

CT DSS LIMS SOP

1.0 Introduction

The CT Division of Scientific Services (DSS) uses a commercial off-the-shelf software owned by, Versaterm (formerly known as JusticeTrax (JT)) LIMS-plus software product, within its Laboratory Information Management System (LIMS). This is a software application used for tracking cases and evidence, generating analytical reports, and producing statistical reports and data. Any modifications to LIMS shall be documented, validated, and authorized.

The software shall be maintained in a manner that ensures the integrity of the data and information.

2.0 LIMS Support

2.1 Scientific Service Administrative Manager (SSAM) and Laboratory Information

System Manager (LISM): The Director's designees responsible for managing the implementation, maintenance and expansion of the LIMS. In addition, the SSAM and LISM are responsible for coordinating services with the department's Information Technology section.

2.2 LIMS Administrator: The SSAM and LISM's designee to manage the daily operations and configurations of the LIMS. The LIMS Administrator is responsible for the upkeep to the LIMS system and to aid users as issues arise. The LIMS Administrator supports the LIMS application, maintains and protects the data, provides hardware and software support and is the primary contact for LIMS assistance. There may also be designated backup(s) to the LIMS Administrator who also receive direction from management.

Primary responsibilities of the LIMS Administrator:

- Provide training to new personnel in the use of LIMS.
- Communicate problems, ideas or solutions relating to information technology and LIMS to LIMS Support.
- Take LIMS and IT-related direction from Lab Management.
- Create and edit Crystal Reports.
- Address chain of custody edits (requested through a Quality Management Software workflow).
- Make case or evidence deletions.
- Add new Laboratory Staff.
- Modify a Laboratory Staff Name (e.g., name change due to marriage).

The LIMS Administrator may also perform limited IT-related functions such as:

- Help laboratory staff add a new printer to their Windows profile, using the "Add a Printer" wizard.

- Reset a bar code label printer.
- Work with agency IT technicians to resolve a LIMS or IT problems.

2.3 System Administrator(s)

Designated individuals in the Department of Emergency Services and Public Protection are system administrators that have authorization and passwords to work on the server units or conduct system administrator functions, such as rebooting the server.

2.4 Database Administrator

Designated individuals in the Department of Emergency Services and Public Protection are system administrators that have authorization and passwords to work on the system for tasks such as database defragmentation.

3.0 Laboratory Management

Laboratory management is comprised of the individuals within the DSS having operational and/or technical responsibility of the Division. Management includes the Director, Scientific Services Administrative Manager, Deputy Directors, Assistant Directors and Laboratory Quality Assurance Manager; all which are found in the DSS table of organization.

4.0 Requesting LIMS Assistance from LIMS Administrator and Requesting LIMS Modifications

If modifications/assistance are needed in the LIMS application, the request is submitted through the requester's chain of command to the LIMS Administrator through a Quality Management Software workflow, "Request for LIMS Administrator (not edit COC)".

If significant changes are needed to a report released to outside agencies, the Quality Management Software workflow "LIMS Report Template Substantive Changes" workflow is opened which requires the Director's approval of the request and a section manager or designee's testing of the changes prior to the update being implemented.

Some modifications may need to be submitted to Versaterm support for accommodation. In the rare occasion a chain of custody edit is necessary, a Quality Management Software workflow "Chain of Custody Edit" is opened which will require the Director's approval of this request.

5.0 LIMS Training

The LIMS Administrator and unit designees coordinate together to provide training to new personnel in the use of the LIMS. Unit specific training may document additional LIMS training. See also the LIMS training checklist which is appended to this document.

6.0 LIMS Security

Please refer to GL-4 LIMS.

Users will ensure that no one else enters or changes data in the application using their log-on and security levels. Unauthorized access to LIMS is prevented by the use of username and passwords.

7.0 User Names and Accounts

LIMS User Accounts are created for all laboratory staff members needing LIMS access. The Director delegates the authority to the SSAM, LISM, LIMS Administrator and designees to create LIMS accounts. The Director will need to approve a request if the person requesting an account is not an employee or intern at the DSS. When new account(s) are needed, an email should be sent to the LIMS Administrator and Cc: SSAM/LISM. The LIMS Administrator or designee will create the LIMS account and forward the LIMS credentials to the requestor.

8.0 Roles and Permissions

Roles can be made as needed, per Laboratory Management discretion, and are created in LIMS by LIMS Administrators. Roles are created to reflect the rights needed by groups of users. Permission levels are determined by Laboratory Management in conjunction with the LIMS Administrators. Security permissions dictate what kind of rights users have in LIMS and are managed through Roles. Permissions accumulate based on the number of roles applied to an individual user. Roles and permissions are maintained in the LIMS application.

