Using LIMS to Support ISO 17025 Accreditation (Driving out cowboy working practices)

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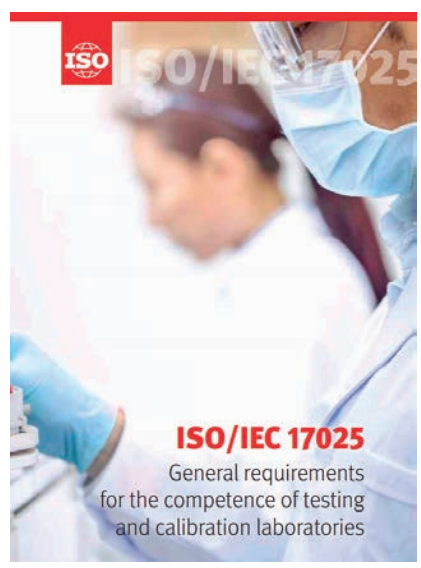

ISO/IEC 17025:2017 [1] is an internationally recognised standard that defines the general requirements for the competence of testing and calibration laboratories. The standard emphasises the need for laboratories to demonstrate their competence and ability to generate valid results. The standard doesn't provide prescriptive guidelines, but encourages a risk-based approach. This involves assessing risks associated with the standard's provisions and minimising them. Effective management of the laboratory process, resources, and data is essential in achieving this. ISO17025 plays a key role in ensuring that a laboratory's customers can be confident in the quality of their results.

This article explores how an Laboratory Information Management System (LIMS) can be integrated into the daily operations of a laboratory to play a key role in achieving, maintaining, and benefiting from ISO17025 accreditation.

Traditionally LIMS have focussed on managing samples, tests, and results, while ISO17025 says surprisingly little about this. Section 7.5 of ISO17025 states that technical records should include the date, person responsible, calculations, and identity of the person checking the data. Amendments to these records also need to be checked. However, other sections of the standard show how a modern integrated LIMS can support ISO 17025 requirements.

ISO17025 Section 6 concentrates on managing laboratory resources, including personnel, facilities, equipment, systems, and support services. An integrated LIMS can play a crucial role in meeting these requirements.

Personnel (Section 6.2)

Section 6.2 of the standard focuses on personnel, specifically staff competency and training. The standard requires documenting competency requirements for functions that impact laboratory results without specifying those functions explicitly. It emphasises that personnel must be competent to perform their assigned activities. While staff competency and training might seem unrelated to LIMS, an integrated LIMS can effectively manage staff training and competency records.

Furthermore, the LIMS should link these records to specific activities to prevent unqualified personnel from performing them. For example, the system can verify the user's competency during analysis and stop them entering results if they lack the necessary training or certification. This principle can also extends to activities such as instrument maintenance and calibration.

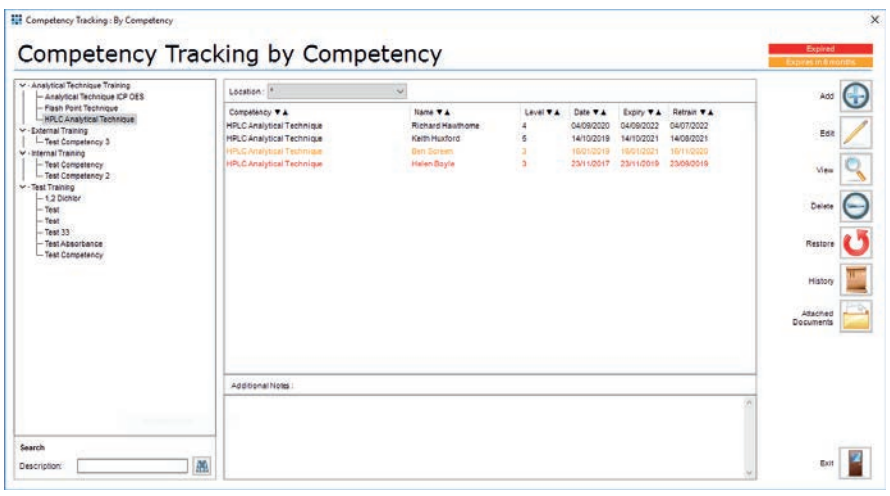

Figure 1. An example of Staff Competency tracking screen in LIMS.

