The Role of LIMS in Supporting ISO 17025 Accreditation

ISO/IEC17025:2017[1] is the international standard that specifies the general requirements for the competence, impartiality and consistent operation of laboratories. It can be used by laboratory customers, accreditation bodies, and other organizations to recognize the competence of laboratories. The key element of the standard is that it requires laboratories to demonstrate that they operate competently and can generate valid results. However, the latest version of the standard (2017) does not prescriptively state how this should be done; rather it encourages a risk-based approach. This requires organizations to assess the risks associated with the provisions of the standard and to show how the identified risks have been minimized. Key to this is the management of the laboratory process, the management of laboratory resources and the management of data that exists in, or is created by, the laboratory.

This white paper will explore the ways in which an integrated Laboratory Information Management System (LIMS) can play a key role in achieving, maintaining, and benefiting from ISO17025 accreditation.

Managing Sample Handling and Testing Processes

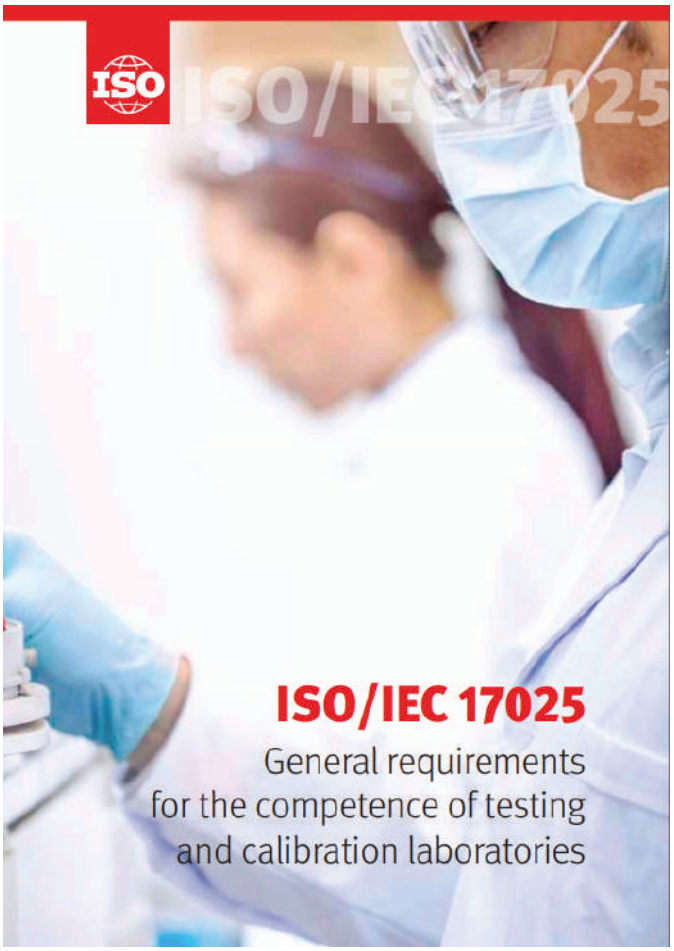
In some circles there is still an impression LIMS focus on the management of samples, tests, and results with, potentially, some workflow management functionality. However, ISO17025 contains surprisingly little on this aspect of the laboratory operation. Section 7.5 (Technical records) is short; it states that technical records shall include the date they were taken, the person responsible for the recording, any calculations involved in arriving at the results and the identity of the person checking the data and results. It also goes on to say that any amendment to those technical records needs to be checked as well. All of this is basic LIMS functionality. As far as supporting ISO 17025 it is more interesting to look at other sections of the standard and how an integrated fully functional LIMS supports these.

Resources Requirements

Section 6 of ISO17025 provides considerable details on the management of laboratory resources. It states specifically that the laboratory shall have available the personnel, facilities, equipment, systems, and support services necessary to manage and perform its laboratory activities. A fully integrated LIMS has a key role in helping the laboratory meet the requirements for this as detailed in a number of the subsections to Section 6.

