QAM-Q-104

Laboratory Data Entry and Review

Revision 15

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Texas Institute for Applied Environmental Research

Laboratory Data Entry and Review

1. Applicability and Purpose

This procedure applies to entry and review of data generated by the laboratory staff at the Texas Institute for Applied Environmental Research (TIAER), Tarleton State University, Stephenville, Texas and the TIAER mobile laboratory. This procedure applies only to TIAER data managed by ESDMS and analyte quality control (QC) data, but not to SAS or other systems to which ESDMS uploads or to other databases used by TIAER. The purpose of this procedure is to ensure proper entry of data into TIAER's ESDMS database and QC Module. Data include descriptive information, comments, field observations and measurements, and laboratory analysis parameters associated with samples. This procedure also covers the comprehensive review of the data entered in the database prior to use for project reporting, statistical analysis, modeling, decision making, and other applications.

2. Definitions

2.1. Chain of Custody/Sample Information Form (COC or COC/SI, form Q-110-1) – a form that accompanies a sample from submission to the laboratory to data entry into ESDMS. All sample information is contained on this form. Refer to QAM-Q-110, "Sample Receipt and Login" for specific description and use of COCs. COCs from entities other than TIAER may be used, as long as all the necessary sample information and signatures are present on the form.

2.2. ESDMS – Environmental Sample Data Management System. An interface to a Sequel Server database (or equivalent) created by TIAER and used to enter laboratory, field, and descriptive data into the database.

2.3. Logbook – a paper or electronic (Elog) collection of data used to record or store information.

2.4. Login Module- an ESDMS interface program maintained on the Login computer where samples are initially entered into the system.

2.5. Personal Logbook – a bound, paginated notebook made and controlled by the Laboratory Manager and assigned to a specific analyst or area. Each personal logbook has a unique number, which is recorded in the Master Logbook (see QAM-A-102, "Laboratory Document and Data Control"). The Personal Logbook may become an electronic log also.

2.6. QC Module –interface maintained in ESDMS on which the samples included in each type of sample batch are identified, along with the results of the quality control samples analyzed for the batch.

2.7. Sample Logbook – a logbook or electronic log that includes a sequential, pre-prepared list of sample numbers used to assign a unique identification number to each sample (See QAM-Q-110-2). All pertinent information from the COC for each sample (descriptive information, including test group code and number of bottles) is copied to one row in the Sample Logbook.

2.8. SAS databases –databases to which TIAER's water quality and other data, which have been reviewed for quality assurance, are transferred for storage, data analysis, data reporting, and use with mathematical modeling. SAS programming software is used with SAS databases, but not by the TIAER Laboratory.

2.9. TCEQ –Texas Commission on Environmental Quality

3. **Equipment, Reagents and Standards**

3.1. Personal Computer (IBM compatible) running under Microsoft Windows operating system software with network connection to a database on the TIAER server

3.2. ESDMS, most current version, including the QC Module and other components

3.3. Laptop computer, which may be used in the TIAER mobile laboratory or main laboratory bench areas as long as data are transferred to a personal computer upon return to TIAER laboratory or office, or is uplinked to the server for file and data storage. NO DATA IS TO BE STORED ON INDIVIDUAL PCs or LAPTOPS. ALL DATA IS STORED ON THE SERVER.

4. **Procedure**

4.1. Laboratory quality control protocols

4.1.1. Sample analytical results are entered manually or automatically into the ESDMS analysis queue and accompanying QC data are entered into the QC Module for calculation and comparison against acceptance criteria. The QC Module is maintained and controlled in accordance with QAM-A-102, "Laboratory Document and Data Control."

4.1.2. Results of all QC analyses are reviewed by the analyst and Laboratory Manager to ensure the batch meets required criteria, as specified in QAM-Q-101, "Laboratory Quality Control".

4.1.3. If all QC data do not meet criteria, corrective action is initiated according to QAM-Q-105, "Corrective Action."

4.1.4. If batches are rerun due to QC results, sample data from both batches are recorded in the personal logbook or ESDMS tables for initial analytical results, but only data from the passing batch are entered into the ESDMS analytical queue. Ensure that reruns are designated with an "R" in ESDMS and associated logbooks.

