Lab Director Approval: Mark Tolbert 08/19/2021

QA Manager Approval: Jeffrey Moore 08/19/2021

Comprehensive LIMS SOP

Access to this SOP shall be available within the laboratory for reference purposes; the official copy of this SOP resides on the official Georgia EPD website at https://epd.georgia.gov/about-us/epd-laboratory-operations. Printed copies of this SOP will contain a watermark indicating the copy is an uncontrolled copy.

1. Introduction

1.1 The EPD Laboratory has in place a comprehensive program to monitor laboratory activities associated with the LIMS. The program is designed to meet the requirements of U.S. EPA document 2185 (8/10/95), "Good Automated Laboratory Practices" (GALP). The goal of this program is to ensure that analytical data generated by the EPD Laboratory is reliable and credible with respect to LIMS activities.

1.2 The LIMS in operation at the EPD Laboratory is Perkin Elmer Labworks Enterprise ES Desktop, version 6.1 Build 6.1.0.220 developed by Labworks, LLC, 230 N. 1200 E., Suite 202, Lehi, UT 84043. The LIMS is operated through the following operating systems currently in use, Microsoft Windows XP, Microsoft Windows 7, and Microsoft Windows 10. All data stored in the LIMS is maintained in an Oracle 11i database. Hardware consists of individual PCs located throughout the Laboratory and two centrally located Dell servers.

2 Personnel Training

2.1 This program includes elements to ensure that all Laboratory personnel are trained in LIMS operation and that the training is documented. Each staff member is instructed in such a manner to ensure that they clearly understand the procedures required to operate the LIMS system with regards to their analytical assignments.

2.2 Training Demonstration

2.2.1 Laboratory personnel are trained in the operation of the LIMS in a manner similar to the requirements of Laboratory SOP 6-001, Initial Demonstration of Proficiency for Analytical Methods. Training is documented on the LIMS Initial Demonstration Form 2

(LIDF). Only one LIDF is created for each analyst. The form is updated as each LIMS activity is completed. The following items are documented on the LIDF:

- Initial Documentation Review
- Analyst Log Into LIMS
- Sample Log In
- Perform Cross Reference Search
- Perform Backlog Search
- Create a Progress Report
- Analytical Batch Creation and Addition of QC Tests to Batch
- Create and Modify Test Codes
- Perform QC Control Charting
- Individual Laboratory Procedures for Data Entry
- Sample Data Validation
- Data Editing Procedure
- Report Generation

2.2.2 The analyst is notified of their LIMS rights and privileges then works for several weeks with an analyst or supervisor proficient in the use of the LIMS. During this time, the analyst continues to review the help section of the software as they are trained in the use of the LIMS.

2.2.3 As the analyst is able to operate the LIMS without supervision, the analyst's proficiency is recorded on the LIDF. As additional training in LIMS operation is required, a supervisor or as an experienced analyst is called upon to assist. Additional review of the software help section is also recommended. As the analyst becomes proficient at a new LIMS activity, the LIDF is updated. Only one LIDF is maintained for each analyst. A copy of the updated LIDF is forwarded to the QA Manager each time a new LIMS activity is recorded for the analyst.

2.3 LIMS Training Records

2.3.1 As the analyst is able to operate the LIMS without supervision, the analyst's proficiency is recorded on the LIDF. As additional training in LIMS operation is required, a supervisor or as an experienced analyst is called upon to assist. Additional review of the

software help section is also recommended. As the analyst becomes proficient at a new LIMS activity, the LIDF is updated. Only one LIDF is maintained for each analyst. A copy of the updated LIDF is forwarded to the QA Manager each time a new LIMS activity is recorded for the analyst.

3 Quality Assurance Unit (QAU)

3.1 EPD Laboratory Managers or their designees serve as the LIMS QAU. The Laboratory LIMS Administrator serves as the contact between Labworks, LLC concerning all LIMS activities. These managers are separate and independent of LIMS development and maintenance activities. They also have direct access to LIMS data, SOPs and other records pertaining to LIMS.

3.2 LIMS Inspections

3.2.1 All data entered into LIMS is reviewed for accuracy and completeness as a part of the final review before data is reported. Initial instrument response, calculations and data transfers used to arrive at the final reported value are inspected for accuracy.

