Quality & process control in LIMS software for NDT laboratories

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Abstract

LIMS software, hereafter referred as OMS (Operations Management System) has been evolving at LMATS over a period of a decade. Similar to the LIMS at scientific laboratories, OMS has been structured by applying experience from the field work, witnessing other lab work, common errors in the industry and most importantly requirements from ISO 17025 & 17020 and relevant test standards. Several process and quality control measures such as standardised terminologies, prohibiting invalid data entry, reference to pre-defined names and numbers for Standards, Materials, equipment, its calibration status, personnel certification and approval of tester/ signatory to comply with Standards are implemented in the OMS. Although OMS is a complete ERP system, it’s process control features (before, during & after testing) makes it a virtual Quality Manager for an Enterprise.

Keywords: LIMS, OMS, ERP, QMS, ISO 17025, Process & Quality control

1 Introduction

The 3 essential pillars or primary objectives of a QMS (Quality Management System) are Traceability, Repeatability & Reproducibility. But often, these 3 essential objectives are not achieved due to human errors or inconsistencies. This is where an automation or a software is a necessity for an Enterprise.

Traceability, Repeatability and Reproducibility is possible using paper-based system if most of us are super-intelligent and have a special gift of attention to details. In today’s era, it is easy to find intelligent people but not necessarily having all required attributes for a laboratory type environment. In a paper-based system, we will need super-human whom can repeat exactly what was done the last time. Hence considering several repetitive processes and several outcome failures, a permanent solution was required to eliminate errors or at least minimise to the $6\sigma$ sigma. To maintain quality of the output as well as controlling process parameters, a concept of LIMS in the engineering lab was introduced about 13 years ago. After concluding that there were no readily available ERP systems for engineering laboratories, work planning commenced on the OMS.

2 Lifecycle of a job

In laboratories, a life of a job starts well before the customer notifies a request for testing or inspection. In order to execute a job from start to finish (till revenue collection is completed); several essential protocols need to be in place to complete a job at an international level of quality. Some of the essential requirements before a job commences are a full documented quality system, human resource, technical
resources such as Standards, procedures, test instruments and finally customer information. After a customer requirement is received a job can be set-up to complete testing and issue a report.

For testing and inspection companies, a report is a documented outcome of a laboratory processes completed by various personnel using various instruments at an Enterprise using several essential variables to derive a constant value in the form of a test or inspection Report.

![Figure 1: A snapshot of a lifecycle of a job in the OMS](image)

### 3 Minimum requirements in a Report

Most international Standards and the local accreditation body will specify minimum requirements to be reported. Some of these are name & address of the laboratory (Enterprise), accreditation number and its site address, job location, accreditation body logo, mandatory accreditation statements, etc. Then as a minimum, a report name, format ID, report number, revision status, issue date and test / inspection date, etc. are required. The report needs to be addressed to the customer name, address, requested by and their reference order number. The report must include description of items tested, its ID, source of identification, Product Standard, test Standard number, procedure number, material Grade and their Revision year. Depending on test requirements, applied test techniques, description, identification, location of a diagnostic area including surface condition and any additional surface preparation are key components on the report for the outcome purpose. A report will be incomplete without a traceability requirement about test instruments, their description, ID and the calibration status. All reports must have tester, inspector, signatory names and their credentials. Most reports will contain measured physical or chemical properties, evaluated performance, detected discontinuities, test restrictions, compliance statements, photographs and any other customer specified data.
4 Minimum requirements in a Test Record (TR)

Data on a Report is derived or transcribed from the original test record and observations, commonly known as Worksheet. In addition to the minimum requirements stated in Section 3, TR will contain several additional data for the purpose of Traceability, Repeatability and Reproducibility. Some of the additional requirements are Worksheet name, format number, revision status, detailed information about test instruments used including their brand, make, model and ID. The TR shall contain environmental conditions such as temperature, illumination, humidity, etc. TR needs to include detailed information about specimen size (thickness, diameter, width), test observations, discontinuities, assessment criteria’s, classification of discontinuities, list of all assessed parameters. Depending on the Enterprise requirements, a TR may also contain administrative tasks such as time taken to complete a job, consumables used, any other costs and in some cases client agreement in the form of their signature indicating completion of testing task as per their request.

