Laboratory Information Management System (LIMS) StoreMan User Specification

# Version history

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Author | Details of change |
| 1.0 | 19/11/2008 | Martin Radley | First release. Bugs addressed #180, #487, #551, #742, #965, #1638, #3348, #3951 |
| 1.01 | 23/1/2009 | Martin Radley | Correct EDMS document number in header |
| 1.02 | 17/11/2009 | Martin Radley | Updates following design discussions |
| 1.03 | 05/04/2013 | Martin Radley | Additional requirement added to section 7.4 |

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# Overview

## Purpose

StoreMan will be used for the inventory management of samples stored in the ultra cold storage facilities operated by the CTSU laboratories. The software will allow both viewing of the contents of the facilities and appropriate processing of the samples stored.

## Assumptions

This user specification assumes the use of LIMS database version 2.5 in Ingres 2006.

## Traceability

Where required, each requirement in this document will be followed by a unique bracketed number. This number will be used in other validation documentation to ensure traceability.

## Features

The following features will be available within the application:

Inventory management

* View contents of tanks, including sample history.
* Transfer blocks of samples between tanks/racks etc where necessary
* Configuration of new tanks/vessels/sites

Sample management

* Track boxes of samples ready for moving off site
* Manage process of removing samples from storage
* Create sample history for samples already in storage
* Handle marked “referred” by Box Reception application
* Create relevant database entries for samples to be analysed from storage

Sample retrieval

* View previous retrieval lists and current location
* Create retrieval list
* Retrieval assistant, to guide user through retrieval and confirm sample acquisition
* Rationalise samples in partially filled boxes

# Audit trail

The application should use the standard LIMS auditing as documented in [EDMS document 1310: LIMS Security and Auditing](http://p180/scripts/qwbcgi.exe/docfetch?id=1310&db=live).

# Performance requirements

## Users

The application should be able to run on more than one PC at a time though steps should be taken to prevent access conflicts (REQ 3.1).

## 3.2 Hardware

The application should run on LIMS buddy PCs (REQ 3.2.1) but will also need to be available to users at the two remote storage sites using a laptop (REQ 3.2.2) Appendix 3 shows details on what functions are required where.

# Log on screen

## Security

This application should use standard LIMS secure access (see [EDMS document 1310: LIMS Security and Auditing](http://p180/scripts/qwbcgi.exe/docfetch?id=1310&db=live) for details)

## Entering application

When valid security data is entered and a project selected the operator should select OK to go to the application main screen (REQ 4.2).

## Leaving application

At any time from the access screen the operator should be able to close the application by selecting close (REQ 4.3).

# Main screen

The following functions should be available from the main screen:

## Inventory management

Button to access the inventory management screen (REQ 5.1).

## Sample management

Button to access the sample management screen (REQ 5.2).

## Sample retrieval

Button to access the sample retrieval screen (REQ 5.3)

## Status indicator

Display boxes awaiting transfer (see REQ 7.1.8), samples for removal and removed individually (see REQ 7.2.6), created retrieval lists (see REQ 8.2.9)

# Inventory management screen

## Browse stored samples

Allow the systematic selection of site then tank then section/segment then rack then box then sample (REQ 6.1.1). At each stage the history of the selection should be displayed (REQ 6.1.2).

## Move inventory contents

Allow the selection of a tank/section or segment/rack/box and allow the selection to be moved to another location of similar size (REQ 6.2.1) or several selections of smaller size (REQ 6.2.2).

## Configure

Allow the configuration of new sites (REQ 6.3.1), new tanks (REQ 6.3.2) and new rack layouts (REQ 6.3.3)

# Sample management screen

## Boxes for transfer

Displays a list of boxes created and filled by Aliquot Allocation where no analysis is required or following result transfer where required (REQ 7.1.1) list can be filtered by single box type (REQ 7.1.2) or multiple box types (REQ 7.1.3), selection can be printed (REQ 7.1.4) and/or exported as a text file (REQ 7.1.5). Allow addition of boxes to the list manually (REQ 7.1.6) and remove boxes from list when Box Reception marks them as stored (REQ 7.1.7). The number of outstanding boxes for transfer should be displayed in the status indicator on the main screen (REQ 7.1.8).