4 LIMS Raw Data Entry and Changes

4.1 Raw data is entered into the LIMS by direct instrument input or manually by individual analysts. Most analysts have been granted the LIMS privileges to allow the entering of raw data as required in the performance of their assigned duties. In either case, all data is reviewed and validated by Laboratory management personnel at the Supervisor or Laboratory Manager level.

4.2 Changes to LIMS raw data are controlled by the Laboratory Director, QA Manager, and LIMS Administrator. This privilege is granted to analysts as needed in the performance of their assigned duties. Labworks Enterprise Desktop meets the requirements of GALP 8.4.5. If LIMS raw data is changed or modified the software provides evidence of the change, preserves the original recorded documentation, records the date of the change, identifies the analyst initiating the change and records the reason for the change. Only analysts authorized by the Laboratory Director, QA Manager, and LIMS Administrator to change or modify LIMS raw data are assigned this privilege. Analysts are trained in this procedure and the training is documented.

5 Software Development and Change Control

5.1 Labworks Enterprise ES Desktop is developed and supported by Labworks, LLC, 230 N. 1200 E., Suite 202, Lehi, UT 84043. All software development and modification is documented, controlled and tested by Labworks, LLC.

5.1.1 Changes initiated within the EPD Laboratory are documented by forwarding a request or

notification to the LIMS Administrator who establishes a permanent file for each change or modification. The LIMS Administrator and Laboratory Director evaluate the requested changes and together with the QAU determine the testing procedures that will be required to evaluate the requested change. Once testing criteria is identified change can be incorporated into the LIMS software by the DNR network administrator. Upon completion of the changes testing procedures previously identified are conducted and reported to the LIMS Administrator. The LIMS Administrator evaluates the results of the testing procedure and approves or disapproves the results in writing. If the testing results are approved, the LIMS Administrator notifies the Laboratory staff of the approval and use of the change. If the testing results are not approved, the LIMS Administrator notifies the Laboratory staff and requires additional software development and retesting. All documentation is maintained in the original file for each change.

5.2 LIMS Problem Evaluation and Corrective Action

5.2.1 If a LIMS associated problem is identified by an analyst, a QAU member is notified. The LIMS Administrator is notified in writing of the specific problem. An administrative corrective action is initiated by the LIMS Administrator who then contacts Labworks, LLC and explains the identified problem. All changes or modifications to the existing LIMS software are coordinated through the LIMS Administrator. Testing of the software change or modification is conducted by Labworks, LLC. Additional testing may be conducted, as required, at the EPD Laboratory. The corrective action resolution is documented by the LIMS Administrator and approved by the Laboratory Director. The LIMS Administrator maintains all documentation on an identified problem in the LIMS activity files.

5.3 LIMS Version Control

5.3.1 LIMS version control is maintained by the LIMS Administrator, Laboratory Director and QA Manager. The current version and subsequent editions of Labworks Enterprise Desktop are documented in the LIMS activity files. The LIMS Administrator are responsible for ensuring that the current version of Labworks Enterprise ES Desktop is installed on all personnel computers (where required) within their assigned Laboratory. Documentation for software version upgrades is maintained in the LIMS activity file.

5.3.2 Each new version of the LIMS software is validated before use. The new version is installed on a separate computer that is not mapped to original data servers. A separate server is established with a point in time picture of the original database. Once all procedures have been validated for each Laboratory and a final review conducted by the LIMS Administrator the updated LIMS version is installed.

5.4 Software Documentation

5.4.1 All software documentation, including historical software, software operating procedures

(manuals), and software change documentation is maintained in the LIMS activity file. The LIMS activity files are maintained by the LIMS Administrator.

5.5 Software Formula Validation

5.5.1 The Labworks Enterprise ES Desktop instruction manual contains a complete description of the software package (see on line manual). Formulas developed for the calculation of reported results and for quality control monitoring are validated as each test method is established by a QAU member.

6 LIMS Security

6.6.1 The Laboratory utilizes the security features of Labworks Enterprise ES Desktop to ensure the security and integrity of LIMS data. This software provides multiple levels of security using an assigned password and security level for each user. Additional security is provided by the ORACLE database. The LIMS Administrator and QAU members assign passwords and access rights privileges to each user. User privileges are assigned only as required in the performance of analyst's assigned duties.

