LIMS Functional Requirements Checklist

LIMS Functional Requirements Checklist for Civil Laboratories

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1 Introduction

The functional requirements checklist based on Saudi Aramco standards 23-SAMSS-070 is derived on the request of Inspection Department (ID) to cover essential functions of Laboratory Information Management System (LIMS).

By enforcing the functional requirements checklist, ID will mandate third party civil testing laboratories to utilize LIMS for managing their laboratories operation in alignment with Saudi Aramco efforts towards digital transformation.

The functional requirements checklist is included the features of sample life cycle, its components and ISO 17025 functions defined in LIMS.

This checklist is considered as a live document and new items can be introduced to close any gap at the sole option of Saudi Aramco based on the findings during the routine/irregular assessments.

2 User Decision Scenarios and Event Driven Work Flow

LIMS shall provide with an easy and secure method of defining the automatic execution of programs that are triggered on any specific sample or test events. The events shall be able to control the workflow defined for completing the sample life cycle. The detail of functionalities of sample life cycle is explained in next section

The event shall be able to define the automated actions but not to limited the below

Sample Login

- Assignment of user-defined sample IDs, product, tests, due date etc.
- Checking duplicate samples with the same product, tests and login time
- Generation of sample labels
- Notification to operation for collection of samples
- Notification to lab for preparation of samples

Sampling (Receiving)

- Perform sampler certification
- Notification to operation if sample is rejected
- Assignment of technicians to tests & notifications

Testing

- Decreasing of quantity of reagents
- Re-format of calculation
- Notify Customers if test is out of spec / control limit
- Reject the test if it is out of spec / control limit

Review and Approval

- Business rule option for auto approval of a test result if it meets with the control and spec limit
- Auto approval of test result if it meets with the control and spec limit; the remaining will queue for manual approval
- Notification of result data, product certificate etc. to customers
- Notification to customers for Out of spec results
- Transferring of result data to ERP (EPM) and in-house applications integrated to LIMS
- Notification to the Lab authorized person if essential test marked for a sample is not performed.

Re-testing & SQC

- Follow the same sequence of steps of sample life cycle for retesting and SQC sample.

Result Reporting

- Result reporting shall be configured as part of review and approval step if immediate reporting is required otherwise scheduled reports around the clock can be configured as per operation needs.

3 Complete Sample Life Cycle

LIMS shall be able to follow the typical sequence of operations; which is called the Sample Life Cycle. LIMS shall provide full automation of status tracking of a sample at each stage. Following standard operations of samples that are usually carried out in a laboratory:

3.1 Sample Registration

#	LIMS Functions/Requirements
3.1.1	The first step in the sample life cycle is to create the initial entry in the LIMS database for one or a group of samples depending on their schedule
3.1.2	The registration process shall allow the user to identify a sample and assign tests automatically and their product-specific limits by using simple point and click operation
3.1.3	LIMS shall allow the laboratory to pre-log (before) and post-log (after collection) samples through a web portal
3.1.4	LIMS shall provide an easy Graphical User Interface (GUI) to log non-routine samples on demand.
3.1.5	LIMS shall provide a logical link between multiple samples that are submitted together for registration.
3.1.6	LIMS shall be able to assign tests/analyses as single or in a group to a sample whose results are measured and recorded as part of a test method.
3.1.7	LIMS shall include a mechanism for scheduling routine samples which shall automatically log samples for each shift around the clock as per defined schedule in the LIMS system.
3.1.8	LIMS shall assign a default test list automatically to the given product when it is selected from a predefined list.
3.1.9	Samples to be scheduled shall be identified by sample name, product, sample point, product specification, and test properties via LIMS screens and reports to authorized users.
3.1.10	LIMS shall have capability to associate special testing instructions and other notes from the lab with each sample.
3.1.11	LIMS shall allow the authorized user to edit the test list assigned to a sample with full audit trailing.

