Standard Operating Procedure for Outsourcing Analyses through a Contract Laboratory

1. Scope and Purpose

The FDEP Laboratory enlists external laboratories to perform overflow work under the following circumstances: a) capacity for the requested analyses has been exceeded; b) the requested analyses are not performed by the FDEP laboratory; and c) the samples cannot be shipped to the FDEP laboratory in time to avoid expiration and therefore must be analyzed at a laboratory with closer proximity to the collection site. This standard operating procedure outlines the Laboratory's process for handling the overflow workload from the point of scheduling samples to reporting results to the client.

2. Scheduling Analyses

2.1. The Project Manager or other appropriate DEP staff schedules the work in the Laboratory Information Management System (LIMS). These analyses are categorized in the LIMS Scheduler as *Overflow*, and can be selected by LIMS analysis, method or analytical component. The contract/PO manager should be consulted when scheduling overflow analyses to confirm the necessary contracts and/or funds are in place to ensure the laboratory providing the service can be compensated.

2.2. If the analysis has not previously been procured, it may need to be added to the system before it can be scheduled. The quote obtained from the contract laboratory should include the cost, along with MDL/PQL information, sampling container/preservation requirements and analysis hold times. This information will be used to create the analysis template, which will be linked to the correct laboratory for display on the FDEP final analysis report.

2.3. If a sampling kit is requested, the DEP Laboratory provides containers for both the regular and the overflow analyses.

2.4. For analyses scheduled by DEP Laboratory staff, the client must be notified in writing or by e-mail that the analyses will be performed at a contract facility.

2.5. Once scheduled, the LIMS Scheduling Tracker may be used to monitor the overflow analyses anticipated in the upcoming weeks. The project manager notifies the contract lab project manager of the anticipated samples. You must copy the Contract or PO Manager on all correspondence. For microbiology analyses, the DEP ROC staff notify the contract labs of incoming samples if appropriate.

2.6. For projects containing a large number of overflow analyses or analyses with a short hold time (e.g. MBAS, Sulfides), the project manager notifies the overflow facility of the projected work. You must copy the Contract or PO Manager on all correspondence. Some analyses with very short hold times or other unique circumstances require samples to be shipped directly from the field to the overflow facility.

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3. Sample Receipt

3.1. Overflow samples are logged in the LIMS upon receipt and stored under proper temperature preservation (see DEP SOP LB-016).

3.2. For short hold tests the receiving staff and project manager must expedite the sample processing and transport so that the samples are analyzed within the holding time. If the test is to be analyzed by a laboratory with multiple campuses, sufficient time must be allowed for the local facility to transport the sample(s) to their appropriate lab to avoid expiration.

3.3. The project manager notifies the overflow facility by email to inform them of the incoming analyses and to set up the delivery or ship date to the facility, if needed. You must copy the Contract or PO Manager on all correspondence.

4. Assigning Tasks

4.1. The project manager signs and fills out a task assignment form (Attachment 1) and prints a summary from the LIMS Browser listing the Analysis ID, Request ID, event identifier and description, the Job ID, LIMS Sample ID and the collection date/time. One task assignment form can contain multiple projects if the samples are being transported the same day, to the same facility. ***Samples cannot be shipped or delivered to a contract lab until the task assignment form has been completed by the project manager and signed by the contract or purchase order manager.***

4.2. The signed and completed task assignment form and LIMS summary are bundled for shipment or transport to the contract laboratory. Samples are shipped/transported with the appropriate temperature preservation regardless of proximity to the DEP Laboratory.

5. Sample Shipping/Transport

5.1. Samples are sent/transported to the overflow facility at a frequency that is based on analysis hold time, event priority and the potential for more overflow samples for that same laboratory to arrive in the next few days. Samples supporting high-priority projects are always transported on the day they arrive at DEP.