A.2 Personnel (Section 6.2)

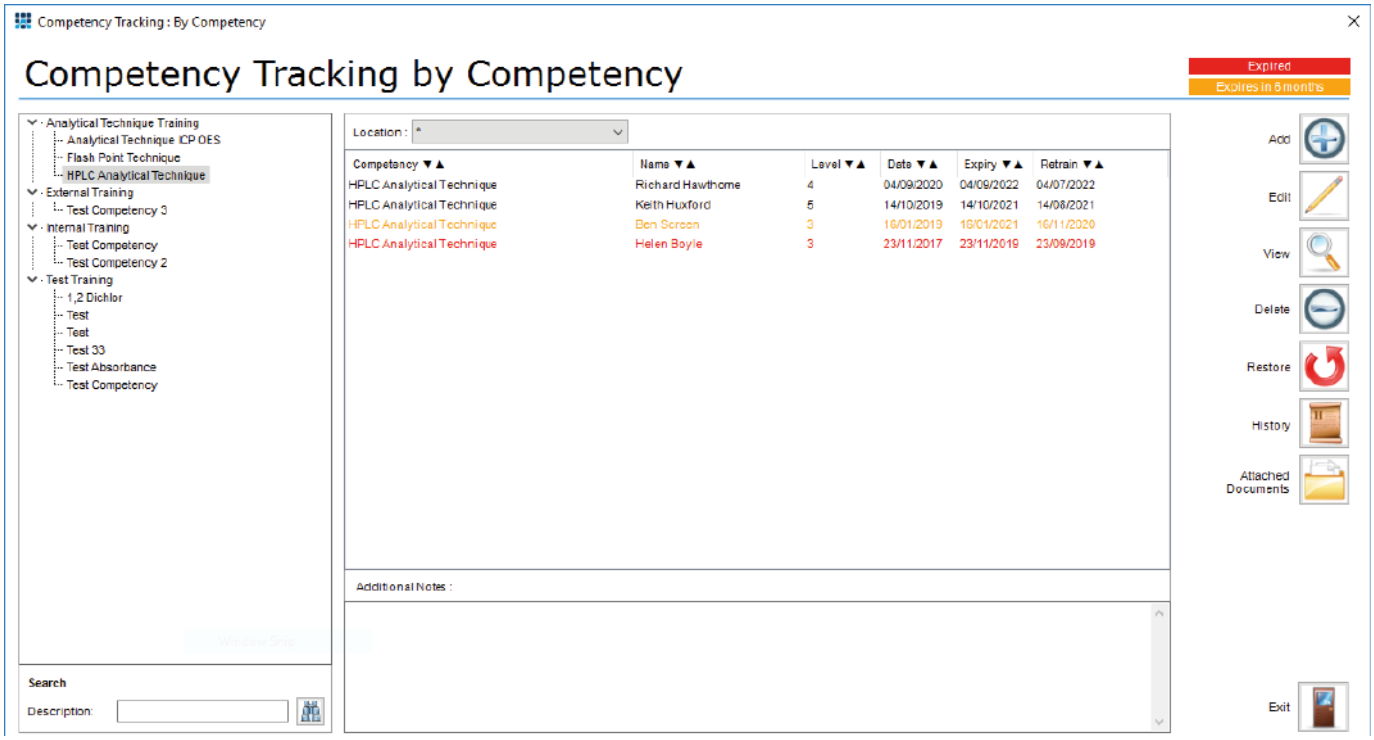
Section 6.2 covers personnel and, in particular, staff competency and training. As an example of the risk-based approach, the standard stipulates that the laboratory must document competency requirements for functions that influence the results of the laboratory activities. However, it does not state in exact detail what these functions are, although it does go on to state that personnel must have the competence to perform the activities they are responsible for. While staff competency and training may initially be perceived as outside the scope of LIMS, this is far from the case. An integrated



LIMS will have the ability to manage staff training and competency records, including the scheduling of training and retraining activities. To take this further, however, the LIMS must be able to link these records to specific activities; preventing personnel not trained or certified in an activity or task from carrying it out. A common example is competency to carry out specific tests or methods within the lab. The system must be able to check the competency of the user at the time that they are performing the analysis. If they do not have the required training or competency, or if it has lapsed, they will be prevented from entering results into the LIMS. The same principle can be applied to other activities such as instrument maintenance and calibration.

A.1 Facilities and Environmental Conditions (Section 6.3)

At first sight it might seem unlikely that LIMS could have a major part to play in helping organizations with the management of their facilities and environmental conditions within the context of ISO17025. When it is understood that this covers the monitoring, control and recording of environmental conditions as required, including where environmental conditions may influence the validity of results, the role of LIMS becomes clearer. However, this role can extend beyond the basic recording of results of environmental monitoring, to the management of the monitoring itself.