3.2 Sample Identification

3.2.1	LIMS shall assign a unique sample identification number automatically. LIMS shall also provide a user-defined structured sample identification number as an additional option
3.2.2	LIMS shall be able to re-assign tests/analyses as single or in a group to a sample whose results are measured and recorded as part of a test method.
3.2.3	LIMS shall have capability to capture and align additional information of test components, priority, level of accuracy, and precision admissible under a given testing method or Lab SOP.

3.3 Sample Collection

3.3.1	LIMS shall notify the proponents by email about the collection of daily scheduled samples
3.3.2	LIMS shall assist the sample collection process (post sample registration) by printing collection lists and generating labels (bar code) for the sample containers.
3.3.3	LIMS shall be able to print labels on the designated label printers located at different labs or operating facilities.
3.3.4	LIMS shall be able to print sample collection sheet to be signed by the reps of lab and inspection department

3.4 Sample Receipt

3.4.1	LIMS shall provide the sample receipt function by enabling the laboratory to record when the sample was received and by whom and additional tests can be ordered for particular samples during the process.
3.4.2	LIMS shall be capable of printing labels automatically or on request, when samples are ready to be collected or in advance with the unique sample identification for scanning/reading later.
3.4.3	LIMS shall provide the functionality to calculate laboratory turnaround times within management reports.
3.4.4	LIMS shall be able to create sample labels containing barcodes and provide direct support for using barcode readers to receive samples.
3.4.5	LIMS shall provide with an easy and flexible method of defining different formats and layouts according to the size of labels.
3.4.6	LIMS shall support suitable compatible barcode printers and scanners.
3.4.7	LIMS shall provide functionality to reject sample and notify the proponents by email with rejection note. Typical rejection conditions include but are not limited to the following: a) Sample is contaminated b) Sampler is not certified c) Sample label tag is dilapidated d) Any other condition which does not meet with the lab in-house quality procedure.

3.5 Work Assignment

3.5.1	LIMS shall provide functionality to assign a sample or group of tests to labs or technicians. The assignment shall be made either automatically or manually by the lab authorized user.

3.6 Analysis

3.6.1	LIMS shall provide user friendly screens to enter results by sample / test which allows entry of any / all test results for a single sample or group of samples.

3.6.2	LIMS shall record results with the time and date of posting and the identification of the operator who performs the test.
3.6.3	LIMS shall enter the test results automatically when the results from lab instrument integration are posted directly into the database as they are obtained.
3.6.4	LIMS shall ensure rule for recording of instrument information along with result entry and prevent entering test results when referred instrument is overdue for service.
3.6.5	LIMS shall provide unidirectional interface to lab instruments for result data transferring.
3.6.6	Product specifications shall be selectable for each sample so that it shall be immediately visible whether a sample meets product specifications.
3.6.7	All testing instructions, methods and lab notes associated with the sample and test shall be viewable during sample life cycle.
3.6.8	LIMS shall process results from virtually any type of test. The results types entered for tests are included but not limited to following: a) Quantitative: Results are entered by typing the numeric result in the appropriate fields. In addition to entering numerical results, results with tags such as greater than, less than, count can be designated; b) Pass/Fail: This is the simplest of the test types. Possible values are Pass, Fail, and Warning. Results are entered by selecting the appropriate choice from a browse list; c) Free Text: Detailed qualitative results are entered by typing the descriptive text freehand in the appropriate fields; d) Menu: This is used when the results can be constrained to a small set of user-defined, specific choices and is often used for appearance testing.
3.6.9	Test results shall be validated during data entry including issuance of a warning message for all out-of-range test results.
3.6.10	Out of range test results shall be automatically flagged and highlighted with different sign and color upon data entry.
3.6.11	LIMS shall display validity ranges on screen during validating the test results.
3.6.12	LIMS shall block the analyst from entering results that are outside the allowable (plausibility) limits.
3.6.13	LIMS shall also provide functionality to implement more than one set of limits for each test.
3.6.14	LIMS shall provide Re-testing function which will be performed on the same sample as many times as required, with clear identification of the different test instances.
3.6.15	LIMS shall provide Re-sampling function which will allow logging a sample based on the previous information, and with a link to the original sample for full traceability.
3.6.16	LIMS shall record each retest along with an appropriate justification which would normally be ordered if a given test was suspected to fail for reasons that may include failed quality control parameters, instrument malfunction or technical judgment.
3.6.17	LIMS shall provide a powerful mechanism that simplifies the creation of complex calculation formulas.