Facilities and environmental conditions (Section 6.3)

At first glance, it may seem unlikely that Laboratory Information Management Systems (LIMS) can play a significant role in managing facilities and environmental conditions within the scope of ISO17025. However, as LIMS functionality can include the monitoring, control, and recording of environmental conditions that may impact result validity, its role becomes clearer. LIMS goes beyond recording results and includes managing the monitoring process itself. Sampling location can be defined and mapped and sampling schedules set up Results that exceed defined contamination limits are flagged, and data trends monitored over time. These capabilities are especially valuable for monitoring contamination in clean environments.

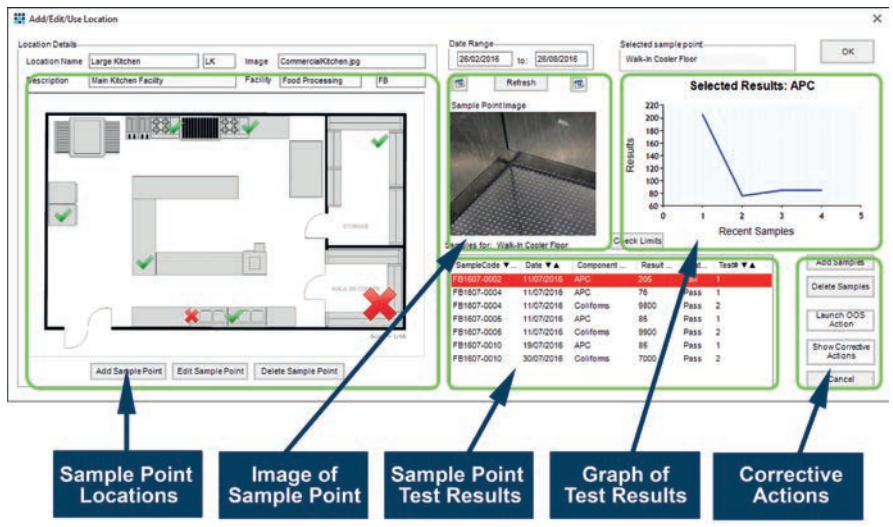

Figure 2. An example of Environmental Monitoring in a LIMS.

Equipment (Section 6.4)

Section 6.4 of ISO17025 covers the management of laboratory equipment, a vital function within the laboratory. Emphasising maintenance and calibration plans, an integrated LIMS enables creation, management, and enforcement of these plans. As each calibration or maintenance event is recorded, together with its outcome, a comprehensive equipment history is created. Equipment that has not been calibrated or maintained according to the required schedule can be taken out of service, as can instruments that have failed calibration or require repair. The use of such instruments can be prevented in the same way as analysts who do not have the correct certification... ISO17025 requires competent operation and valid results, and a LIMS plays a key role in achieving and maintaining accreditation.

ISO17025 defines standards, reference materials, reference data, reagents, and consumables as equipment. Inventory management within the LIMS allows complete management and traceability of these items. Key data such as supplier, amount, expiry dates, lot numbers and Certificates of Analysis can be recorded. Stock levels can be tracked and linked to reordering requirements. Inventory usage can be linked to specific tasks, for example identifying the exact reagents, and amounts used, for specific analyses or analytical runs. Linking inventory to tasks in this way automatically updates stock levels, and provides traceability as to how and where reagents have been used.