6.6.2 Laboratory Managers are responsible for requesting rights and privileges for each new and existing staff member in their Laboratory. The request is made in writing to the Laboratory Director and LIMS Administrator by filling out the LIMS Rights and Privilege Request form 13.2 and forwarding it to the QA Manager, who along with the LIMS Administrator reviews and evaluates the request. Upon approval, the LRPRF is noted as approved and a Labworks account is established for the staff member. The original form is maintained in the QA office and a copy is returned to the Lab Manager for filing in the staff member's training folder.

6.6.2.1 Managers may request changes in a staff member's rights and privileges by forwarding a request to the QA Manager. No changes are made in LIMS rights and privileges without the approval of the Director and QA Manager. Upon approval by the Director and QA Manager, the LIMS Administrator makes the appropriate changes in LIMS for the revision.

7 Hardware

7.1 As an agency of the Georgia State government, IT infrastructure services encompassing mainframes, servers, service desk, end user computing, disaster recovery and security are being transitioned to IBM by the Georgia Technology Authority.

7.2 LIMS Desktop Unit (personal computer)

7.2.1 The minimum desktop unit purchased by any DNR associate or program should be configured as follows: Dell Standard Plus Desktop Opti 380 or equivalent. Specifications

are as follows:

- Processor CISC - Core 2 Duo 2.93GHz, E7500
- Memory RAM 4GB
- Storage Devices DVD-Recordable DVD±RW
- Storage Devices Hard Drive 250GB SATA Drive
- Video Controller 2048x1536 Intel GMA 4500
- Input Devices Keyboard USB Keyboard and USB Opt Wheel Mouse
- Dell 19in LCD Monitor- Desktop E1910 Video Resolution 1440x900 1440x900, NI

Any new system purchased/leased should be purchased with Microsoft Office Suite or Microsoft Office Suite Professional installed. Exceptions must be approved by the Director of Systems Development.

7.3 Network Servers

7.3.1 Network hardware consists of two centrally located servers. Dell PowerEdge 2650 for the LIMS Database and Dell Poweredge 2850 for production. These servers are maintained by DNR personnel on permanent assignment at the EPD Laboratory. Network servers are configured as follows:

Poweredge 2950 LIMS Database Server

- High performance and availability in a rack-dense 2U form factor.
- Hot-plug hard drives and optional hot-plug power supplies and fans for high availability.
- Embedded Remote Access (ERA) port provides remote management capabilities
- 2 Intel Quad Core Xeon X5355 @ 2.66GHz processors
- Installed RAM 32 GBs
- Storage Devices 6 Hard Drives, 750G, 7.2K rpm, RAID 5
- Storage Devices DVD ROM drive
- Network Adapter Intel Pro/1000 Gigabit Ethernet.
- Rack dense data protection provided by the Power Vault 112T. The dual drive design can hold up to two (2) tape drives and up 160GB (DLT VS80) of compressed data in a slim 1U form facto

PowerEdge 2850 Application, File and Print Server

- 2 Dual Core Intel(R) Xeon(TM) CPU 3.20GHz processors.

- Installed RAM 4 GBs.
- Storage Devices 6 x Hard Drives, 146GB, U320, 15K rpm, RAID 5.
- Storage Devices CD-RW/DVD Drive Combo.
- Network Adapter Intel Pro/1000 Gigabit Ethernet.

7.4 Network Maintenance

7.4.1 Network maintenance and management is transitioning to AT&T under the guidance and oversight of the Georgia Technology Authority. Tape backups are stored on site and off site in the Program Coordination Branch Chief's office. As each weekly data backup is conducted, the new backups are stored and the previous backups retrieved for reuse.

8 Records Retention

8.1 All documentation and records, or a copy of, pertaining to LIMS activities are maintained in the LIMS activity file under the supervision of the QA Manager. Original LIMS training records are maintained in the individual analyst training records.