3.6.18	LIMS shall perform calculation automatically of the final results from intermediate results.
3.6.19	LIMS shall provide tools to create calculation across tests and also across samples.

3.7 Analysis Review

3.7.1	LIMS shall enable authorized users to review samples, tests and results singly or as a group via folders & multi selection.
3.7.2	LIMS shall also enable authorized lab personnel to authorize or reject samples, tests or results prior to “releasing” them from the laboratory.
3.7.3	LIMS shall provide facility to enter free text message or a drop-down list of comments to be added to a sample as review comments.
3.7.4	LIMS shall provide an additional release step where a two-step approval process is required.
3.7.5	LIMS shall make sure that no changes will be made to the samples once they are in an authorized or rejected state.
3.7.6	LIMS shall provide “Reactivate” function for reactivating the sample, tests or results by a privileged user authorized by the lab.
3.7.7	LIMS shall keep track of all changes made to LIMS results including a reason for the correction.
3.7.8	LIMS shall highlight or display out-of-range results separately for closer review.
3.7.9	LIMS shall provide a ‘review by exception paradigm’ where results meeting product specification or within user-defined control limits are passed automatically through test review and only unexpected test results are queued for manual review.
3.7.10	LIMS shall provide functionality to review the history data of the particular sampling point.
3.7.11	LIMS shall store standard operating procedures (SOPs), test methods and material safety data sheets (MSDS), as a Hyperlink.
3.7.12	SOPs shall be viewable on demand by clicking the link during sample life cycle.

3.8 Reports

3.8.1	The report generators within a LIMS shall be flexible to accommodate the different reporting needs of individual clients. Test results, along with QC data, shall be reported to the customer in variety of forms, including electronic data deliverables, and web-based systems.
3.8.2	LIMS shall provide with an easy, flexible and secure method of defining the automatic execution of reports and programs on the basis of any specific sample or test changes.
3.8.3	LIMS shall provide seamless integration with a window-based third-party reporting tools, word processor and spreadsheet.
3.8.4	LIMS shall provide an easy way to generate reports without the need for SQL skills.
3.8.5	Reports shall be run interactively, printed, e-mailed, or filed for viewing, including PDF & HTML for web sites and scheduled for routine execution on clock or calendar events.
3.8.6	Following reports as a minimum requirement shall be included for monitoring and managing the daily lab operation: a) Certificate of Analysis report b) Summary reports for internal laboratory used by laboratory management for measuring turn-around time. c) Reports by collecting statistics and time-stamps at various points in the process. d) Reports on number of samples processed by technician, shift, day of week, and hour of day help to identify peak demands and other problems that eventually provides good documentation to justify new instruments or personnel. e) Report about overdue samples and work remaining in the system to help lab management in determining the work load and lab response time. f) Report about the number of tests done to estimate the consumption of reagents and supplies. g) Report on Instrument calibration and maintenance records h) Quality control reports prepared for internal laboratory use. i) Statistical reports to evaluate the performance of a given method within the laboratory. j) Control charts generated based on analysis of specific QC samples.
3.8.7	LIMS shall have the ability to define event triggers for sending e-mails according to sample/test status. Following notifications/reports shall be included as a minimum: a) Notification about scheduled samples to be collected in next x hours b) Notification Off Target Report c) Notification about expired/ re-order inventory d) List of instruments calibrated in next x days (x days shall be easily configurable in LIMS system)

3.9 Audit Trailing

3.9.1	LIMS shall maintain and track all changes of dynamic and static data under audit control.
3.9.2	Audit records shall include the user, date-time of change, the old value, and new value which will be encrypted in the database, and will not be changed.
3.9.3	The lab authorized user only shall be able to view or report audit history.