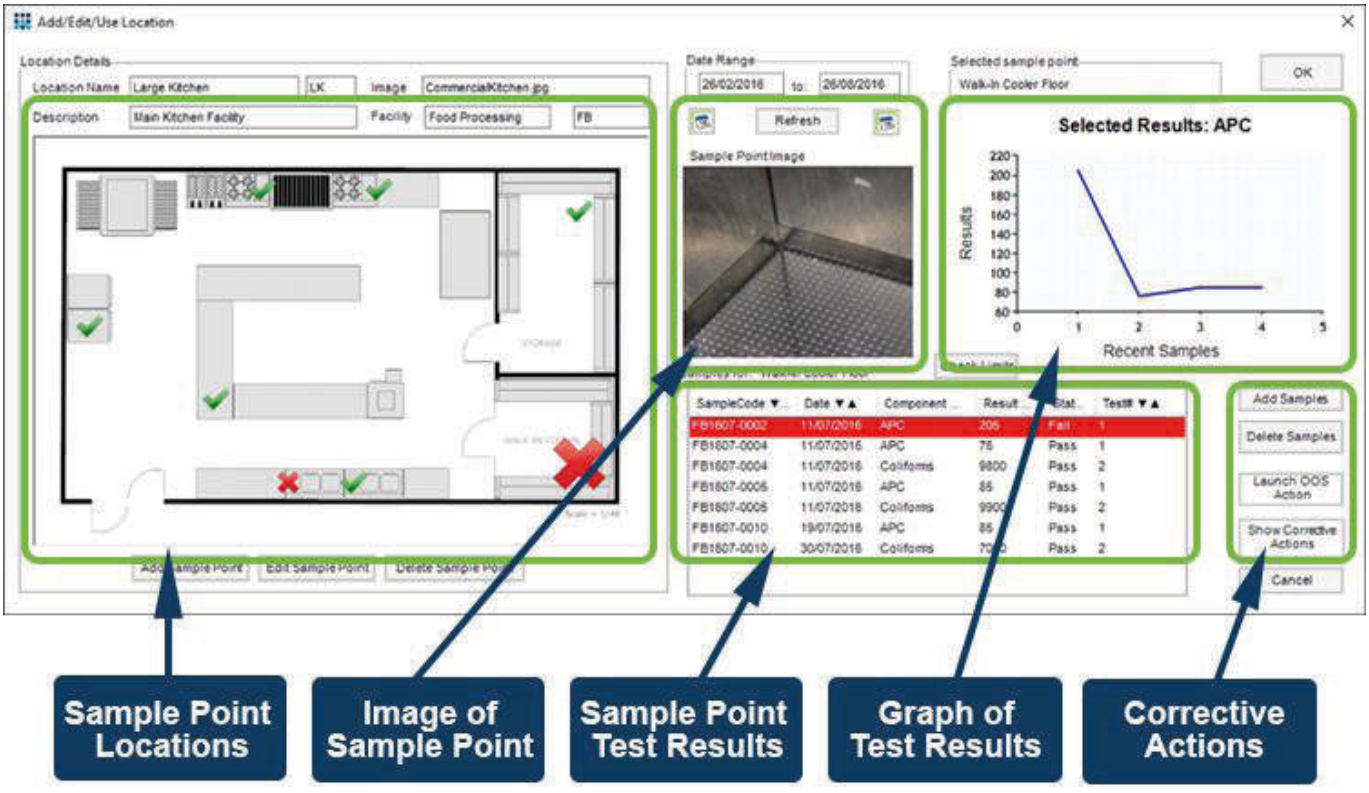


Example of Tracking Staff Competency in Matrix Gemini LIMS

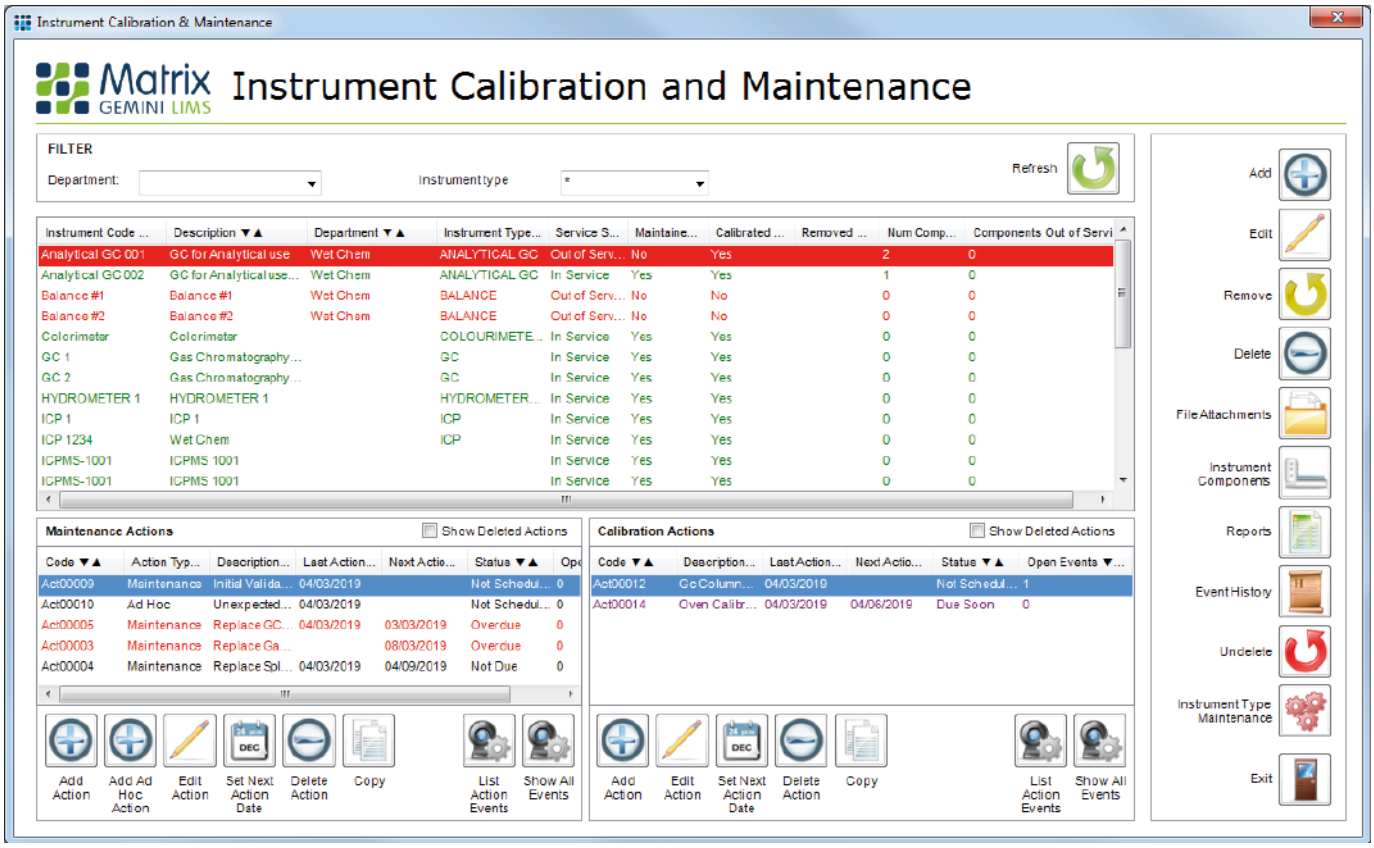
An integrated environmental monitoring function will allow sampling locations within the facilities to be defined and mapped. A sampling schedule may also be defined based on the frequency of sampling and the type of testing needed for those locations. If testing gives a result that exceeds the specified contamination limit, that result can be flagged as such. Results can also be tracked and charted over time to show if there are any significant data trends, even if limits have not been exceeded. This type of functionality is particularly useful for tracking microbial or particulate contamination within clean environments.

A.3 Equipment (Section 6.4)

The management of equipment in the laboratory is a key aspect of ISO17025. Not surprisingly, maintenance and calibration plans, and the ability to prevent equipment being used if it has not been serviced, is not in calibration or is out of service for some other reason, is emphasized. An integrated LIMS will have an instrument management system that allows maintenance and calibration plans to be defined, managed, and enforced. These plans cover maintenance and calibration requirements, as well as frequency, and allow the results of all calibration and maintenance events