4.1.5. ESDMS and any other computer software developed by TIAER is documented in sufficient detail and is suitably validated as being adequate for use. As validation, all calculations will be verified independently. Validation records are maintained by the Laboratory Manager.

4.2. Logging into ESDMS

4.2.1. Log in samples in accordance with QAM-Q-110, "Sample Receipt and Login". Login data required prior to transferring sample containers to the laboratory include test group code, site, date, time, number and type of containers, and status of pH and temperature measurement. Descriptive information, comments, field observations, and field measurements may be entered after samples have been transferred to the laboratory.

4.2.2. Choose the ESDMS icon on the desktop computer.

4.2.3. ESDMS validates the user based on their user profile and permissions granted by the administrator. Each ESDMS user must perform all functions under their own unique ID.

4.3. Raw laboratory data

4.3.1. All laboratory sample data are entered into the analyst's personal logbook, either as hand-written entries or printouts that are affixed to the bound page. Hand entries are made in indelible blue ink. Electronic logbooks may also contain raw data readings taken directly from analyst observations. Analytical runs entered on Elogs are printed and taped into personal logbooks of the analyst.

4.3.1.1. Each logbook page contains the analyte or test name, date, and unique identifiers of any reagents and standards for traceability. Ensure that all equipment, reagents and materials used are properly noted by identification, lot number or other uniquely identifying label where available. Include any and all dilution,

preparation and spiking descriptions that are not included in another designated logbook.

4.3.1.2. Initial and final times and dates for each analytical run batch are included in the logbook.

4.3.1.3. If data, templates or other records are taped into logbooks, the analyst initials and dates across the seam of the affixed record and logbook page, and then covers that area with tape in order to indicate an unequivocal data record.

4.3.1.4. Some data in the personal logbooks, such as observations and calculations, are not entered into the database. Refer to QAM-A-102, "Laboratory Document and Data Control," for further descriptions, issuance and uses of logbooks in general.

4.3.1.5. Errors and corrections to logbooks are handled in accordance with QAM-A-102, "Laboratory Document and Data Control."

4.3.2. Analytical results are carefully entered into ESDMS either by automated or manual method.

4.3.3. Do not round off data to any significant figures until the final reporting of the data to the client. All manipulations and calculations are done with unrounded data only.

4.3.4. Computerized raw data are maintained, controlled, and backed up to the TIAER server in accordance with QAM-A-102, "Document and Data Control". All logbooks, printouts, and other compiled data are maintained and stored per QAM-A-102. Printouts of E-log worksheets with analytical runs are affixed to Personal Logbooks when complete.

4.4. ESDMS manual laboratory data entry

4.4.1. From the main screen, click on Sample Management, and then click on Manual Data Entry to reach the analyte list.

4.4.2. Select the analyte to be entered from the pull-down list.

4.4.3. The analyst's name should show to be correct for the analysis performed. The default is the name of the person who logged into ESDMS, which can be changed if entering data for another analyst.

4.4.4. From the pull down lists on the screen, select the correct time and date for starting and ending of the analytical run. The selected time and date will automatically fill in for all samples

4.4.4.1. If more than one analytical run batch needs to be entered, enter results, as described below, for only one analytical run batch at a time prior to saving.

4.4.4.2. Time and date will clear for all samples in the remaining batch after the first batch has been saved. The correct time and date for the next analytical run batch can then be selected.

4.4.5. Using the personal logbook or E-log worksheet, manually type in data for associated samples in the "Meas. Results" cells.

4.4.6. Enter any dilutions or comments as necessary.

4.4.7. Do not round data closer than 5 decimal point, if applicable, at data entry. Rounding is performed at the reporting stage after all calculations and QC manipulations are complete.

4.4.8. Review prior to saving

4.4.8.1. Check all entries against the personal logbook data.

4.4.8.1.1. Include times, date(s), sample number, analytical value, dilution factor in the review.

4.4.8.1.2. Check the QC results for the run to ensure that any QC samples that did not pass have been addressed according to QAM-Q-101 and QAM-Q-105.

4.4.8.1.3. Check to ensure that the following have been entered: logbook control number, logbook page number, standard/blank ID numbers, PB & QCB IDs, Reruns (R) and FS if present.