## Discard sample/s

Allow selection of sample (REQ 7.2.1.1) or samples (REQ 7.2.1.2) (Bug # 1638) for removal from storage and display list of samples that have been marked for removal (REQ 7.2.2). Allow status to be updated when removed (REQ 7.2.3) and then again when discarded (REQ 7.2.4). When discarded produce an appropriate sample event form (see appendix 1 for example) with details completed and saved in K:\lab\LIMS\Archive\Sample Event Records\LIMS generated\*project name* (if no project name subdirectory exists, one must be created) with a filename in the following format AUTO\_SEF-*ST-nnnnnnnn-ID* where *ST* = study initials (see appendix 2), *nnnnnnnn* = sequential number starting at 00000001 for each project and *ID* = participant ID to which the form relates (REQ 7.2.5). Display samples marked for removal and removed individually on the status indicator on the main screen (REQ 7.2.6). User should be allowed to add notes at each stage of the process (REQ 7.2.7) (Bug #551).

## Analyse samples

Create appropriate database entries for samples to be analysed. List of samples for entry creation may be either a text list (REQ 7.3.1), stored box (REQ 7.3.2) (Bug #3348) or retrieval list (REQ 7.3.3). If list is generated from stored samples (ie box or retrieval list) only create entries for samples of appropriate status (REQ 7.3.4) (Bug #3951). Users should be requested to select the appropriate profile and descriptor values to be inserted into the database (REQ 7.3.5) (Bugs #742, #965). Duplicates of existing entries at same status should not be created (REQ 7.3.6) and a warning should be generated if duplicates are found at status’ other than invalid or complete (REQ 7.3.7) (Bug #487).

## Referred boxes

Box Reception may mark boxes as “referred” where a discrepancy has been noticed in the box details. The following functions are needed to handle these discrepancies:

Confirm entered details as correct (REQ 7.4.1)

Mark expected box as invalid (REQ 7.4.2)

Allow edit box name (REQ 7.4.3)

Allow edit of first or last ID (REQ 7.4.4)

Allow edit of first or last position (REQ 7.4.5)

Allow sign off of boxes (REQ 7.4.6)

Allow edit of tank/rack/slot for existing records (REQ 7.4.7)

# Sample retrieval screen

## Previous lists

Allow previous retrieval lists to be viewed, first list names (REQ 8.1.1) then list of boxes samples retrieved into with current storage location (REQ 8.1.2).

## Create list

Allow import of list of sample ID’s, cryovial ID’s or box names from either a text file (REQ 8.2.1) or from specimen table (REQ 8.2.2) and allow selection of primary aliquot choice and secondary aliquot choice (REQ 8.2.3). Generate list of sample ID’s with location of primary aliquot choice and secondary aliquot choice in separate columns (REQ 8.2.4), or where appropriate a list of box numbers (REQ 8.2.5) and allow list to be ordered alphanumerically by any column (REQ 8.2.6). Ask user if samples are to be retrieved to new boxes (REQ 8.2.7), if user specifies yes then allow a destination location to be mapped to each sample barcode (REQ 8.2.8), this would be a new box for the sample to go into once retrieved, if user responds no then use existing box numbers and locations and assume the samples will be kept in the original location (REQ 8.2.9). Where no destination is specified new boxes should be generated unless whole boxes are being retrieved (REQ 8.2.10) and they should be filled sequentially (REQ 8.2.11). After creating a list the following options should be given, Save or Discard (REQ 8.2.12). If Save is selected the user should be asked to name the list prior to it being saved (REQ 8.2.13), if Discard is selected an “Are you sure?” message should be displayed with the “Yes” response returning to the sample retrieval screen (REQ 8.2.14) and the “No” response returning to Save/Discard option (REQ 8.2.15). Created lists should be displayed on the status indicator on the main screen (REQ 8.2.16).

