LabVantage®

ISO 17025:2017 POSITION PAPER

General Requirements for the Competence of Testing and Calibration Laboratories

LabVantage is a great asset to meet the ISO 17025:2017 requirements that can be controlled via software.

EXECUTIVE SUMMARY

This position paper provides a high-level overview of how LabVantage Solutions supports customers concerning compliance with ISO 17025:2017: "General Requirements for the Competence of Testing and Calibration Laboratories" by using LabVantage software.

ISO 17025 are general requirements for the competence of testing and calibration laboratories. The standard was first published in 1999, with the second release in 2005 after it was agreed that it needed to have its quality system words more closely aligned with the 2000 version of ISO 9001. The third release was issued in 2017.

The current 2017 standard comprises eight elements: Scope, Normative References, Terms and Definitions, General Requirements, Structural Requirements, Resource Requirements, Process Requirements, and Management System Requirements.

LabVantage ISO 9001:2015 Certification

To ensure our software development and support activities are adequate to industry standards, and meet the needs of our customers, LabVantage had become ISO 9001:2015 certified in 2016 for the design, installation, and provision of laboratory software. This includes processes and procedures to describe, manage, and control the following quality system elements: Context of the Organization, Leadership, Planning, Support, Operation, Performance Evaluation, and Improvement.

Relationship between ISO 17025 and ISO 9001

ISO 9001 is the general standard that specifies the requirements for a quality management system. Laboratories that meet the requirements of ISO 17025 also operate following the requirements of ISO 9001 that are relevant to calibration and testing activities. However, ISO 9001 compliance does not mean that a lab conforms to ISO 17025.

Summary

The testing and calibration laboratory's compliance with ISO 17025 regulations are achieved by:

1) The development and enforcement of policies and procedures, which are unrelated to the LabVantage implementation and

2) The configuration and implementation of LabVantage to assist the testing and calibration laboratory compliance to the regulations.

In summary, LabVantage can be a great asset to meet the ISO 17025:2017 requirements that can be controlled via software.

Detailed Analysis of How LabVantage Can Assist in ISO 17025 Compliance

The following is a detailed analysis of the ISO 17025:2017 regulations and how LabVantage can be configured to assist the testing and calibration laboratory in meeting those requirements. Successful compliance with ISO 17025 includes the testing and calibration laboratory's policies and procedures and the configuration and implementation of LabVantage software.

LabVantage can help with compliance but requires several supporting procedures:

- Labs must have all relevant procedures and documents in place to implement the system correctly.
    - Procedures for instruments and reagents, error handling, Corrective Actions-Preventive Actions (CAPA), roles and responsibilities according to each person's competence, and LIMS procedures to mention a few.
    - All analytical methods that are normally used.
    - Specifications for the sample types.
- Implementation must be controlled so that all relevant meta-data will be included when using the live system.
- Validation is needed, both for the system itself and the static data entered into the system, before the system can be used in a production environment.

ISO 17025 also calls for procedures that may be unrelated – or only partially related – to using instruments with the LabVantage system.

4.0 GENERAL REQUIREMENTS	
4.1	IMPARTIALITY • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system.
4.2	CONFIDENTIALITY • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system.
5.0 STRUCTURAL REQUIREMENTS	
5.1	STRUCTURAL REQUIREMENTS • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system.
6.0 RESOURCE REQUIREMENTS	
6.1	GENERAL • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system.
6.2	PERSONNEL • LabVantage ensures analysts can perform tests and calibrations that they are qualified or trained for based on the task and date of the training. Analyst certification component allows the tracking of training, certifications, and their expiration dates. • Specific roles and job functions are assigned to each user to authorize or prevent the execution of certain tasks and activities.
6.3	FACILITIES AND ENVIRONMENTAL CONDITIONS • Environmental monitoring may be implemented to ensure environmental conditions are adequate for testing. This includes a sampling schedule, sample controls, tracking of samples, identification of out-of-specification results, reporting of the facility conditions, and a graphical capability to import building diagrams or pictures to show the locations of the monitoring samples. • The scheduler functionality defines routine schedules to take environmental samples.

6.0 RESOURCE REQUIREMENTS (CONT.)

6.4	EQUIPMENT LabVantage can: • Define the equipment and instruments needed to perform testing and calibrations. • Ensure the equipment has been calibrated or qualified to meet the laboratory specifications before use or before placed in service. • Ensure that authorized people can use the equipment and others can't. • View equipment use, maintenance instructions, and procedures. • Retain equipment calibration records with the necessary information that includes the manufacturer, model, serial number, unique identification, location, current and next calibration dates. • Develop and maintain equipment inventory and maintenance plans. • Place equipment into or out of service based on calibration, overloading, mishandling, or shown to be defective until fully repaired. Additionally, out of specification results may be investigated for root cause using the Laboratory Investigations module to implement and track corrective and preventive actions. • Trend results based on equipment, used as part of the investigation process. • Ensure equipment function and calibration status are checked and shown to be in specification before return to service. • Intermediate calibration checks are recorded to maintain confidence in the equipment as per defined procedures.
6.5	METROLOGICAL TRACEABILITY LabVantage can: • Ensure equipment used for tests and calibrations are calibrated and maintained before being put into service. • Trace calibration of equipment to International System of Units (SI), NIST, and other standards.
6.6	EXTERNALLY PROVIDED PRODUCTS AND SERVICES • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system. • Nevertheless, LabVantage can track and monitor laboratory consumables such as reagents and standards used in the laboratory.

