Protocol for the Preparation and Document Control of Standard Operating Procedures (SOPs), Forms, and External Documents

1.0 STANDRARD OPERATING PROCEDURES

Standard Operating Procedures (SOPs) are "how-to" documents that describe the various standardized procedures conducted in the lab. SOPs may also be used to document policies and procedures that apply to the entire lab. An SOP's content should be clear and unambiguous, enabling both novice and experienced personnel tounderstand and follow the procedures described in the SOP. SOPs provide a basis for uniformity, consistency and accountability and are invaluable as training vehicles for new personnel. A sound SOP can help minimize the introduction of systematic errors in a method by ensuring that all personnel follow a consistent procedure.

Laboratory SOPs are written by technicians, chemists/biologists, and/or analytical group supervisors involved in carrying-out the procedures described in the SOPs. The supervisor or manager reviews and approves the SOP. The SOP is uploaded to the intranet/internet sites by the Quality Assurance (QA) Officer or his/her delegate using the SOP Update Utility in LIMS. SOPs are broadly classified into three categories – Chemistry, Biology and Bureau. Chemistry and Biology SOPs document sample preparation and analysis procedures conducted in each section. Bureau SOPs document policies and procedures that apply to all sections in the laboratory.

The procedure by which an SOP is implemented is as follows:

1. A technician, chemist/biologist, and/or analytical group supervisor involved in carrying-out the procedure prepares a draft SOP detailing the methodology.

2. The draft SOP is reviewed by the manager in charge of the workgroup and submitted to the QA Officer as a final SOP.

3. The QA Officer (or delegate) reviews the SOP for completeness and posts the final SOP to the DEP Laboratory Internet site in 'portable document format' (PDF). The name of the SOP authorizer (supervisor submitting the final version), the effective date, and the revision date are recorded using the SOP Update Utility module of the Laboratory Information Management System (LIMS). The SOP expiration date is set one year from the effective date.

Note: *The LIMS SOP Update Utility is also used to record and track Laboratory Forms. Forms are processed similar to SOPs but do not need to be updated on an annual basis. They are updated only when necessary and have no expiration date.*

4. To revise an existing SOP or implement a new one, the revised or new SOP is submitted to the manager in charge of the pertinent work group. The manager reviews the SOP and submits it to the QA Officer, indicating whether the change is a minor or major revision. Minor revisions are those which do not involve modifications to the method, while major revisions indicate the method has been altered. A change in procedure that produces results that are incomparable with those reported before the method was modified would also justify a major revision. All SOPs must contain an Appendix of Significant Changes made during the revision period. The Appendix must include the date of any revisions and should indicate the SOP sections that have been edited. The final SOP should be submitted to the QA Officer (or delegate) as a

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Word document with the "track changes" feature turned on to incidate the content altered during the revision.

Note: *In cases where a specific SOP version has been certified by NELAP and subsequently undergoes a major revision, additional steps are required. The supervisor submitting the revision must also submit a method validation package and the appropriate paperwork for requesting NELAP certification of the new SOP version. Two successful proficiency testing studies (where available) must have been performed using the revised SOP and submitted by the PT provider to the accrediting authority.*

Submission of the SOP to the QA Officer by the EM constitutes approval of the revised or existing SOP. The QA Officer will re-post the revised SOP with a new effective date. A new version number will be issued for all new SOPs as well as those with revisions. The most recent revisions of all SOPs are maintained on the \\FLDEP1\DEAR\LABS\SOPs directory as well as on the Laboratory's Internet site (https://floridadep.gov/dear/florida-dep-laboratory/content/dep-laboratory-quality-assurance-manual-and-sops). SOP revisions no longer in use are archived in the same location in Microsoft Word format. ***Supervisors are responsible for ensuring that analysts are trained on new or revised SOPs.***

Note: ***Only the ONLINE version of any SOP is recognized as the official version; all other copies, including printed SOPs are considered unofficial and uncontrolled.***

5. For most methods of analysis, separate SOPs are written for the sample preparation and sample analysis portions of the analysis. Where the methodology does not require extensive preparation and/or analysis, these two SOPs may be combined into a single SOP. In addition, a separate equipment SOP may be written detailing the methods, materials, and schedules used in routine inspection, cleaning, maintenance, testing, calibration and standardization of the equipment. The equipment SOP may also specify the actions to take to correct equipment failure or malfunction; alternately such information may be included in preparation and/or analysis SOPs.

Each draft and official SOP shall contain or reference the following elements (where applicable):

1) identification of the test method or equivalent;
2) applicable matrix or matrices;
3) scope and application, including components to be analyzed;
4) summary of the test method;
5) definitions;
6) interferences;
7) safety;
8) equipment and supplies;
9) reagents and standards;
10) sample collection, preservation, shipment and storage;
11) quality control;
12) calibration and standardization;
13) procedure;
14) calculations;
15) method performance;

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16) pollution prevention;
17) data assessment and acceptance criteria for quality control measures;
18) corrective actions for out-of-control data;
19) contingencies for handling out-of-control or unacceptable data;
20) waste management;
21) references; and
22) any tables, diagrams, flowcharts and appendices.