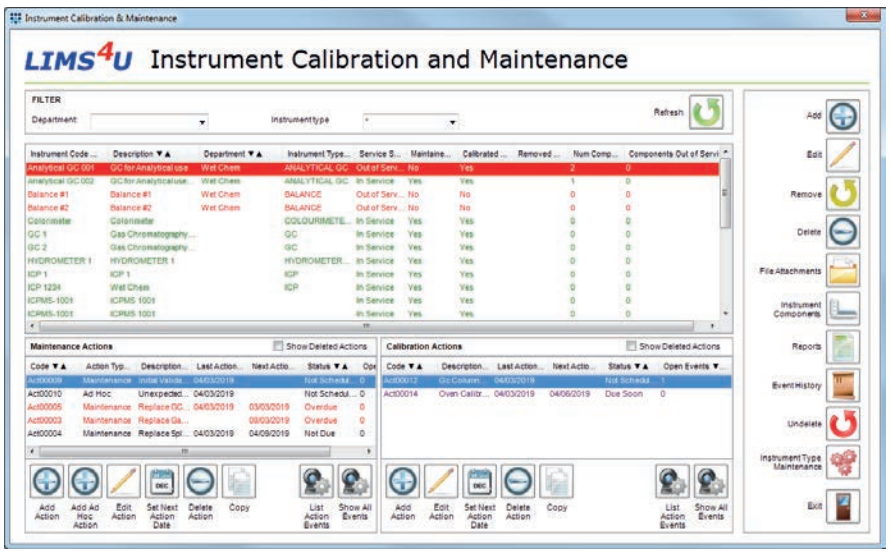

Figure 3. Example of Instrument Calibration and Maintenance in LIMS.

4. Process requirements:

ISO 17025 emphasises proper resource management and process requirements. Section 7 of the standard covers processes, offering an opportunity for LIMS to support process definition and enforcement, showcasing its value.

Section 7.1 outlines the requirements for the review of requests, tenders, and contracts in a laboratory. This process ensures that customer requests are feasible and covered by existing contracts. The use of a LIMS can enforce this review by preventing the processing of requests until they have been approved by a qualified person. As customer portals become more common, this review becomes increasingly important to ensure the requests are valid. .

In Section 7.2, the focus is on selecting and verifying appropriate tests. LIMS can automate this process by assigning methods and tests based on the material being tested and other factors. It ensures the use of the latest method version and assigns relevant limits to validate results. LIMS allows the setup of projects for method validation and records the validation outcomes.

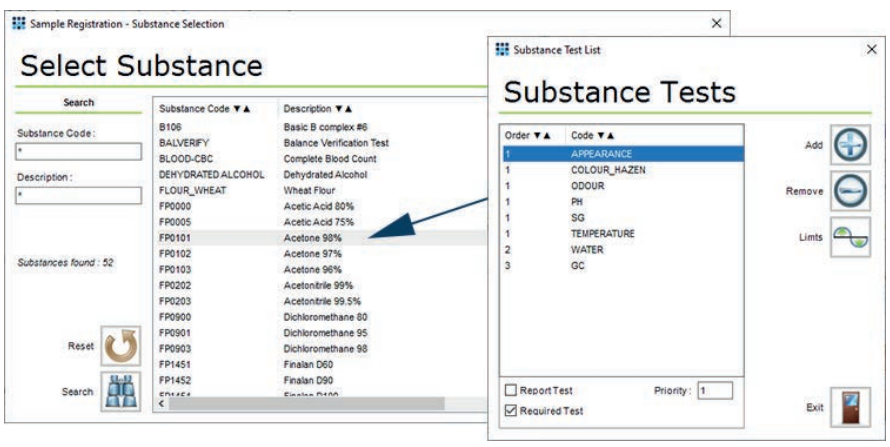

Figure 4. Example of Tests Dictated by Chosen Substance in a LIMS.

Sampling (Section 7.3)

Sampling is crucial for maintaining consistency and reliability in calibration and testing laboratories. It involves the collection of samples, recording data such as sampling date and time, and the person responsible, as well as ensuring adherence to defined sampling plans. LIMS play a vital role in managing sampling data, providing unique sample identification, and accommodating diverse sample information. LIMS must be able to support various sample types and adapt to new sampling requirements. ISO 17025 emphasises the importance of sampling and testing competence.

Measurement uncertainty and Validity of results (Section 7.6 & 7.7)

Measurement uncertainty in calibration laboratories is a complex area. LIMS can play a role by automatically applying specified limits during result entry. It can also handle more complex calculations when limits are not applicable. LIMS functionality, such as managing reference materials, tracking instrument calibration, controlling retesting and replicate testing, and generating control charts, ensures result validity. Additionally, LIMS allows correlation of results across different batches, as all the required data is centralised.

Reporting of results (Section 7.8)

Reporting is a crucial aspect of testing and calibration laboratories. It involves delivering the data and information generated by the laboratory to the consumer or customer. Accuracy and completeness are essential in reports, which must include all the information required by the customer. ISO17025 requires the review and authorisation of results before their release, and LIMS supports these steps. LIMS allows for flexible reporting options, enabling the creation of customer-specific reports in the required format. By automating report generation and making them available for review after approval, LIMS streamlines the delivery of results to customers.