5 Sources of Error

Considering the concepts of 6σ, there are several probabilities of error that may occur before, during & after testing which may lead to an erroneous or an invalid report. Hence to implement preventive measures and bring the quality or process parameters under the 6σ limit, a laboratory needs to have fail-proof process control system which shall ensure that the quality of the entire testing and inspection lifecycle process is not dependent on the mood of the employee on the day or absence of key managers from the workplace or Assumptions that he/she knows what to do. Some of the sources of errors during the lifecycle of a job or the source of information (Data) on a job pack are included in this section.

5.1 Personnel

As per ISO 17025 and ISO 9712, any person performing a test shall be authorised for certain types of activities. In many cases, an authorisation level for the test personnel is forgotten by his/her supervisor or lapsed over a period of time or inadvertently incorrect personnel are utilised for unauthorised tasks. Inadvertently, a trainee whom might be experienced but still not documented as a Competent person may execute unsupervised testing. Or a person authorised to perform testing only (non-signatory) may inadvertently sign a report. A report shall be signed only by a person whom is authorised to release technical information (Signatory).

In many cases, an internal or external audit reveals that the authorised person did not complete his periodic competency test? Or his/her certifications have expired before he/she completed testing. Or their certifications / qualifications are missing during audit. These leads to NCR’s but moreover a quality and process control failures.
5.2 Standards & Materials

In a testing and Inspection industry, client specifications are the most important document before a test or job is commenced. Client specification will generally refer to Product Standards, Codes, Test method Standards, material grade Standards or other client prepared specifications. Hence, it is important for a person whom is setting up a job or a testing personnel or the Signatory to know these specifications and have direct access to read requirements and acceptance criteria. In many cases, these documents are not available for direct access to the testers or Signatories which leads to errors or false calls. Or some personnel become complacent and erroneously write incorrect name and number of the Standard. Occasionally incorrect spelling can lead to completely different requirements than the executed testing.

There are several test method Standards where the test method process is almost similar, but the calibration or reference parameters are different. Hence it is important for the laboratory personnel to know the relationship between a test specification and the applicable test method standard otherwise they may inadvertently use incorrect test method. E.g. using Australian test method for an ASME code. Incorrect test procedures or its identification in the test process can lead to other errors. Generally, a test Standard or a test procedure includes various test techniques. By referring just to the test Standard number, a test personnel may apply incorrect test technique in the absence of a robust system to communicate test technique unambiguously.

Incorrect material grade or a Standard number mentioned on a report is the most common error in our industry. Not all ferrous materials are Carbon steel and not all stainless steels are similar. For the purpose of NDT each ferrous material or stainless steel may have different test outcome for different grades of steel. For metallurgical testing laboratories, lack of direct access or incorrect reference to older Standards for material’s physical and chemical properties can lead to erroneous test or a report.

5.3 Equipment

One of the largest sources of error on reports and test records are the equipment information. In many cases, test personnel may inadvertently use instruments which are not calibrated to demonstrate traceability to the national standard. An Enterprise may not have a flagging or a reminder system to calibrate their instruments as per the Schedule. It is important for an Enterprise to have control measures so that non-calibrated instruments are not used. An Enterprise depending solely on human brain to remember everything and calibration records may also face challenges of losing those paper-based calibration records. Traceable records for the past few years is important and dependent on your jurisdiction requirements. It may be 3 years or 30 years in some countries.

Due to lack of instruments identification, incorrect asset numbers may get recorded on the TR and subsequently on reports. In the absence of Organisation’s own Asset identification number, a TR may
reveal same serial number for 2 different assets because 2 different manufacturers have the same serial number as per their own production batches. A TR or a report may indicate ambiguous instrument data such as brand, make and model which may not differentiate assets during audit or investigation.