Form 1 - LIMS Rights and Privileges Request Form (LRPRF)

File Location: S:\ApprovedForms\LIMS Rights and Privileges Request Form(6_1).doc

Georgia Department of Natural Resources

Environmental Protection Division

LIMS Rights and Privileges Request Form (LRPRF)

Date: _____ LIMS Version: 6.1

Name: _____ Manager's Approval/Date: _____

Initials: _____ QAM Approve/Date: _____

Lab Director's Approval/Date: _____

Group Membership

☐ ADMIN ☐ METALS
☐ AIR ☐ ORGANIC
☐ GOMS ☐ PROTOZOAN
☐ INORGANIC ☐ RECEIVING

Labworks Privileges

☐ Allow user to add new files to the Desktop	☐ Generate invoices	☐ Run Result Entry
☐ Run Analysis Maintenance	☐ Run Location Maintenance	☐ Generate final reports (standard/custom)
☐ Validate analysis results	☐ Create, modify, and delete location list defaults	☐ Change previously posted result
☐ Analysis State Modify	☐ Display or print location list	☐ Enter, load, import, or calculate results
☐ Modify/delete previously loaded analysis objects	☐ Specify login printing	☐ Setup result entry templates
☐ Load analysis objects	☐ Setup login templates	☐ Report Template State Modify
☐ View analysis objects	☐ Show non-validated results in LWExplorer	☐ Run Result Entry Template
☐ Run APPROVAL	☐ Run Control Charting	☐ Inactivate selected samples
☐ Run Archieve	☐ Run Trend Plot	☐ Login samples
☐ Assign analysis to analyst	☐ Run Export Setup	☐ Modify previously logged samples
☐ Assign analysis to Instrument	☐ Run Form Editor	☐ Validate samples before release
☐ Run AUDITTRAIL	☐ Run INVENTORY	☐ Send Message
☐ Display or print audit trail	☐ Run Multi Sample Login	☐ Run Special Info Setup
☐ Run Back Logo	☐ Run Single Sample Login	☐ Setup special information screen forms
☐ Generate backlog reports	☐ Run Multi Comp Transfer	☐ Set analysis result specifications
☐ Perform QA/QC batching tasks	☐ Setup calibration/spike mixture files	☐ Generate predefines SQC charts
☐ Setup analysis result calculations	☐ Add/Remove Form Designer Tools	☐ Setup and/or generate SQC charts
☐ Configure Audit Trail Points	☐ Modify System Global Image List	☐ Generate system status report
☐ Configure Electronic Signature Point	☐ Run MOR Report	☐ Modify system result abbreviation list
☐ Convert specs 60 into 61	☐ Generate Monthly Operations Reports	☐ Create, modify, delete analysis definitions
☐ Run Custody Tracking	☐ Setup Monthly Operations Reports	☐ Display or print analysis list information
☐ Perform sample custody tracking	☐ Run MOR Setup	☐ Display trend plot groups
☐ Create new document reference	☐ Run Modify Sample	☐ Define and and configure trend plot groups
☐ Run Document Reference	☐ Manage analyte report limiting on samples	☐ NEW USRCONFIG PRIVILEGE
☐ View existing and previous document references	☐ Setup analyte reporting groups for projects	☐ View audit trail from Electronic Records Viewer
☐ Delete error log entries from error viewer	☐ Run ProjectAnalyteMgmt	☐ View Signature Point Event Log
☐ Run Exception Report Setup	☐ Define value selection pick lists	☐ Run Validate Sample
☐ Generate exception reports	☐ Run PickList Setup	☐ Run WORKFLOW
☐ Setup automatic exception reports	☐ Run Progress Report	☐ Select codes for batched worksheet generation
☐ Run Exception Report	☐ Delete special pricelists	☐ Run Excel Calculation Setup
☐ Run Export	☐ Setup special pricelists	☐ Perform Excel calculations
☐ Export sample data	☐ Print receipts route and work sheets from modify	☐ Define Excel calculations
☐ Setup data export formats	☐ Generate progress reports	☐ Run Cross Reference
☐ Run Instrument Maintenance	☐ Setup progress report templates	☐ Perform cross reference search for samples
☐ Modify Instrument Maint. and Calibration Records	☐ Setup Personnel Training	☐ Define cross reference searches
☐ Run Instrument Conversion	☐ Run QA Batching	☐ **Microbiology Database**
☐ Run Instrument Library Setup	☐ Run Quality Report	☐ **Chemistry Database**