9.0 Entering a New Case in LIMS

Please refer to ER SOP-02 General Evidence Submissions

10.0 Assigning Laboratory Case Numbers

When a Request for Analysis form for a brand-new case initially enters the Division, a laboratory case number is assigned. However, if there is an existing laboratory case number, in most situations, that number is used instead of assigning a new laboratory case number. This means agency case numbers must be searched prior to assigning a laboratory case number.

Please refer to ER SOP-02 General Evidence Submissions

11.0 “CASE INFO” Tab

The “Synopsis” field is used to record non-critical information, as well as other communications regarding cases (e.g., comments, amendments, chain of custody edit documents, approvals, any evidence acceptance issues, phone calls/emails).

12.0 “AGENCY” Tab

The “Agency” Tab is used to track agencies and the agency case numbers involved in cases. For each agency within a case there is normally an associated agency case number. However, if multiple agencies are listed, one agency and its associated case number must be identified as the primary agency for a case.

Normally, the primary agency is the agency that appears on the RFA with their corresponding agency case number. Exceptions to this are permissible. Additionally, if a case being received will be added under an existing laboratory case, the agency and associated agency case number are identified as primary and may be changed, as needed.

13.0 “OFFENSE” Tab

The Offense, City, and Date, must be entered. If the offense is missing LIMS may not print a receipt for the evidence submitted. Also, the city prints on the receipt and will be blank if not added.

The “State”, “County” and “Country” fields may fill in by default and are based on the primary agency. Additional info may be recorded as needed.

14.0 “INDIVIDUALS” Tab

If additional information relating to individuals involved in the case (e.g., Suspect or Victim) is available on the RFA form, then this information can be recorded in this tab. The “scene” can also be added if not a crime against a person. Example: “larceny of a fire department”.

15.0 “EVIDENCE” Tab

15.1 Entering Evidence

Each sealed container/package of evidence shall be logged into LIMS as a submission and receive an evidence bar code. The evidence description must include the agency item number, (when it is available/known) and the physical description.

Examples:

001 #1 Bag with “2 swabs from mouth of water bottle”

002 #3 Envelope with “(1) Projectile”

003 TX O.C.M.E. “Specimen(s)”

Evidence descriptions may be edited in LIMS. If the description is edited, a new barcode label may be printed.

15.2 Evidence Kits

Evidence Kits are shortcuts designed within LIMS which can be used to eliminate redundancy in data entry. Please refer to these ER SOPs for usage:

ER SOP-09 Guidelines for Receiving Sexual Assault Collection Kits

ER SOP-11 Guidelines for Receiving DUI Urine and DUI Blood Evidence Collection Kits

15.3 Evidence Barcode Labels

Evidence barcode labels (submission or item) will not be used on anything other than evidence or evidence containers.

15.4 Itemizing Evidence

Please refer to GL SOP-4 LIMS for evidence and report itemization (see *note below).

Itemization must be done if evidence is created or removed from an existing piece of evidence and is placed into a separate, sealed entity to be used for tracking purposes. Example: taking an aliquot of powder and placing it into a sealed test tube for analysis does not need itemization.

To create a new evidence item:

On the Evidence tab, choose <Add Evidence>.

In the Description field, enter the item number and concisely describe the new item.

Initial custody information is recorded at the time the Evidence Control officer receives/accepts the evidence from a submitting agency and transfers the evidence to another lab staff member or lab storage area.

Print the evidence barcode and affix it to the new parent container.

*Note: Report sub-items: When creating reports in cases with multiple agencies, the agency receiving the report should be listed in the description to ensure it is returned to the correct department, to show in LIMS who was given a report, and so that it prints on the return receipt.

Ex: DNA report – Vernon PD
DNA report – SAO
DNA report – OCME

15.5 Evidence Submission

Please refer to ER SOP-3 “General Evidence Submission” for more details on how the evidence receiving staff accepts evidence through LIMS for the laboratory. Refer to ER 1.1 Evidence Submission Guidelines for details on what constitutes an acceptable item of evidence for the laboratory.

16.0 Chain of Custody

As evidence is received, transferred, and analyzed in the laboratory, information is captured within LIMS.

Chain-of-custody (COC) for the Division begins when the laboratory receives the evidence and does not end until the evidence is released from the laboratory’s care. The RFA form and the LIMS chain-of-custody records must accurately reflect the movements of evidence.

17.0 Temporary Vault Storage

If necessary, temporary storage locations can be created and used within LIMS.

18.0 “REQUEST” Tab

Request for Service

The Request for Analysis field is used to document LIMS [services] analytical examinations requested in a RFA form.

Please refer to ER SOP-02 General Evidence Submissions for guidance.

19.0 Completed Case

A LIMS Service is generally considered complete or closed when it has been “Admin Reviewed”. Other LIMS services may be considered complete at other milestones.