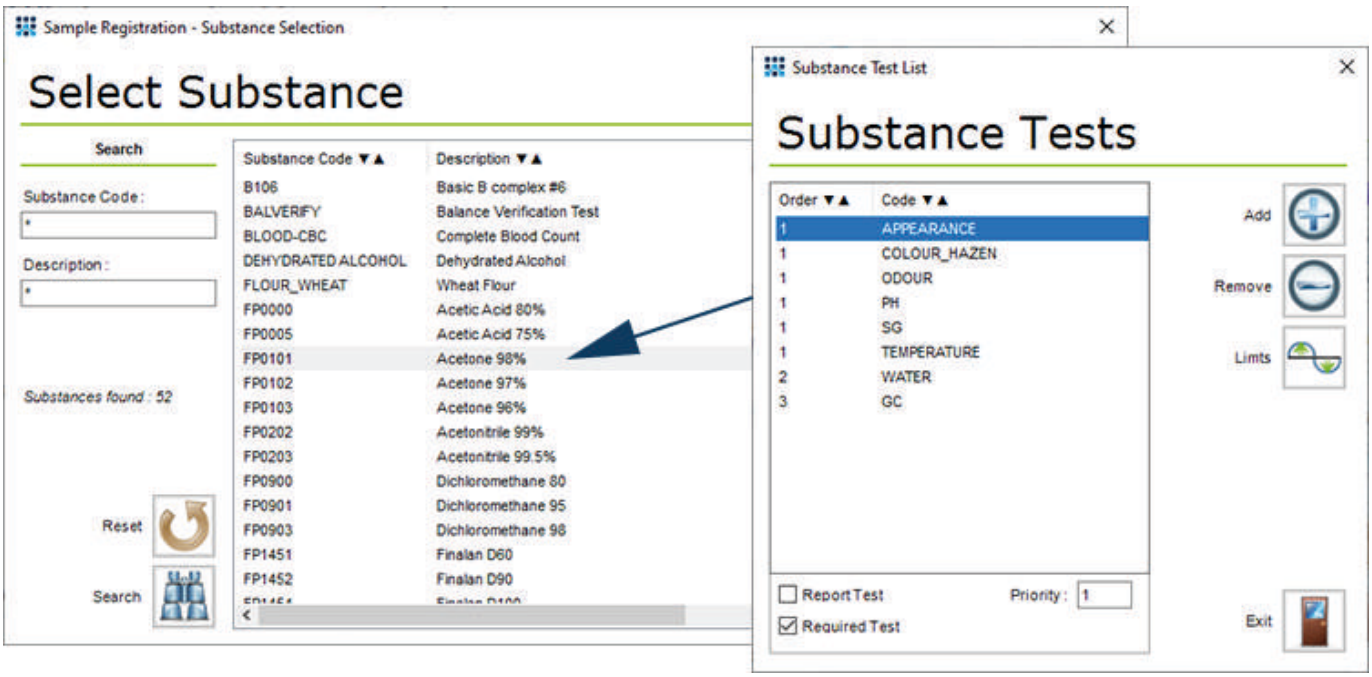
Example of Environmental Monitoring in Matrix Gemini LIMS



Example of Instrument Calibration and Maintenance in Matrix Gemini LIMS

to be recorded. The maintenance and calibration history of any equipment can therefore be fully tracked. Equipment status can be checked at the time of use and, in the same way that an analyst can be prevented from recording results for a test if their certification is not current, the use of the instrument can be prevented if the status is not correct.

ISO 17025 also defines standards, reference materials, reference data, reagents, and consumables as equipment. Here the inventory management functionality of LIMS comes into play. Inventory management will allow the receipt of equipment of this type to be recorded together with other key data such as the supplier, amount, use by dates and Certificates of Analysis. Data such as the certified values of standards can also be recorded. Amounts (or stock levels) can be managed and inventory used for specific purposes can be recorded, for example the consumables and reagents used as part of an analytical run. Linking inventory to specific tasks in this way also allows for the amount used to be automatically decremented from the available stock, allowing stock levels to be monitored and stock to be reordered when it falls below defined levels.



