Standard Operating Procedure for Records Maintenance and Storage

1.0 Scope and Purpose

This standard operating procedure is designed to outline the laboratory's procedure for the storage, retention and dissemination of electronic and paper records generated from analytical test methods. As required by law, all records (paper and electronic) generated by the Laboratories may be subject to disclosure according to the guidelines *and exclusions* published in Chapter 119 of Florida Statutes.

2.0 Procedure

2.1 Electronic Records

Most of the data generated by the laboratory during the analytical testing process is in the form of electronic records. These data consist of raw data files generated by analytical instrumentation, chromatography acquisition software, etc. as well as processed and final database records residing in the Laboratory Information Management System (LIMS).

All raw data files, including processed chromatography data and instrument files are stored on a server maintained by the Office of Technology and Information Services (OTIS). Those files are organized by file type and date of generation and are copied onto backup tapes by staff at the Southwood Shared Resource Center (SSRC). Backup of those materials are available for recovery for approximately 6 weeks. Locations of the network drives and the nomenclature used to name files for different analyses are described in the laboratory's various analysis SOPs, which document the procedures that generate the data stored in these files. The files are also archived to a separate hard drive maintained by the DEAR Scientific Services Support Program as needed. A spreadsheet (Lab-Data-Metadats.xlsx) summarizing the locations of the lab's electronic and paper data and metadata is archived here (\\FLDEP1\DEAR\Labs\SOPs\). Software and hardware systems are maintained to ensure that raw data are available for a period of not less than five (5) years after completion of the laboratory project.

The SSRC maintains the Oracle database where LIMS records are stored. A complete backup of the oracle tables is exported each night to a password-protected server administered by OTIS. This server is backed up to tape by SSRC staff. Backups of the oracle table content and LIMS programming code are also backed up to DVD daily and weekly. A second copy of the weekly backup is stored off-site, with at least two (2) years retained. The records in the LIMS database are maintained to ensure their availability for a period of not less than five (5) years after completion of the laboratory project.

The OFFICIAL COPY is the on-line version. All other copies are considered unofficial and uncontrolled.

The LIMS has a Laboratory Notebook module that is used to maintain electronic logbooks containing metadata for some groups in the lab. Examples include thermometer and pipette calibration logs, autoclave logs, instrument maintenance logs etc. Sample preparation worksheets are created and archived in the Prep Worksheet Manager in the LIMS.

Electronic copies of the final reports are archived in a manner similar to that used to archive raw data files described above. (\\fldep1\dear\labs\Lab3\lims_archive) The electronic final reports are also made available to the laboratory's clients. These reports may be sent via email to the client or placed on an FTP (File Transfer Protocol) server for client access. Both of these protocols are considered secure methods for data transfer. The email servers and client software for handling email are password-protected; additionally, these systems are protected by a firewall. The Department's FTP server predominantly handles "anonymous" FTP requests, which allows anyone to download any file. The laboratory clients have password-protected accounts for accessing and downloading the project reports.

2.2 Paper Records

Copies of pertinent raw and processed data may be maintained in electronic and paper format. Some groups have paper records storing metadata including sample preparation logbooks, reagent preparation logbooks and instrument maintenance logbooks. These (paper) logbooks are assigned unique serial numbers and tracked in the LIMS Document Control System. When a logbook is full, it is closed and archived. A new logbook takes its place. The closing date and archival location of the logbooks is documented in the LIMS Document Management System.

Additionally, the laboratory maintains paper copies of the cover page, all final analytical reports and all client custody records. Those records are maintained in the laboratory and archived offsite as needed in the State Records Center. All paper records are maintained in a temperature and humidity controlled environment and are protected by fire suppression equipment.

The laboratory maintains two document control systems (DCS) for tracking the archival of paper records and laboratory logbooks. The DCS for archival is an electronic database that resides on a server maintained by OTIS and is available through the Department Intranet. Paper records are boxed, labeled and submitted to the State Records Center for archival. The State Records Center assigns the boxes a tracking number that is entered into the document control system, along with a description of the box contents, the date range of records in the box, the date of archival and the name of the submitter. When records are needed for retrieval, the document control system database is searched for the pertinent box identification number and that number is submitted to the State Records Center for retrieval. The DCS for tracking laboratory logbooks is a module in the LIMS

The OFFICIAL COPY is the on-line version. All other copies are considered unofficial and uncontrolled.

and is used to assign serial numbers and store the relevant metadata. Records of logbook transactions are stored in Oracle along with the LIMS analytical data.

2.3 Records Availability

Laboratory clients may contact the laboratory with a request for access to electronic or paper records. It is a policy of the laboratory to only make copies of records available to the client entity that submitted samples to the laboratory unless a) the client indicates via telephone, e-mail, memorandum or letter that records are to be released to another party or b) a valid request is made under Chapter 119 of Florida Statute. Records associated with criminal or civil investigations will be released to parties other than the client only if the requirements and exemptions of Chapter 119, Florida Statute are satisfied and if the client entity indicates in writing that such a release is to be made. Original records will be released only upon written request satisfying the above criteria. The recipient of original records must sign and date the record release log maintained by the laboratory. The log also contains information related to the identity of the records and the individual releasing the records. Unless prevented by judicial order, the laboratory will retain a copy of all original records which must be released.

In the event that the Laboratory Programs cease operation, all records will be turned over to the Department's Chief Information Officer and all clients will be notified. The Department will continue to maintain client access to electronic and paper records for a period of not less than 5 years after the completion of the laboratory project.

2.4 Records Retention

It is the laboratory's policy to retain all records for not less than 5 years after the date of generation.

Appendix of Changes

03/18/2008	Added language explaining existing handling procedures for original records
04/15/2008	Changed references to the Bureau of Information Systems (BIS) to the Office of Technology & Information Services (OTIS); also altered language to indicate that the servers housing analytical data are maintained by OTIS.
03/17/2009	Added section 2.3 - Records Retention

The OFFICIAL COPY is the on-line version. All other copies are considered unofficial and uncontrolled.

01/25/2013 Revised language to indicate that only the cover pages of final reports are now archived as paper.

07/02/2015 Updated storage of electronic records and added the LIMS Document Control System for tracking laboratory logbooks.

The OFFICIAL COPY is the on-line version. All other copies are considered unofficial and uncontrolled.