5.2. Hand Delivery

- Samples are checked out of the LIMS to the individual delivering them using the overflow checkout feature in the LIMS Custody module and placed in a cooler with cold packs or ice and a temperature control bottle if thermal preservation is required.
- The signed task assignment form accompanies the samples to the overflow laboratory and is completed, noting the date/time of delivery and signatures to transfer custody from the DEP staff. A copy of the form is left at the overflow laboratory and the original returned to the project manager.
- Sample containers are not retrieved from the overflow facility unless they are scheduled as criminal case samples or specifically requested by the client. If samples are for a criminal case, indicate on the bottom of the task assignment form that the containers must not be discarded. Notify the contractor that the samples should be

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returned to DEP (by shipment or pickup). Have the task form signed for relinquishing/receiving the samples.

5.3. Sample Shipping

- Repeat step 5.2.1
- Sign and enter the date shipped on the task assignment form, and make a copy to enclose in the cooler with the samples.
- Ship samples priority overnight.
- Return the original paperwork to the project manager.

5.4. Task Assignment Form Processing

- Once the samples arrive at the overflow lab, the custody portion of the task assignment form is filled out to acknowledge sample receipt and is signed by the overflow laboratory's contract manager to accept the task. The signed task form is then e-mailed to the project manager and the contract manager within a couple of days of sample receipt. If an executed task form is not received within a few days of sample shipment, the DEP project manager should request it.
- For samples that must be shipped directly to the overflow laboratory due to holding time restrictions, a partially completed task assignment may be sent along with the samples from the sampling staff to the overflow laboratory. The overflow laboratory should confirm their arrival and the number of samples/analyses and email back the task form to the Project Manager and the Contract Manager for completion and signature before continuing any work. The completed signed task form can then be emailed back to the overflow laboratory. Alternately, the task assignment form may be filled out after the overflow laboratory confirms their arrival and the number of samples/analyses. The task form is then completed after the work is logged in to the LIMS and Sample IDs determined; it is then e-mailed to the overflow laboratory along with the sample metadata (Field IDs, Collection date/time) as soon as possible so they can begin processing the analyses. The Contract Manger should NEVER sign a form until all known variables have been filled in and verified.
- The Project Manager retains the original copy of the task assignment.

6. Checking TNI Certification

TNI (The NELAC Institute) certification may be checked or confirmed on the DEP website (https://fldeploc.dep.state.fl.us/aams/index.asp) that hosts a copy of the Department of Health (DoH) database. If appropriate, the certification number is associated with the overflow laboratory in the LIMS Analysis Editor so that it will be displayed on the cover page of the FDEP Laboratory Analysis Report. If the analysis is not TNI certified, the client should be notified to verify that the results will be still be suitable to meet the project goals.

7. Tracking Task Assignments

Both the project and contract manager track task assignments in a common spreadsheet. Task assignments are identified by a sequential number preceded by a two letter ID code for the overflow lab.

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8. Managing and Reporting Data

8.1. Data Acquisition

Results of overflow analyses may be received by the following means:

- The overflow laboratory may submit a paper report and mail it.
- Results may be submitted electronically by attaching a report or electronic data deliverable (EDD) to an email directed to the project or contract manager.
- The overflow laboratory may place a report or EDD in a directory on its FTP site.

8.2. Initial Evaluation

Once the report or EDD is received, the project manager and/or QA Officer reviews it for errors (required data elements missing from the deliverable, results not properly qualified, etc.). If such errors are discovered, the DEP Laboratories staff work with the overflow laboratory to resolve any problems and re-issue reports or EDDs as appropriate.

8.3. Upload Results to LIMS

- Manual
  The LIMS Results Editor is used to enter data manually (Laboratory → Technical → Results Editor). The tests must have been logged in and assigned a valid LIMS sample identifier. If the laboratory has reported date/time values in Central Standard Time (CST), they are incremented by one hour and entered as Eastern Standard Time (EST). Once a result, analysis date and time, and any appropriate data qualifiers or comments are entered, the values may be uploaded to the oracle tables.
- Electronic
  Results delivered as tab-delimited text in a pre-determined format may be electronically entered into the LIMS, using the Overflow Upload module (Laboratory → QC → Overflow Upload). Current EDD formats include Adapt EDD, Overflow, and Biological. The process is initiated by selecting the name of the overflow laboratory, then navigating to the file from the appropriate directory. For laboratories that have been flagged as ones that report times in CST, the upload program will automatically increment the collection, received, prepared and analysis dates to EST. If an EDD from the laboratory has been uploaded before, the program uses associations stored in a cross-reference table to translate the overflow laboratory's test and analyte names to those accepted by the LIMS. If this is a new overflow laboratory or an analysis that has not been previously procured, the program will prompt the user to manually create these associations. Once the grid has been populated, the data are reviewed to make sure they have been correctly parsed. If everything is correct and the upload prompt indicates 'Yes', the results and metadata may be uploaded to the LIMS.