Example of Tests Dictated by Chosen Substance in Matrix Gemini LIMS

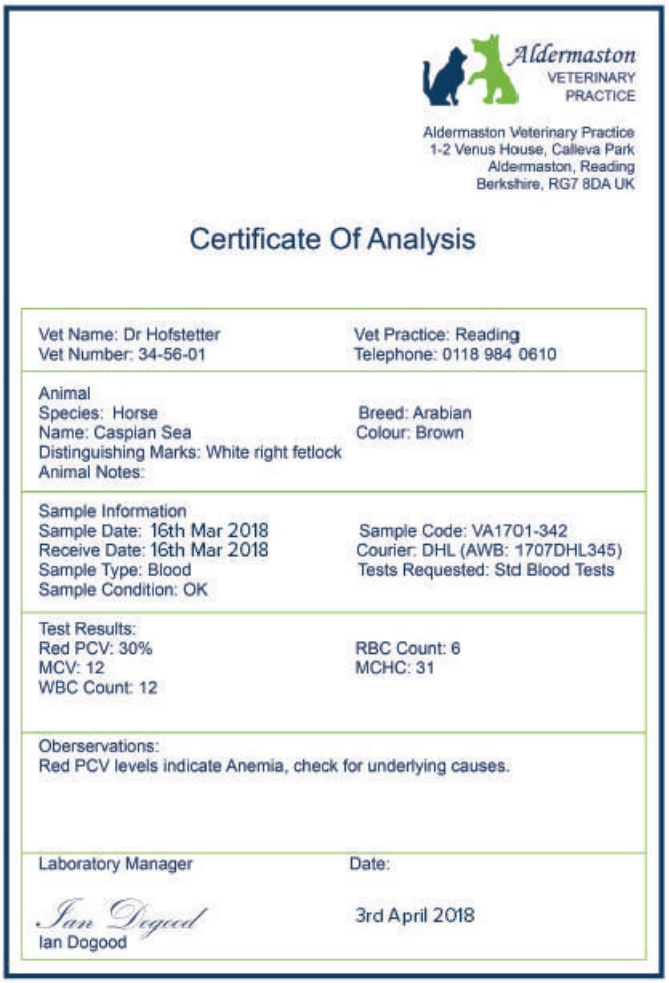
Process Requirements
It is clear that ISO17025 requires proper management of the resources within the organization, but the processes within the organization are as important. Processes are covered in section 7 of the standard and again provides an opportunity for LIMS to prove its value by supporting process definition and enforcement.

B.1 Review of Requests, Tenders, and Contracts (Section 7.1)
Section 7.1 covers the review of requests logged by customers, which may be required before work can be started. A LIMS can prevent the processing of a request until it has been reviewed and approved by a qualified person. As systems become more open through the use, for example, of customer portals that allow them to log requests on-line, this type of review is becoming more important to ensure that the customer has asked for something which is possible and covered by any contract that is in place.

B.2 Selection of Methods (Section 7.2)
In Section 7.2 emphasis is placed on the selection and verification of the appropriate tests to be used. LIMS can play a big role in ensuring that this requirement can be met by, for example, automatically assigning methods and tests based on the material (or substance) under test, or other factors such as the submitter of the testing request. The system ensures that the latest version of the method is applied and, if appropriate, relevant limits are assigned to check the validity of results. Where validation of methods is required projects can be set up within LIMS to help manage the process and record the results of the validation process.

B.3 Sampling (Section 7.3)
Sampling, and the way that sampling is carried out, is a key element in ensuring consistency of operation within a calibration or testing laboratory. As well as helping to define sampling plans or interfacing with complex sample planning software such as used in the UK water industry, LIMS records and retains the sampling data that can form part of the testing or calibration that the laboratory does, as defined in section 7.3 of the standard. This can include information such as date and time of sampling, id of the person who carried out the sampling as well as recordings of any deviations from the defined sampling plan. The LIMS will, of course, also provide unique identification for the samples. It is important however that the LIMS is flexible enough to support different information for different types of samples and, in addition, easily supports the needs of new sampling requirements that may be required.

B.4 Measurement Uncertainty and Validity of Results (Section 7.6 & 7.7)
Measurement uncertainty is a complex area, especially for calibration laboratories, and again one where LIMS can have a role to play. Where a test method used by a testing laboratory specifies limits these can be applied automatically by the LIMS at the time of result entry. More complex calculations can be implemented where these types of limits are not applicable. For example, measurement uncertainty for a run, or batch, of samples that includes QA/QC samples (controls, spikes, duplicates, replicates etc.) can be determined from the results recorded for the run. Linked to this is ensuring the validity of the results where many other aspects of LIMS functionality have a role to play. Reference materials can be managed and tracked using inventory management functionality, calibration of instruments can be tracked using instrument calibration and maintenance options, retesting and replicate testing can be controlled, and control charts produced as required. Reporting functions allow the review of reported results. Correlation of results for characteristics of an item across different batches is possible because the required data is all in the same place.