5.4 Customer information

Customer is the most vital part of any Enterprise. Without customers an Enterprise cannot exist and hence it is very important to handle customer requirements and moreover their emotional expectations respectfully. One of the common errors on Report is incorrect spelling of the customer contact name or their company name or their legal address or other contact details.

It is important to have correct and exact client’s company name on a report to prevent any unforeseen legal events. Without correct client company name, an Enterprise may face several challenges in future including not getting paid from the customer. Similarly, a correct and exact job address is very important on the report. In the absence of this information, a traceability or the repeatability can be lost.

6 Job set-up and Control measures in OMS

Correct Job (Test or inspection objectives) can be set-up after having correct control measures on sources of errors mentioned in Section 5. A typical job set-up will contain as a minimum information about customer, Specifications, test techniques plus additional instructions specific for a job. Several process controls have been implemented in the OMS and lock-out mechanisms to eliminate or at least minimise probability of errors throughout the life of a job in a laboratory type Enterprise.

6.1 Preventive controls on unauthorised personnel

The OMS ensure that only authorised persons can view or edit or select certain fields in the test data entry UI. Using the user management UI, the Quality Manager (QM) or his/her delegated competent personnel can authorise to perform testing or signatory to a specific Test Standard number. For example, instead of issuing approval for UT on all materials or all type of products or all UT Standards, the QM can authorise testing to a specific Standard number e.g. AS 2207 or AWS D1.1 Section 6 or ASME V Art 5. This has been implemented because a competent person in UT on welds as per AS 2207 may not be competent as per ISO requirements.

The QM can provide access to a typist or a trainee to enter test data and nothing else. Their name cannot appear in the UI. They can only work under an authorised tester or a Signatory. Authorised testers are allowed to enter test data in all fields. But they cannot finalise or sign a report. Only authorised signatories are permitted to enter test data in all fields, verify, edit, revise, finalise, sign and email reports to the customer.
OMS stores qualification string for all users to standardise terminologies and also eliminate errors of incorrect printing on a report. All Certifications / Qualifications / Skills / Competencies / Practical assessment attainment dates, expiry dates and reminder dates can be stored in the OMS. Using the reminder date, the OMS emails automatically to the active users and the QM. OMS will not stop reminding Enterprise staff unless they have entered new dates. OMS stores all related documents for the listed competencies. This eliminates probability of losing quality records. Records can be viewed, added but cannot be deleted. Most importantly, OMS vaults personnel signatures so that nobody can download or illegally use. A signature does not appear on a report unless they login using secured password.

6.2 Preventive controls on Test Method Standards

For the purpose of repeatability, a competent person shall save accurate test Standard number in the OMS so that all personnel within the Enterprise can refer to the same data for reporting or other purpose. All superseded test method numbers are marked Inactive and not displayed during job set-up to prevent inadvertent reference by users in the Enterprise. Based on a customer need, they can be made active. A competent person can select only Active test method numbers when setting up a job. This will prevent Enterprise personnel to use or type incorrect Number on technical records. User can access interpretation (procedure) of the Test Standard directly from the OMS.

6.3 Preventive controls on Acceptance criteria Standards

For the purpose of reproducibility, a competent person shall save accurate Test Specification (Acceptance criteria) in the OMS so that test personnel within the Enterprise can refer to the same data for reporting or other purpose. A relationship between the Test Specification and the Test method is defined (linked) by a Competent person so that personnel will see only relevant test methods when setting up a job. This will prevent errors such as AS 1210 (a Product Standard) which refer to another Australian test method but the personnel inadvertently using ASME V test method.

All superseded test specifications are marked “Inactive” to prevent inadvertent reference. Based on a customer need, they can be made active. Personnel can select only Active test specifications when setting up a job. This will prevent personnel from using or write incorrect Number on the record. Test personnel can access simplified Acceptance criteria directly in the OMS.

6.4 Preventive controls on Materials

For the purpose of traceability, a competent person shall save accurate materials data from current Standard so that authorised personnel within the Enterprise can refer to the same data for compliance
and test purpose. A correct and Standardised internationally adopted name of a Material Grade is saved so that test personnel cannot type incorrect material name.