3.10 Statuses

3.10.1	LIMS shall track the status of each sample through every step in the lab by implementing the chain of custody feature.
3.10.2	LIMS shall update sample status automatically throughout the sample life cycle. Following sample status shall be included as a minimum. a) 'Logged' b) 'Un-Received', 'Received', c) 'In-Progress', d) 'Completed', 'In-Complete', e) 'Authorized', 'Approved' f) 'Rejected' and 'Expired' / "Cancelled", "Dropped" g) LIMS shall be able to configure additional status types, if it is required by Saudi Aramco.

3.11 Standards and Reagents

3.11.1	LIMS system shall provide functions to track the key data relating to standards and reagents, including active/inactive status, expiration dates and associated sample results.
3.11.2	LIMS shall check that all standard reagents and solutions are within a valid expiration, and/or re-standardization period.
3.11.3	LIMS shall automate sample log-in for re-standardization testing.
3.11.4	LIMS shall store manufacturer documents (certificates of analysis, safety data sheets, and so forth) for chemicals.
3.11.5	LIMS shall store standard factors for solutions that can be used in calculations on tests.
3.11.6	LIMS shall reassign the shelf space when a sample is discarded. Retain period shall be defined based on product type.

4 Additional LIMS Requirements

4.1 Extensive User Interface

4.1.1	LIMS system shall provide an extensive administrative interface so that end users can configure the application as much as possible without programming or direct database intervention.
4.1.2	LIMS user interface shall have ability to add, remove and change design and form elements on the screen to create productive forms/templates and workflows with minimal programming.
4.1.3	LIMS shall provide powerful programming tools to configure LIMS system to meet changing requirements.
4.1.4	LIMS shall present the user with an explorer metaphor for easy navigation of the sample-test-result hierarchy, with extensive use of icons and color as visual cues for the sample-test-result objects and all stages of the testing life cycle.
4.1.5	LIMS shall provide user friendly screens/templates to modify/add static data by the lab authorized user
4.1.6	Explorer views shall be configurable based on any criteria via database queries. The below typical views must be included as a minimum: a) All un-received samples; b) All in-process samples; c) All samples whose results are completed, awaiting authorization; d) All today's authorized sample results based on Sample type; e) All today's authorized sample results based on Plant, Labs

4.2 User Security

4.2.1	LIMS system shall provide extensive security measures, which may be tailored to meet the special needs of the plant/laboratory.
4.2.2	LIMS shall provide an option to integrate with Saudi Aramco enterprise secure directory (domain, active directory) to use corporate security procedure.
4.2.3	LIMS shall provide a role-based solution that allows user access to certain LIMS functionalities defined in their assigned role.
4.2.4	LIMS system shall provide a central point of registering security profiles for users.
4.2.5	LIMS shall deploy time-out function set for each user individually.
4.2.6	LIMS shall be able to define specific menu for each individual user or group of users.
4.2.7	LIMS shall be able to disable a user account automatically if the maximum number of login failures is exceeded. Only LIMS administrator or authorized person shall be allowed to enable the user account.
4.2.8	LIMS shall provide functionality to restrict user access in the following ways: a) By location, e.g., access to own data only b) By type of authority, e.g., read/write/delete c) By function d) By workflow

4.3 Instrument Interface

4.3.1	LIMS shall provide functionality to interface the LIMS to laboratory equipment for automatic collection of result data. The interface shall be able to capture instrument generated raw and metadata either as files or directly via RS-232 or TCP/IP communication ports.
4.3.2	Test results to be collected from the instruments shall be configurable. Selected data shall be mapped to templates that determine what data need to be collected.
4.3.3	Data validation, specification checking, calculation and sample status updates shall also be applied to data captured by the interfaces

4.4 Integration of Laboratory Informatics Solutions

4.4.1	LIMS shall exchange data to ERP automatically without user interference.
4.4.2	LIMS shall support a wide variety of techniques to interface to other systems. Typical interfaces include but not limited to: a. File transfer (XML, CSV, FTP, SFTP, etc.) b. Direct database access (via ODBC) c. Application programming interfaces (local and remote) d. OLE Automation / ActiveX / OPC e. Mail messages f. J2EE web/application services
4.4.3	LIMS shall support trigger-based tasks that produce selected result data in a text file format or through an open modern standard industry interface like OPC to be transferred to other process applications upon test validation at regular intervals.
4.4.4	LIMS shall provide a certified seamless bi-directional interface to company ERP system and other corporate applications as part of quality solutions.