Aldermaston VETERINARY PRACTICE

Aldermaston Veterinary Practice
1-2 Venus House, Calleva Park
Aldermaston, Reading
Berkshire, RG7 8DA UK

Certificate Of Analysis

Vet Name: Dr Hofstetter
Vet Number: 34-56-01
Vet Practice: Reading
Telephone: 0118 984 0610

Animal
Species: Horse
Name: Caspian Sea
Distinguishing Marks: White right fetlock
Animal Notes:
Breed: Arabian
Colour: Brown

Sample Information
Sample Date: 16th Mar 2018
Receive Date: 16th Mar 2018
Sample Type: Blood
Sample Condition: OK
Sample Code: VA1701-342
Courier: DHL (AWB: 1707DHL345)
Tests Requested: Std Blood Tests

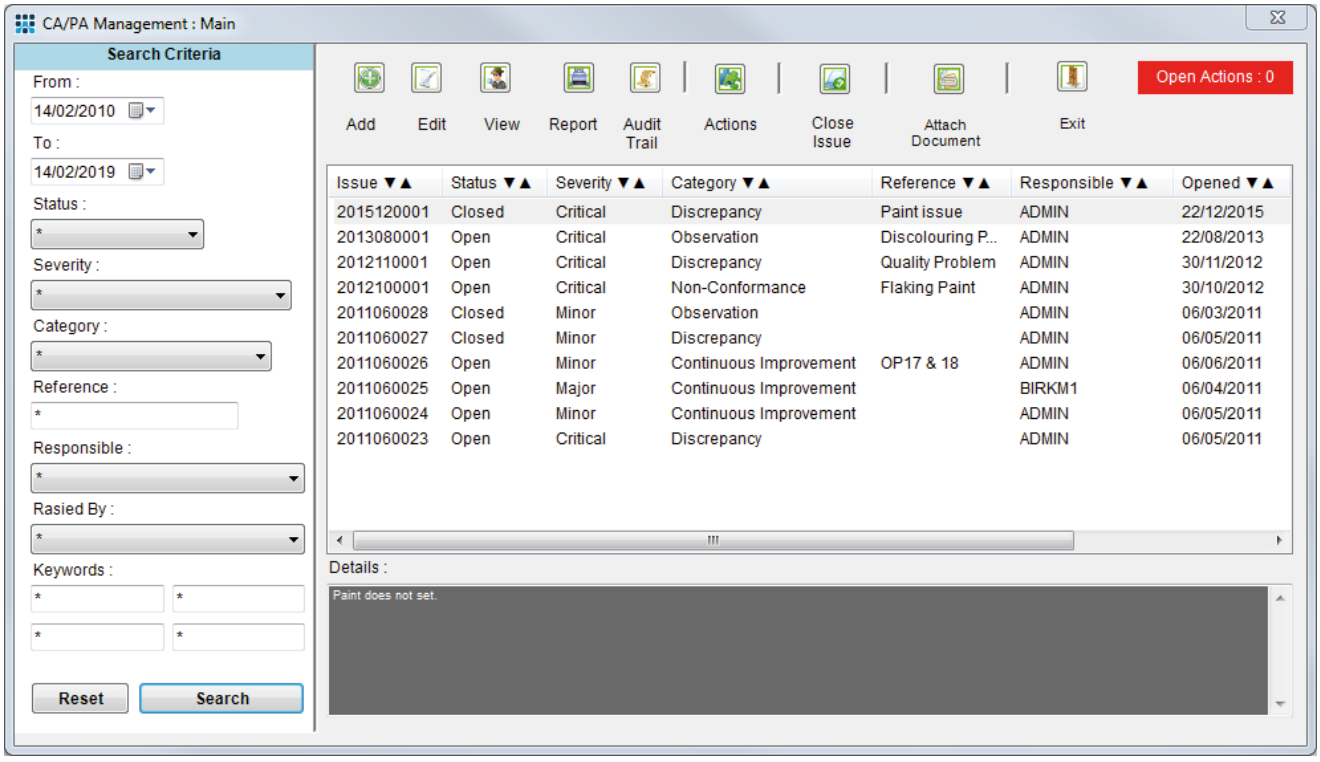
Test Results:
Red PCV: 30%
MCV: 12
WBC Count: 12
RBC Count: 6
MCHC: 31

Oberservations:
Red PCV levels indicate Anemia, check for underlying causes.