4.4.8.2. After all entries have been reviewed and corrected, if necessary, click Evaluate QC and Save Results at the bottom of the screen.

4.4.8.3. If incorrect data are inadvertently saved, contact the Laboratory Manager, who will determine whether a CAR needs to be written.

4.4.9. Enter other batch data if present and continue from the start.

4.4.10. When all data have been entered and saved, click Close.

4.4.11. If there is any question concerning validity of data entry at this point, click View Sample Data from Views and Reports in the menu to inspect data. Notify the Laboratory Manager of any incorrect results entered. The Laboratory Manager will determine whether or not a CAR is written.

4.5. ESDMS automated laboratory data entry

    4.5.1. Text file format and designation. Files from instrument computers are named with a date stamp suffix that must be changed to the more simple form for ESDMS to recognize. Formatting must be in the following comma delimited pattern: sample number, dilution factor, date, time, analytical result.

        4.5.1.1. After transfer from the instrument computer, open the date stamped file in Notepad or other text editor to view the file, if necessary.

        4.5.1.2. All five components of each sample record are separated by commas. ESDMS will automatically remove spaces before and after commas.

        4.5.1.3. If the sample has been diluted, see the instrument SOP for instructions on correct documentation of the dilution factor. An example of a properly formatted sample that has been diluted 20 times: "1000089405,20.0,05 Dec 2012,10:49:35,22.34953".

        4.5.1.4. Save the file in simple name format in a computer folder that can be immediately recalled and uploaded. The data file generated from the autoanalyzer must include the analyte abbreviation within the file name. The ".txt" extension will be added automatically. Numbers representing the date of analysis are typically included in the file name. For example, a data file for nh3 could be "nh3-091512a.txt".

    4.5.2. Uploading file to ESDMS

        4.5.2.1. In the QC module, select Sample Management, then Automated Data Entry.

        4.5.2.2. Select the analyte to be entered from the pull-down list.

        4.5.2.3. The analyst's name should show to be correct for the analytical run batch analyzed. If batches for more than one analyst are ready, the uploading process will have to be repeated for each analyst.

        4.5.2.4. Click on Select Data File at the bottom of the screen.

        4.5.2.5. From the window that pops up, select the name of the text file to be uploaded from the proper computer folder.

        4.5.2.6. The results enter automatically into the screen.

        4.5.2.7. Add the logbook and page numbers, and QC and Prep batch IDs, FS and reruns (if present), residual 1st polynomial equation and Cal Std results.

4.5.2.8. Review results carefully to ensure they match the data file from the instrument. Check sample number, date, time, dilution factor, and results. Ensure that all QC samples have been run. The program will alert the analyst of any QC results that do not meet the established criteria. Correct any errors.

4.5.2.9. When review is complete, click Evaluate QC and Save Results at the bottom of the screen.

4.5.2.10. If any errors occur, notify the Laboratory Manager.

4.6. Data Review is based on five levels

4.6.1. The **first level QC review** requires that the analyst double check his or her own work. This is partly accomplished through use of the QC Module and ESDMS prior to and immediately after data entry.

4.6.2. Upon completion of data entry and review by analysts, the Laboratory Manager makes a **second level QC review** of quality control and acceptance criteria associated with each data point, as well as completeness, reasonableness and integrity of the data in the logbooks. This level of review is by individual analyte.

4.6.2.1. The Laboratory Manager verifies that the quality control acceptance limits are met by reviewing the QC data in the QC Module of ESDMS for the analyte of interest, then checking off each row of data. Upon review and approval of the data in the QC Module, the Laboratory Manager checks Approval for each environmental sample and QC sample.

4.6.2.2. The Laboratory Manager reviews logbook entries for items that include but are not limited to the following

4.6.2.2.1. samples that lack results without an explanation,

4.6.2.2.2. values that appear to be unreasonably large or small,

4.6.2.2.3. data that do not appear to have been generated according to TIAER protocols,

4.6.2.2.4. samples run out of order with no explanation,

4.6.2.2.5. batches containing an incorrect number of samples,

4.6.2.2.6. calibration curves not passing the correlation coefficient,

4.6.2.2.7. recovery of calibration standards, including the LOQ calibration standard, outside of acceptance limits,

4.6.2.2.8. cross outs or uninitialed error corrections,

4.6.2.2.9. missing results sheets or calculations,

4.6.2.2.10. manual calculations (spot checked), and

4.6.2.2.11. anything else that may not be appropriate or correct.