4.5 Document Management

4.5.1	LIMS shall provide document management tool to manage, secure, track laboratory documents.
4.5.2	Document Manager Tool shall provide the template-based configuration to manage the lifecycle of a variety of laboratory documents. - including creation, approval, distribution, version control, and full access control.
4.5.3	LIMS shall provide master list and status reports to track the documents due for revision.

4.6 Material Inventory

4.6.1	LIMS system shall provide tracking of lab stock items. This may be used for the retention samples, reagents, instrument parts, chemicals, etc.
4.6.2	LIMS shall provide the ability to track the inventory amounts of samples received and consumed during testing.
4.6.3	LIMS shall ensure to maintain the below standard information of an inventory item as a minimum; Inventory Type, catalog number, chemical name, Location, Quantity, Stock Units, Expiration Date, Reorder Quantity, supplier info etc.
4.6.4	LIMS shall provide different inventory reports based on inventory type, re-order level, location, expiry date and labels of different format and sizes for different inventory item categories.
4.6.5	LIMS shall provide tracking/updating of inventory items through bar code scanning as an additional tool.
4.6.6	LIMS shall store MSDS sheet against chemical entries which shall be viewable on screen and reports

4.7 Analyst Certification

4.7.1	LIMS shall provide tools to maintain and enforce of proper and recent analyst training of testing methods in compliance with industry or internal quality standards
4.7.2	The analyst certification records option shall integrate and enforce these requirements by possessing the following features: a) Entry and maintenance of analyst certification records b) To prevent access to an analysis or instrument by an uncertified user c) Reporting of training records documents d) User certification expired in next X days

4.8 Investigation Module (Non-Conformance)

4.8.1	LIMS shall provide ability to identify, investigate, disposition, and report non-conformities incidents.
4.8.2	LIMS shall provide a user configurable template to record one or more samples and their related static items to be grouped together for further analysis in LIMS to determine the nature of problem.
4.8.3	LIMS shall record the status of the investigation together for easy analysis, reporting and interpretation.
4.8.4	LIMS shall provide full track of corrective action plans, approval steps, root cause analysis, and reporting.

4.9 Instrument Method Calibration and Full QC Checks

4.9.1	LIMS shall incorporate features to support instrument calibration and maintenance, to ensure that test results are gathered from the properly calibrated and maintained test equipment.
4.9.2	LIMS shall create a schedule for the frequency of calibration or maintenance and ensure to prevent entering test results when equipment is overdue for service.
4.9.3	Calibration and maintenance records shall be entered in the LIMS as they are performed. LIMS shall capable of providing instant SQC charts facility for providing a clear, graphic illustration of instrument performance to detect trends and take a proactive role to prevent instrument-related problems.

4.10 Statistical Quality Control (SQC)

4.10.1	LIMS shall provide the advanced functionality for generating and printing plots based on the consistency of results obtained on past batches of a product or sample. The LIMS shall: a) Provide for the setting of quality targets and a program for continuing quality improvement; b) Provide for statistical routines to support SQC; c) Provide for automatic generation of SQC reports. Reporting requirements include: Custom charts, standard deviation, control charts, histograms, Pareto charts, scatter plots, X-bar charts, and range charts etc.; d) Include analysis ID and instrument ID in SQC charts; e) Be able to put notes in SQC charts.
4.10.2	The QC ranges as derived from these control charts can be used to set the limits as used by the laboratory to evaluate their internal processes or used to compare how the laboratory's performance compares to the published performance of a given method.