# Validation of LIMS Software Development or Modifications that Affect the Calculation/Assessment of Analytical Results

## 1.0 Scope and Purpose

The FDEP Laboratory has developed a Laboratory Information Management System (LIMS) for the scheduling of laboratory workload, processing of raw analytical data, calculation of quality control measures, and dissemination of results to clients. This SOP describes the process for validation of modifications to the LIMS data tables or interface that may affect the calculation, assessment, or reporting of analytical results.

## 2.0 Procedure

2.1 New functionality or a modification to a LIMS module is identified. A request is usually made by entering a case in the LIMS Help Desk but may also be made by email or phone. The requester is provided the opportunity to fully describe the issue, which may indicate that more than one analytical group may be affected.

2.2 If the request represents an immediate need, the case is picked up by a staff member of the Scientific Support Services Program (SSSP) and the requester is notified via email.

2.2.1 The requester further articulates the details associated with the issue via email, phone conversation or a meeting with the appropriate staff members. If the change will affect more than one analytical group, individuals from each potentially affected group participate in the dialog until any issues are resolved.

2.2.2 Modifications to the LIMS code or interface are made. The requester is notified and asked to begin testing. If the modification affects more than one analytical group, supervisors from all groups are similarly notified.

2.2.3 The requester, along with other staff as appropriate, tests the modification to ensure that the change or new development results in the correct calculated result or assessment.

2.2.4 Further modifications are made if necessary, until the issues are resolved.

2.2.4.1 Feedback is provided to the SSSP, either confirmation that the modification gives the intended result or a report of remaining issues or problems. This feedback must include the date of testing and the name(s) of any data files used to test the software change, if applicable. Individuals from all


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analytical groups that may be affected test independently and report the results.

2.2.4.2 Analysts may retain paper copies of validation exercises in their individual work areas or offices, or a common area.

2.2.5 If a Help Desk case was created, it is closed by the SSSP Developer. A resolution is added to the record to include a brief description of the code or interface change, the test date, the individual(s) performing the testing and the filename(s) used (if applicable).

2.2.6 The software modification is also documented in the LIMS Development Tracking System (DTS). The DTS tracks the following metadata for code/interface/oracle table changes: Name of requester, date requested, details about the request, programming staff assigned to make the change, date change was completed, any files or records used to validate any new calculations, staff member performing the validation, current version number of the module and the date that version was implemented.

2.3 If the request does not represent an immediate need, the case is placed on a list for prioritization.

2.3.1 Periodically, the SSSP meets to review and prioritize outstanding Help Desk cases. Those selected for action are ranked according to Laboratory Program priorities and available resources.

2.3.2 The case with highest priority is picked up by a member of the SSSP and the procedure outlined in 2.2 above is followed.

## Appendix of Changes

07/25/2016 – Updated link to SSS Help Desk

09/04/2019 – Remove reference to the SSS Help Desk



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