4.6.2.3. After review of each page in the personal logbook

4.6.2.3.1. The Laboratory Manager makes a single line through the personal logbook page and initial and date in red, indelible ink.

4.6.2.3.2. All blank spaces and void-outs are filled in with single lines and initialed and dated similarly.

4.6.2.3.3. No data are entered on a personal logbook page after the Laboratory Manager's review mark in red has been added, unless it is initialed and dated by the person making corrections and cosigned by the Laboratory Manager.

4.6.3. The Laboratory Manager is responsible for

4.6.3.1. reviewing and supervising the review of data at the bench level, in logbooks, and in the ESDMS database.

4.6.3.2. maintaining and controlling the analyte logbooks for accuracy and security in accordance with QAM-Q-101 and QAM-Q-102.

4.6.3.3. ensuring that samples associated with any QC not meeting criteria are rerun or the results are either flagged or not reported.

4.6.3.4. making data corrections in ESDMS as necessary; if data uploaded to SAS require corrections, the Laboratory Manager corrects the data in ESDMS and the data are uploaded again.

4.6.3.5. consulting with the Radiation Safety Officer (RSO) for radiochemistry data and safety, where applicable.

4.6.4. At a **third level QC review**, the Laboratory Manager compares values entered into ESDMS to those in personal logbooks to ensure there are no transcription errors. This review is performed from the Initial Laboratory Review queue in the Lab Manager section of ESDMS and is done on an analyte-specific basis.

4.6.4.1. From the main ESDMS screen, click Lab Manager after login.

4.6.4.2. From the Lab Manager Menu, click Initial Review.

4.6.4.3. Choose the analyte to be reviewed from the pull down menu.

4.6.4.4. Review the entered data against the personal logbook of the analyst who performed the analysis.

4.6.4.4.1. Click or check the Approved column cell of each sample reviewed or use the space bar and down arrow to select the Approved column cells.

4.6.4.4.2. Add comments or QC flags, as required.

4.6.4.5. After initial review, click the Approve Run button at the bottom of the screen.

4.6.4.5.1. Continue approval of other analytes, as needed, then click Close.

4.6.4.5.2. A message may appear indicating the module is checking for samples that are ready for transfer to the final review queue. ESDMS asks if samples are to be transferred. Note: A sample is ready for transfer only if all results indicated by its test group code have been entered and approved.

4.6.4.6. The data have now been moved to the Final Review queue.

4.6.5. At the **fourth level QC review,** the Laboratory Manager reviews all information and analytical results for each sample as a whole. Data on the original COC and any accompanying paperwork is compared against all entered sample data. Analytical results for different analytes on the same sample are reviewed to verify reasonableness.

4.6.5.1. From the Lab Manager Menu, click the Final Review button for liquids or solids, depending on matrix.

4.6.5.2. If all sample analyses have been completed and all data have been initially reviewed, the samples will be in this queue.

4.6.5.3. Verify that all information for times, dates, site, comments and other information entered on the COC for that sample is accurate, complete, and matches the data entered in ESDMS.

4.6.5.4. If corrections or additions are required, right click the cell to be amended. A screen pops up for correction. Enter the corrected value or information and a note explaining the reason for the correction. ESDMS automatically logs

the time, date, reason, and person entering the correction for the purposes of a QA audit trail.

4.6.5.5. Review the entire sample data, looking for values indicating lack of reasonableness, e.g., orthophosphate phosphorus greater than total phosphorus or ammonia greater than TKN.

4.6.5.5.1. If data for one sample are not reasonable, review the logbooks for the values in question. Review the QC data to determine any cause for unreasonable data. When reviewing for reasonableness, if one analyte is inappropriately greater than another and either analyte is greater than its PQL, a CAR is written for the sample.

4.6.5.5.2. Initiate corrective action, according to QAM-Q-105.

4.6.5.6. After data entry has had final review, check the Laboratory Analysis column for each sample.

4.6.5.7. Initial and date the review section of the COC. After the fourth level is complete, the Laboratory Manager forwards copies of the COCs with field sheets attached to the Field Data Reviewer and may exit the system. The original COC and any composite sheets are retained by the lab.