20.0 Relating Requests to Evidence Submissions

All submitted evidence for a case should be related to a LIMS service request. This may be done by analysts or the Evidence Receiving Staff.

If the evidence item is highlighted by the mouse and “right” clicked, and related evidence tab is then available.

21.0 Milestones

Milestones indicate the status of requests to help track progress through various analytical stages. The status of requests for services, in general, are considered “in progress” requests until the “Admin Review” milestone is marked.

21.1 Unassigned

Request has not been assigned to an analyst.

21.2 Assigned

This milestone is automatically set at the time a request is assigned for analysis. The assignment is done either by the Evidence Receiving staff, case management staff, a supervisor, forensic science examiner or Laboratory Manager.

21.3 Findings Entered

This milestone is marked automatically when the assigned analyst has entered the information in the “Edit Findings” section. The “Findings Entered” milestone must be created in order to proceed to the next milestone.

21.4 Draft Complete

This milestone is marked after the “Findings Entered” milestone and is used to indicate that a Request for Service is ready for technical review. A Laboratory Report may or may not be printed at this time. The assigned analyst has the appropriate permission to mark a Request for Service “Draft Complete”.

21.5 Technical Review

This milestone is marked after the Draft Complete milestone and is used to indicate that a request has been successfully technically reviewed. The person conducting the peer review is responsible for marking this milestone. Exceptions to this are handled on a section by section basis.

21.6 Administrative Review

This milestone is usually indicates that a request is complete and that a report can be distributed to the customer. It can only be set to Administrative Review after the Technical Review milestone is marked. For some services a report is automatically generated after this milestone is reached. For this reason, caution must be used when marking a releasable milestone.

21.7 Amended Report

When an issued report needs to be changed, amended or re-issued, for any change of information, the original report will be uploaded as an attachment in LIMS. An “Amended Report Required” workflow will be created in Quality Management Software to verify this step was completed. The workflow must be approved by a Deputy Director or manager. For reports generated through LIMS, the request is then unreleased by a LIMS Administrator or designee. Once the original request is ready for the analyst to amend the report, the analyst will select the button found on the original released request with the 3 dots or by selecting “Additional Data”. Inside the Ext Data form the analyst will select “Amended”, type the reason for the amended report and enter previous report dates that were released.



22.0 Evidence

Each section will have LIMS storage locations clearly identified for storing evidence. Storage locations can be designated by box, shelf, cabinet, or general area. Each location description must be unique enough to distinguish it from other locations and detailed enough regarding the location or intended use.

23.0 LIMS Security/Maintenance

The LIMS server is put through a defragmentation every week. Since this does not affect case information, a performance check is not necessary.

Backups:

- a. Weekly and Daily backups allow data to be retrieved at the end of each day for the last 2 weeks.
- b. Hourly backup allows to restore the database for any date for any hour for the last 1 week.

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- c. Backups performed off the server by IT provide restoration of any backup file for the last 30 days.
- d. There is an audit database, “sqllims32_audit” that keeps a log of audit data since year 2005.

Actual LIMS data and LIMS backups reside on separate environments.

Semi-Annual Maintenance:

The following tasks will be completed twice a year and a performance check will be completed afterwards.

- 1. Make a full backup copy.
- 2. Update indices.
- 3. Update statistics.
- 4. Perform a database integrity check.
- 5. Make a full backup copy.

24.0 Validation and Performance checking

Please refer to GL 22 Policy on Validation and Performance Checks.

If a new LIMS is implemented, it will be validated prior to its introduction.

For the current LIMS, a performance check will be done after any scheduled maintenance, such as a system maintenance (twice a year). If a significant upgrade (going to a new version of the current LIMS) is performed the LISM will work with the SSAM and Director to determine if a full validation is warranted. For example, patches to address bug fixes may not need a full validation.

A performance check consists of the LIMS Administrator checking the functionality of the system, ensuring that crystal reports were not corrupted and running a mock case through the system. The performance check will be documented by way of memo from the LIMS Administrator.

These are the steps taken:

- 1. Create a new case.
 - a. Add agency and agency case number.
- 2. Add case info in Synopsis memo field.
- 3. Add offense.
- 4. Add individuals.
- 5. Add evidence including kits.

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- a. Transfer evidence.
 - b. Print evidence barcodes.
6. Create requests and associate evidence.
7. Assign requests
 - a. Verify that assignment notification went out.
8. Complete a final report.
 - a. Include all milestones: draft complete, tech review and admin review.
 - b. Verify milestones.
 - c. Print final report
9. Print case barcode.
10. Print case report.
11. Print and verify chain of custody.
12. Add and delete a related case.
13. Run and verify an Ad Hoc Query.
14. Run and verify a Crystal report.
15. Go into evidence receiving and see if they have experienced any issues.