Safety Aspects

- 5.1 All aspects of this procedure conform to the criteria established in QAM-Q-101, "Laboratory Quality Control" and QAM-S-101, "Laboratory Safety".
- 5.2 The Master Logbook remains in a locked file or area controlled by the LM, who is responsible for the issuance of all logbooks and worksheets pertaining solely to the laboratory.
- 5.3 When a laboratory employee terminates, the LM sends notification to TIAER's Database Manager on the day of the termination. The DB Manager removes all passwords and access to all computer systems for the terminated employee.

6.0 References

- 6.1 Good Laboratory Practice Standards, ed. by Willa Y. Garner, et al., American Chemical Society, Washington, D.C., 1992
- 6.2 Standard Methods for the Examination of Water and Wastewater, Online Edition (EPA approved), ed. by Arnold E. Greenberg, et al., APHA, AWWA, Washington, D.C.
- 6.3 National Environmental Laboratory Accreditation Conference (NELAC) TNI Standard, 2016, The NELAC Institute.

7.0 Attachments

- 7.1 Example Master Logbook, A-102-1
 - 7.1.1 Example Signature and Initials Log, A-102-1
- 7.2 Example Laboratory Controlled Form Logbook, A-102-2

Working Copy

QAM-A-102
Laboratory Document and Data Control

Attachment 1

Example Master Logbook

Issue Date	Retire Date	Logbook#	Logbook Title	Initials

Form A-102-1

Attachment 1.1

Example Initials and Signature Log

Name	Signature	<u>Written</u> <u>Initials</u>	<u>Electronic</u> <u>Initials</u>	Date

Form A-102-1.1