4.6.6. **The fifth level QC review** of the COC and field data sheets is performed by staff members selected by the Data and Field Operations Supervisors. These staff members are assigned permission to make changes and additions to descriptive, observational, and field data in ESDMS (Note: refer to TIAER field and data procedures for how this is done).

4.6.7. After all reviews are complete the COCs and attached sheets are stored in binders.

4.7. Access to data records and files stored in the laboratory and archive areas.

4.7.1. Archived or active data logbooks, records, and any other electronic or paper files relating to laboratory data that are stored solely in the laboratory or archive areas are accessed through the Laboratory Manager. The Laboratory QAO, Project QAO, and laboratory personnel may review laboratory data, records, files, and documents at any time at their discretion.

4.7.2. Non-laboratory and non-QAO personnel complete an entry in the Laboratory Data Access Logbook (Q-104-1, Attachment 1) when accessing raw data from the laboratory. Any person

accessing the laboratory *archives*, including the Laboratory Manager, completes an entry in the log.

4.7.3. Control of processed data that have been approved and reported, entered into ESDMS or other programs, and released from the laboratory may not be the responsibility of the Laboratory Manager and do not require an access log entry.

4.7.4. Any person accessing archived or raw data through the Laboratory Manager complies with all TIAER laboratory policies and procedures on ethics, data integrity, corrections, changes, reproduction and dissemination of the data.

4.7.5. Archive areas include a fire-proof file cabinet for data and files between one and two years old. Data and files older than two years may be kept in secured storage areas. Records retention complies with project QAPPs or for at least five years, whichever is more restrictive. After the retention period, records and data files may be destroyed in accordance with State of Texas regulations.

5. Quality Control and Safety Aspects

5.1. No spreadsheets, forms, files or data storage mechanisms are saved on individual PCs or laptops. All data, forms and sheets are saved on the server only. Do not use the "save as" feature for any program except with the express, written consent of the Laboratory Manager who is responsible for ensuring that all data generated by the laboratory are of acceptable quality prior for entry into the database. The Laboratory Manager is the only person allowed to change *laboratory* data in ESDMS. Changes to the database are documented by an internal audit trail within ESDMS that notes when and what changes were made and by whom.

5.2. In cases where personnel shortages exist in the laboratory or where specialty analyses are performed, the Laboratory Manager may act as both an analyst and Laboratory Manager for data entry and review. In such circumstances, the Laboratory manager reviews his/her own data objectively and as independently as he/she would for any other analyst's data.

5.3. The Laboratory Quality Assurance Officer and/or second laboratory analyst reviews at least 10% of the analytical results in the database and QC Module against laboratory notebook data to ensure data have been entered correctly. The logbook is intialled and dated to indicate completion of the review.

5.4. Changes to descriptive, observational or field data in ESDMS are made only by the Laboratory Manager or staff members in other sections, but only the Laboratory Manager makes changes to lab data.

5.5. All aspects of this procedure are conducted in accordance with QAM-Q-101, "Laboratory Quality Control". Any discrepancies or nonconformances that affect data quality are addressed and documented in accordance with QAM-Q-105, "Corrective Actions". No safety aspects are associated with this procedure. Data are reported in accordance with either the requirements of the QAPP under which the data are collected or with QAM-A-103, "Laboratory Data Reporting".

6.0 References
6.1 Environmental Sample Data Management System Users Manual, most current version, Texas Institute for Applied Environmental Research.
6.2 National Environmental Laboratory Accreditation Conference (The NELAC Institute- TNI), 2016.
6.3 TIAER Quality Assurance Manual, QAM-Q-100

7.0 Attachments
7.1 Example Laboratory Data Access Logbook Sheet, Q-104-1

Date	Name of person accessing data	Signature of person accessing data*	Data Accessed	Laboratory Manager Approval

* by signing I hereby agree to comply with all TIAER laboratory SOPs, ethics policy and data integrity rules, and any changes, corrections, dissemination or reproduction of the data comply with these procedures.
Q-104-1, rev. 15