Managing complaints and non-conforming work (Section 7.9 & 7.10)

Sections 7.9 and 7.10 of ISO17025 refer to complaints and nonconforming work. Complaints need to be tracked and managed, while procedures must be in place for handling nonconforming work. A LIMS can manage complaints and non-conformances if it has an integrated Corrective Action, Preventive Action (CAPA) management facility. This facility enables tracking and management of CAPAs from creation to resolution, recording associated actions for full traceability of the process.

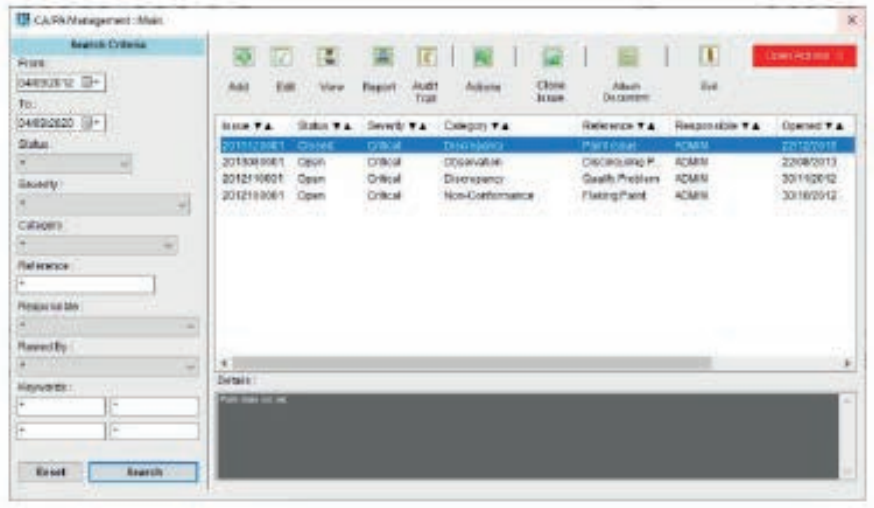

Figure 5. An Example of CAPA Management in a LIMS.

Control of data and information management (Section 7.11)

Section 7.11 Control of data and information management emphasises the importance of easy access to necessary data and information for laboratory activities. It raises questions about the ease of accessing critical information such as the latest version of Standard Operating Procedures, equipment calibration status, and availability of reagents. An integrated LIMS can streamline data access and management by consolidating all relevant information, including customer details, requests, contracts, training records, and technical records. This centralised approach ensures efficient access to the required data set, even across different geographical locations , facilitating the smooth functioning of the laboratory.

Section 7.11 highlights the importance of validation in laboratory information management systems (LIMS). It acknowledges that LIMS can encompass both computerised and non-computerised systems, including paper-based or spreadsheet-based records. Validating these systems, especially paper-based ones, can be challenging. LIMS, with their integrated information and functionality, minimise the need to validate multiple systems. Many LIMS come with supporting materials such as validation scripts and packs, making the validation process easier. The pharmaceutical industry, with its experience in validation, has found LIMS to be well-suited for the task.

Implementing a validated LIMS ensures efficient and compliant information management in the laboratory.

Summary

ISO17025 is a quality management system that requires management commitment to be effective. While a LIMS can support the quality management system, it cannot replace management commitment. However, investing in and implementing a LIMS demonstrates management commitment and supports various aspects of the QMS. A LIMS helps with compliance by showing that processes and operational requirements are in place and adhered to. It also reduces audit and inspection overheads by integrating information into a single place. Additionally, it instils confidence in customers that the laboratory is competent and the data valid. Modern integrated LIMS are crucial for achieving and maintaining ISO17025 accreditation

References:

1. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories https://www.iso.org/standard/66912.html

2. LIMS System Validation White Paper https://www.autoscribeinformatics.com/resources/white-papers/lims-system-validation

More Information:

A more detailed paper with worked examples on LIMS can be requested from Dr Phil Williams at phil@lims4u.co.uk or on LinkedIn at 'LIMS4U'. Phil, with over 37 years' experience in Lab automation, founded LIMS4U in 2020 and offers LIMS marketing services primarily via LinkedIn (over 28,500 followers).

Acknowledgements

Thanks to Autoscribe (https://www.autoscribeinformatics.com/) who supplied some of the figures and dialogue used.

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