8.4. Final Review and Assessment

- Once the data are uploaded to the LIMS, results can be assessed for technical consistency and usability in the Data Review/Authorize module (Laboratory → Administrative → Data Review/Authorize). This final review will confirm that the relevant dates are in logical order and that certain qualifiers (e.g., Q, J) have been appropriately applied and alert the user if they have not.

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- If this assessment indicates the dataset contains errors, the project manager will notify the overflow laboratory. Depending on the nature of the problem(s), the overflow laboratory may re-issue an amended report and EDD.
- When this final evaluation is complete and no unresolved issues remain, the job associated with the overflow samples is authorized for release.

8.5. File Management

- All files submitted by the overflow laboratory are saved to \\fldep1\dear\labs\lab3\Supplemental Event folder using the LIMS event name as the first string (e.g. SW-DIST-2016-02-04-04 Lab Name Report.pdf).

8.6. Reporting Results

When all of the analyses associated with a sampling event have been authorized for release, the LIMS event enters the certification queue. Certification and reporting of final results involves several steps.

- A draft copy of the final report is reviewed by a senior laboratory manager. If any issues are discovered, they are resolved with the supervisor of the relevant analytical group.
- An automated process then transfers the following files to a passwo**rd protected directory on the Laboratory's** FTP site: the final report, a comma-delimited text file containing all sample and QC results (if requested), the sample submittal and chain-of-custody forms, and any other relevant files associated with the event. A notification email is sent to the contact associated with the analysis request with a link to the directory containing the files listed above. Files are retained on the FTP site for a period of four months.
- That same automated process copies the files to an archive directory on a central server.

9. Invoice Payment

9.1. Within 5 business days of receiving the overflow lab invoice and report (both written and electronic, if applicable) the report must be reviewed and the invoice submitted for payment.

9.2. Follow the procedures for contract task assignment or purchase order payments outlined in the Process Contract Payment document located in: \\fldep1\dear\Labs\Lab5\Admin\ContractInformation\OutsourceWork\Manager\ContractChecklist&PaymentForms_DEP55-263.

Appendix of Changes

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Attachment 1

STATE OF FLORIDA DEPARTMENT OF ENVIRONMENTAL PROTECTION
TASK ASSIGNMENT/NOTIFICATION FORM: DEP Contract: LAB #

Contract Manager: Sara Armour, MS 6500 (850) 245-8084
2600 Blair Stone Rd.
Tallahassee, FL 32399-2400

Contractor: Test America (850) 878-3994
2846 Industrial Plaza Drive
Tallahassee, FL 32301

State Approval By: _____ Contractor Approval By:_____*
Project Manager Project Manager

Contractor Representative Contacted: Matt Jones Date:

Means of Contact:

Task Assignment Number: TA Maximum Cost: Turnaround Time:

Sample Delivery Date: _____

ProjectName/Description: (include purpose, location, etc.)

Parameter Group/ Method	**Sample Matrix**	**# of Samples**	**# of QC Samples**	**DEP ID #**	**Unit Cost**	**%mark-up**	**Cost (if any)**

Total:

Total Number of Containers Shipped:

QC Instructions: Report batch matrix spikes

Samples released to Contract Lab by: _____Date/Time: _____ Deliver Method:

Samples Accepted by:
_____Date/Time_____*****

*** Please sign and return by FAX at (850) 412-0497 or email to sara.armour@dep.state.fl.us**

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