While mechanical and chemical testing, the OMS can self-validate test results with the acceptance criteria. For NDT – It is at a design stage for automatic validation for compliance. The OMS have materials library in excess of 10,000 material Grade types and its physical and chemical properties which are used for Acceptance criteria. This will eliminate incorrect reference to materials data or superseded Standards.

6.5 Preventive controls on Equipment

OMS upholds a list of all assets within an Enterprise. For the purpose of traceability, OMS generate an unique ID for assets. An Enterprise can create a predefined standardised Categories and sub-category (Classification) for Assets and also for correct linking to test methods e.g. MT or UT or Mechanical or Chemical. Classification also helps in finding relevant asset data during audit. The OMS contains description of Assets, manufacturer, brand, make, model, supplier, cost, assigned to, location (branches, site), its status (Active, Inactive, stock item, lost, under repair, written-off) and any ancillaries received, inward inspection, photograph of as received items, acquired date, replacement cost for insurance.

Most importantly, the OMS manage calibration data. OMS act like a quality manager for an Enterprise to maintain, monitor & remind users for calibration, maintenance, annual inventory or licensing renewal. On behalf of the Enterprise, the OMS will not display asset for selection in the test data UI, if the calibration has expired. OMS will email user at the set reminder date about calibration renewal. If no action, then OMS will email to the section manager at a trigger point and then to the QM. Emails will continue daily to the User, Section manager at trigger date and the QM after trigger date; until a new calibration is not entered or asset marked Inactive. (OMS is planning to eliminate emails and use OMS as a platform to remind and lock-out users). OMS maintain all past and future calibration dates and related data to prevent inadvertent loss or mismanagement by users. Calibration data templates can be created within OMS so that paper need is eliminated.

6.6 Preventive controls on Customer information

Similar to most of the readily available CRM’s, the OMS retains customer information except the data structure is different to assist Laboratory type enterprises. It has several preventive measures to validate customer data so that the report quality is maintained. The OMS automatically validate and mark inactive client contacts whom have left the customer’s organisation. Several other features but this is not the forum for that discussion.

6.7 Preventive controls on test data entry
For the purpose of traceability, repeatability and reproducibility, OMS permits a competent person to create a reference data master list for standardised terminologies. These master data controls the user about what they can type or use in the test data UI. Data population for input boxes has been predefined so that users inadvertently do not use or enter incorrect test variables. For example - only approved chemicals for Penetrant testing can be used by a test personnel.

For the purpose of minimum data to be captured or reported as per Standards, a competent person can configure test item and process related essential variables in the OMS to make those fields Discretionary or Mandatory for test data acquisition or Reportable for reporting essential fields. There are several validation rules implemented for most of the input boxes so that the test personnel cannot enter invalid data. As an example, input boxes have been validated at a level of Pipe sizes to type correct unit of measurements, thickness as a number box, sensitivity as % or W.

7 Conclusion but improvement continues…

Quality and process controls mentioned in Section 6 and data input controls eliminate most of the common errors in the industry and maintains consistency in quality & delivery leading to a Traceable, Repeatable & Reproducible tests results.

Although OMS is focused on LIMS principles, it is a complete ERP system for Laboratory type Enterprises. Other features which was based on the same principles of traceability and repeatability, are automatic Debt recovery by way of set protocols, provides Enterprise Management report such as Sales report (to the level of test type), Productivity report, Time study report and most other common accounting reports. OMS has timesheet entry module through a mobile phone and Payroll summary functions. It can automatically upload bank statements for received payment and several other common accounting functions.

Most importantly, it contains the Quality system documents, internal contact list and automatic emails configuration for repeatable and consistent body contents. OMS also contain a Lead management (CRM) customised for Laboratories wherein a Quotation containing standardized laboratory related terminologies can be created. There are several other laboratory related critical interfaces to replace all paper based system and eliminate human dependency in decision making in the OMS.