Any SOP greater than 10 pages in length shall include a 'Table of Contents'. Additionally, every SOP shall have a meaningful and descriptive title and shall be prefaced with the following header information:

1) Effective Date - the date the current version is implemented in the laboratory. Under routine circumstances, this will be the date the document is updated in the LIMS by the QA Officer.
2) Revision Date - the date any major or minor revisions were made to the document. This is entered by the revision author and confirmed or updated by the supervising EM before submittal to the QA Officer. It will be used to determine the expiration date.
3) Name of Author or Revision author(s)
4) ID number and version control number (to be entered by the QA Officer only)

The footer shall contain the page numbering and statement in the following format:

Page X of Y (where X is the current page; Y is the total number of pages)
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Information presented in the SOPs shall be organized as descrived above, using the listed header and footer throughout the document. Content associated with each item may be arranged for optimal usability by the staff it is intended to support.

Note that some procedures (sample log-in, data review, other non-analytical practices) may not be consistent with this format. Those SOPs describing processes other than sample preparations or analyses (software operation, receiving room operations, administrative SOPs, etc.) must explicitly detail all aspects of the procedure or process described therein.

Appendices A, B and C display the general format of SOPs for Sample Preparation, Sample Analysis and Equipment respectively.

2.0 FORMS

Laboratory forms are documents that are used to record metadata generated in the course of an analysis. Forms are reusable templates, typically created using a word processor or a spreadsheet. Many spreadsheet forms contain fields or cells that perform calculations on raw data entered by the analyst. Examples of such forms include pipette calibration forms, TCLP extraction forms and forms for recording TSS and TDS data.

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Forms are generally created by a group supervisor or senior analyst. To ensure the integrity of calculations in forms, spreadsheets containing calculations must be locked and password-protected by the supervisor or designee who authorizes the finished version of the form. The mechanics of protecting a worksheet is best accomplished by first selecting the entire worksheet and locking all cells in the worksheet. The author of the spreadsheet then selects and unlocks only those cells that need to be edited by the bench analyst. Finally the author protects the worksheet using a password prior to releasing the form for use by analysts. The form is also sent to the QA officer who posts a PDF of the form in the laboratory document control system. The password is kept confidential and is known only to the author of the spreadsheet and select designees. Forms do not have an expiration date and can be updated by supervisors when changes are necessary.

3.0 EXTERNAL DOCUMENTS

External documents are documents that are not generated by lab personnell but created by external sources such as EPA, Standard Methods, TNI, ASTM and instrument and equipment manufacturers. They include regulations, calibration and test methods and instrument and equipment manuals used by lab personnell. As in the case of forms, PDFs of test methods currently in use by the lab are controlled, using the same document control system as SOPs. Test methods also have no expiration date but can be updated as new versions or revisions of test methods are released. Older versions of methods that are no longer in use are archived.

Manuals published by instrument and equipment manufacturers come in multiple formats – paper, or electronic (PDFs, HTML documents on disk etc.); many of the older instruments in the lab have paper manuals. Lists of manuals currently in use, their format (paper or electronic) and location (room number) are tracked by group in the LIMS document control system. The lists are updated as needed, when older instruments are retired and new ones are placed in service.

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Appendix A: Sample Preparation SOP

Effective Date:
Revision Date:
Revision Author:
SOP # (issued by QA Officer)

Title

1 SCOPE AND APPLICATION

1.1
1.2
1.3

2 SUMMARY OF THE METHOD
Method Reference:

3 APPARATUS AND EQUIPMENT

3.1

3.1.1
3.1.2

4 REAGENTS AND CHEMICALS

5 SAMPLE COLLECTION, PRESERVATION, AND HANDLING

5.1
5.2

6. SAMPLE PREPARATION PROCEDURE

7. SAMPLE ANALYSIS PROCEDURE
Reference analysis SOP, if applicable

8 QUALITY CONTROL

9. SAFETY/HAZARDOUS WASTE MANAGEMENT

10. REFERENCES

Appendix of Changes

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Appendix B: Sample Analysis SOP

Effective Date:
Revision Date:
Revision Author:
SOP # (issued by QA Officer)

Title

1 SCOPE AND APPLICATION

1.1
1.2
1.3

2 SUMMARY OF THE METHOD
Method Reference:

3 APPARATUS AND EQUIPMENT

3.1

3.1.1
3.1.2

4 REAGENTS AND CHEMICALS

4.1
4.2

5 SAMPLE PREPARATION PROCEDURE
Reference Preparation SOP, if applicable

6 SAMPLE ANALYSIS/QUANTITATION

7 DATA ARCHIVAL

8 QUALITY CONTROL

9 SAFETY/HAZARDOUS WASTE MANAGEMENT

10 REFERENCES

Appendix of Changes

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Appendix C: Equipment SOP

Effective Date:
Revision Date:
Revision Author:
SOP # (issued by QA Officer)

Title

1 SCOPE AND APPLICATION

1.1
1.2
1.3

2 EQUIPMENT DESCRIPTION (INCLUDE SERIAL NUMBERS, ETC)

2.1

2.1.1
2.1.2

2.2

3 REAGENTS AND CHEMICALS

3.1
3.2

4 EQUIPMENT OPERATION/SOFTWARE
Include software version number

5 EQUIPMENT MAINTENANCE/DOCUMENTATION

6 SAFETY

7 REFERENCES

8 TECHNICAL ASSISTANCE CONTACTS

Appendix of Changes

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Appendix of Significant Changes

11/01/2005	Edited item #4 and SOP examples to require an Appendix of Changes to document edits made to SOPs.
11/14/2007	Edited protocol to remove chemistry-specific references so the procedure applies to the entire Bureau. Updated references to server location.
11/10/2008	Added language to indicate the QA Officer may allow a delegate to review and upload new or revised SOPs to the LIMS system.
10/26/2011	Added language indicating that only the online version of any SOP is considered offical.
05/23/2018	Added sections describing the preparation and control of laboratory forms and external documents.

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