## Retrieval assistant

Allow selection of retrieval list that are either in progress or new (REQ 8.3.1). For new lists give the option to divide the list (REQ 8.3.2), if “Yes” is selected allow user to define division points in list (REQ 8.3.3) and present each section for retrieval in turn with the option to re-order each sub-section by sample ID, primary aliquot location, secondary location or destination (REQ 8.3.4). If no is selected allow whole list to be ordered by sample ID, primary aliquot location, secondary location or destination (REQ 8.3.5). Following this division and re-ordering the user should be asked to save the changes prior to commencing retrieval with the option going back to re-order if necessary (REQ 8.3.6). For in progress lists these steps should be skipped (REQ 8.3.7).

Work through list or sub-section by giving the storage location and sample ID of each sample on the list in the order saved above (REQ 8.3.8) as each sample is retrieved it’s barcode should be scanned, if the scanned barcode matches that on the list the destination location should be displayed and the next ID/location should be displayed (REQ 8.3.9) if the ID’s do not match a warning should be displayed and re-entry of the barcode required (REQ 8.3.10). When working through the list the previous five successfully entered ID’s should always be visible (REQ 8.3.11). The option to exit the process saving progress should be offered, with an “are you sure?” message in case of accidental selection (REQ 8.3.12).

## Rationalise tanks

Function to eliminate empty spaces in a tank. Initially it should work as the create list function (see section 8.2) but the sample list should be generated from the current contents of the box/rack/section or segment/tank selected for rationalisation (REQ 8.4.1). Then the retrieval assistant (see section 8.3) should be used to guide the user through the transfer from the existing boxes into the new ones (REQ 8.4.2).

# History

All actions throughout the application should add to the sample and or box history (REQ 9.1). (Bug #180)

# Appendix 1

**SAMPLE EVENT FORM (SEF)**

**study name here (XX)**



**Study:** study name here

**Reference number:** SEF-XX-00000001-ABC123

**Date:** 01/04/2010

**Sample ID:** ABC123

**Sample Type:** EDTA

**Event Details:** e.g.No EDTA sample received, citrate sample received, unsuitable for analysis.

Dispose of sample as patient has withdrawn consent

**Missing vacutainers:**

**The following vacutainers were missing:** EDTA

# Appendix 2

**Sample disposal:**

**Reason for Disposal:** Patient has withdrawn consent for sample storage

**Barcode ID (if different from sample ID** above): 0011223344

**Date of Disposal:** 01/05/2007

**Method of Disposal:** Sharps bin for incineration

**Initials:** XY

**Missing results:**

**The following test results will be missing:** Cholesterol, Trig, ApoA, ApoB, HDL, LDL

**Reason:** Citrate samples unsuitable for lipid analysis

Other:

|  |  |  |
| --- | --- | --- |
| Database | Project name | Study code |
| ldb1 | SEARCH | SE |
| ldb2 | HARP | H1 |
| ldb3 | HPS | HPS |
| ldb4 | ETHER | ET |
| ldb6 | PROCARDIS | PC |
| ldb8 | ISIS | IS |
| ldb10 | HARP II | H2 |
| ldb11 | Whitehall | WH |
| ldb13 | Experiment | EX |
| ldb14 | SHARP | SH |
| ldb15 | ASCEND | AS |
| ldb16 | HAPIEE | HP |
| ldb17 | Kadoorie | KA |
| ldb18 | Breakthrough | BBC |
| ldb19 | EXQA | QA |
| ldb20 | HPS2-THRIVE | TH |
| ldb21 | Mexico | MX |

# Appendix 3

|  |  |  |  |
| --- | --- | --- | --- |
| Feature | Section | Run on buddy PC | Run on laptop |
| Inventory management | 6.1  6.2  6.3 |      |      |
| Sample management | 7.1  7.2  7.3  7.4 |        |        |
| Sample retrieval | 8.1  8.2  8.3  8.4 |        |        |
| History | 9 |  |  |