Form 2 – LIMS Initial Demonstration Form (LIDF)

File Location: S:\ApprovedForms\LIMS Initial Demonstration Form (LIDF) – Updated 01-16-2019

Georgia Department of Natural Resources
Environmental Protection Division Laboratory

LIMS Initial Demonstration Form (LIDF)

Date:_____

Analyst:_____ Manager Approval/Date:_____

Position:_____

Hire Date:_____

Laboratory:_____

LIMS Version:_____

LIMS Activity	Date	Supervisors Initials
Initial Documentation Review		
Analyst Log into LIMS		
Sample Log In, Print Labels, Receipt		
Perform Cross Reference Search		
Perform Backlog Search		
Create/Perform a Progress Report		
Analytical Batch Creation/Modification		
Addition of QC Tests to Batch		
Create and Modify Test Codes		
Perform QC Control Charting		
Individual Laboratory Procedure for Data Entry		
Sample Data Validation		
Data Editing Procedure		
Report Generation		
Create Log In Template		
Run Calendar Log for ID Systems		

Form 3 - LIMS Raw Data Verification Form

File Location: S:\ApprovedForms\LIMS Raw Data Verification Form – Updated 01-16-2019

Department of Natural Resources
Environmental Protection Division Laboratory

LIMS Raw Data Verification Form

Date:_____

QAU Member:_____

Laboratory Method:_____

Analytical Method:_____

Laboratory Sample ID:_____

Analytical Batch ID:_____

Date of Verification:_____

Brief Description of LIMS Activity:_____

_____

_____

Raw Data Component	Verification Check	Component Verified Y/N, N/A
Date Sample Collected (Log in Only)	Review Documentation	
Date Sample Received (Log in Only)	Review Documentation	
Sample Identification (Log in Only)	Review Documentation	
Sample QC Batched	Review LIMS Data	
Sample Preparation Documented in LIMS (Volume, Mass, Final Volume)	Review LIMS Data	
Sample Documented on Run Log	Review Run Log	
Instrument to LIMS Data Transfer or Manual Entry to LIMS	Review Instrument and LIMS Raw Data	
Date Sample Analyzed	Review LIMS Data	
Sample Calculations Correct	Manually Calculate Results	
Final Report Data Correct	Review Final Report	
Other (describe)		

Corrective Action Reference/Recommendations:_____

_____

_____

Form 4 – LIMS Version Validation Form

File Location: S:\ApprovedForms\LIMS Version Validation Form

Georgia Department of Natural Resources
Environmental Protection Division Laboratory

LIMS Version Validation Form

Labworks Features	Managers Initials	Comments
Labworks Features		
Bac-T Casecard Program		
Create, change and print analysis code		
Create, change and print location code		
Create, change, perform cross reference searches *		
Define, perform excel calculations		
Display and/or print audit trail		
Enter, load, import, change or calculate results		
Setup and export sample data (2 sample export, print exports)		
Generate and define SQC charts (Control Chart) (1 test/lab)*		
Generate backlog report *		
Generate exception report		
Generate Nugent QA/QC report		
Generate progress reports and setup progress reports templates		
Generate system status report		
Generate, setup final reports (standard/custom)		
Login (samples, canisters, and filters), specify label printing, setup template, and etc. (Attach to form) *		
Modify System Results Abbreviation List		
Perform QA/QC batching tasks		

Georgia Department of Natural Resources
Environmental Protection Division Laboratory

Labworks Features	Managers Initials	Comments
Perform sample custody tracking and lable printing during login		
Register and modify desktop programs		
Select codes for batched worksheet generation		
Set analysis results specification		
Setup analysis results calculation		
Setup calibartion/spike mixture files		
Setup custom laboratory forms		
Setup results entry templates		
Setup special information screen forms		
Validate analysis and sample results		

* Copy of report or documentation from each Labworks version checked for accuracy (Attach)

LIMS Administrator: Date/Initials _____/_____

QA Manager: Date/Initials _____/_____

Generate Final Report for all reports printed from each Labworks version.