Laboratory Manager
Ian Dogood
Date:
3rd April 2018

B.5 Reporting of Results (Section 7.8)
Reporting is a vital part of any testing or calibration laboratory as it is the point at which the product of the laboratory, that is the data and information produced, is delivered to the consumer or customer of that product. Clearly it is essential that the correct information is delivered and reports, in whatever format, must include all the information agreed with the customer. The ISO 17025 section on reporting (7.8) also requires results to be reviewed and authorized prior to their release. LIMS supports the review and authorization steps required, so that reports cannot be issued until reviewed or authorized by an approved user. Flexible reporting options allow the creation and management of customer-specific reports which contain all the required information in the format or formats required for specific substances under test. With all the information required coming from the LIMS, reports can be automatically generated and made available for review once the results of the testing have been approved. This speeds report creation and review, and therefore delivery of the results to the customers.

B.6 Managing Complaints and Non-conforming Work (Section 7.9 & 7.10)
Sections 7.9 and 7.10 refer to complaints and nonconforming work. Complaints must be managed and tracked, and procedures must be in place for handling any nonconforming work that is identified. Complaints and non-conformances can be managed within a LIMS provided it has an integrated Corrective Action, Preventive Action (CAPA) management facility. Such a facility allows the tracking and management of the CAPA from the time it is created, through to the time that it is resolved. The actions associated with the CAPA are recorded together with the corrective actions identified and implemented allowing full traceability of the CAPA process.



Example of CAPA Management in Matrix Gemini LIMS

B.7 Control of Data and Information Management (Section 7.11)

Section 7.11 Control of data and information management is not especially long but it may have far reaching consequences. It firstly states that the laboratory shall have access to the data and information needed to perform laboratory activities. While this may seem like a statement of the obvious it is perhaps worthwhile asking how easy it is for your lab staff to access the data and information they require to do their jobs. Can an analyst easily access what can be proven to be the latest version of a Standard Operating Procedure to ensure they are carrying out a technique correctly? How easy is it to check the calibration or maintenance status of a specific piece of equipment that is needed particularly if, for example, is it located in a different facility or building? How simple is it to check there is enough reagent in stock to carry out a specific technique, is it still within its use by date and where is it? All of these are part of the data set that a laboratory must be able to access in order to function, in addition to all the information about customers, requests, contracts, training, environment and technical records. By implementing an integrated LIMS this data can be brought into a single place.

Another key aspect of 7.11 is the concept of validation[2] of the laboratory information management system (or systems) that are in use. It must be remembered that laboratory information management systems may be computerized or non-computerized systems, meaning that paper records count. The pharmaceutical industry has had to face the challenge of validation for many years and experience has shown that paper-based systems, and even spreadsheet-based systems, can be difficult to validate. LIMS are well suited to validation; integrating information and functionality into a LIMS minimizes the number of different systems that need to be validated and, because of their long history of use in the pharmaceutical industry, many LIMS come with supporting material, such as validation scripts and packs. These are designed to help the process of validating the information management system.

Summary

ISO 17025 at its heart is a quality management system, and while an integrated LIMS will support the quality management system (QMS), it cannot replace management commitment to making a QMS work. However, investing in and implementing a LIMS provides evidence of management commitment as it supports so many aspects of the QMS. It can help ease the burdens of compliance by showing that the processes and operational requirements defined as part of the QMS are in place and are being adhered to. The LIMS can also reduce audit and inspection overheads by integrating information in a single place. Equally importantly it gives confidence and assurance to customers or collaborators that work is carried out competently and that the data and the information produced is valid. The capabilities of modern integrated LIMS make them a vital support system for successfully achieving, maintaining, and gaining benefit from ISO 17025 accreditation.

REFERENCE

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

Tim Daniels

Tim Daniels has over 30+ years of experience working in national and international markets across a range of software/high-technology products. As worldwide Marketing Manager at Autoscribe Informatics Tim works with product development, technical services, sales, and management teams across the company to drive marketing goals and achieve growth plans. Autoscribe Informatics provides database management solutions such as Laboratory Information Management Systems (LIMS) that, uniquely, are graphically configurable, requiring no scripting or custom coding to configure solutions. Tim's broad background in marketing and technical roles provides a unique blend of practical knowledge and insight to drive all aspects of product and corporate marketing at Autoscribe Informatics.