7.0 PROCESS REQUIREMENTS	
7.1	REVIEW OF REQUESTS, TENDERS AND CONTRACTS • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system.
7.2	SELECTION, VERIFICATION AND VALIDATION OF METHODS LabVantage can: • Store procedures for the sampling, handling, transport, storage, and preparation of items to be testing. • Document and manage any deviation from the standard procedure using the Laboratory Investigations module to implement and track corrective and preventive actions. • Define the testing and calibration methods based on the customers' requirements and needs. • Ensure that the latest version of international, regional, or national standards are used by allowing only the current approved version in the software to be used. • Record test results at the time of generation. • Identify detections limits, limits of sensitivity, linearity. Limit of reproducibility and robustness. • Define and validate calculations as part of method approval. • Perform statistical process control • Interface to instruments.
7.3	SAMPLING LabVantage can: • Define the sampling plan and procedures for sampling substances, materials, and products for testing and calibration. • View sampling plans online at the sampling location. • Document planned or unplanned sampling plan deviations. • Identify the type of sampling, sample id, location, quality to sample, actual quantity sampled, and environmental conditions.
7.4	HANDLING OF TEST OR CALIBRATION ITEMS LabVantage can: • Protect the integrity of the test or calibration samples. • Implement barcodes to track samples and ease data entry. • Uniquely identify all samples throughout the life of the item so they cannot be confused with other samples. • Document and record any abnormalities or deviations from normal or specified conditions. • View sample handling instructions, including conditional storage conditions online, that are associated with the sample.
7.5	TECHNICAL RECORDS • Refer to section 7.8, "Reporting of Results."

7.0 PROCESS REQUIREMENTS (CONT.)	
7.6	EVALUATION OF MEASUREMENT UNCERTAINTY • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system. • Partial compliance is met by the Laboratory Investigations module used to assist in this evaluation.
7.7	ENSURING THE VALIDITY OF RESULTS LabVantage can: • Trending of results is available in the review and release of samples. • Replicate tests or calibrations using the same or different methods. • Retest or recalibrate samples. • Analyze data for both in and out-of-specification results and the planned action identified to correct a problem and prevent incorrect results from being reported. • Statistical analysis of results. • Control and use of reference and control materials. • Monitor the laboratory's internal and external samples.
7.8	REPORTING OF RESULTS LabVantage can configure test reports or calibration certificates to include: • Results of each test calibration or series of tests / calibrations in an accurate, clear, unambiguous, and objective method per any specific instructions. • Title, name, and address of the laboratory, location of the testing, unique report or certificate identification, page numbers, customer's address, identification of methods used, test / calibration description, test / calibration specification, results, sample receipt date, sample date, deviations from the plan, statement of compliance to requirements / specifications, and any other information that is captured in the software. • Deviations from the test methods, a statement of compliance, a statement on the uncertainty of measurement, comments, sampling date, unambiguous identification of the material sampled, sampling location, sampling plan, and any environmental conditions impacting sampling. • Environmental conditions during the calibration, statement of compliance with metrological specifications, traceability of measurements, calibration results before and after repair or adjustment. • The opinion or interpretation of results for each test / calibration. • Results performed by subcontractors and the identification of those tests / calibrations, the contracting laboratory. • Whether transmitted test or calibration results meet or fail specifications. • Each type of test or calibration to minimize misunderstanding or misuse. • Amendments to the test report or calibration certificate after issuance and a unique report or certificate identification.

7.9	COMPLAINTS • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system.
7.10	NONCONFORMING WORK • LabVantage can create, manage, and track nonconforming work using the Laboratory Investigations module.
7.11	CONTROL OF DATA AND INFORMATION MANAGEMENT LabVantage can: • Control access to the data and information via role-based user groups. • Protect the data from unauthorized access, tampering or loss. • Provide online user manuals within the application. • Provide a full audit trail to capture all changes to data that complies with 21 CFR Part 11, EU GMP Annex 11, and more.
8.0 MANAGEMENT REQUIREMENTS	
8.1	GENERAL • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system.
8.2	MANAGEMENT SYSTEM DOCUMENTATION • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system. • Nevertheless, LabVantage supports the laboratory in maintaining compliancy with procedures: for example, the SOPs for methods execution are visible in relevant pages, if attached to the methods.
8.3	CONTROL OF MANAGEMENT SYSTEMS DOCUMENTS • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system. • Nevertheless, LabVantage allows documents and testing procedures to the attached and viewed.
8.4	CONTROL OF RECORDS • LabVantage can manage testing and calibrations data, generate data reports, and complies with 21 CFR Part 11, EU GMP Annex 11, and more, for electronic records and signatures. For details please see the 21 CFR Part 11 / EU GMP Annex 11 Compliance white paper.
8.5	ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system. • Partial compliance is met by the LabVantage Laboratory Investigations module to implement and track corrective and preventive actions.

8.0 MANAGEMENT REQUIREMENTS (CONT.)	
8.6	IMPROVEMENT • LabVantage can document and manage deviations using the Laboratory Investigations module to implement and track corrective and preventive actions.
8.7	CORRECTIVE ACTIONS • LabVantage can document and manage deviations using the Laboratory Investigations module to implement and track corrective and preventive actions.
8.8	INTERNAL AUDITS • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system.
8.9	MANAGEMENT REVIEWS • Compliance must be maintained according to company and laboratory procedures and is outside the scope of the LabVantage system.

LabVantage®

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ABOUT LABVANTAGE SOLUTIONS

A recognized leader in enterprise laboratory software solutions, LabVantage Solutions dedicates itself to improving customer outcomes by transforming data into knowledge. The LabVantage informatics platform is highly configurable, integrated across a common architecture, and 100% browser-based to support hundreds of concurrent users. Deployed on-premise, via the cloud, or SaaS, it seamlessly interfaces with instruments and other enterprise systems – enabling true digital transformation. The platform consists of the most modern laboratory information management system (LIMS) available, integrated electronic laboratory notebook (ELN), laboratory execution system (LES), and scientific data management system (SDMS); and, for healthcare settings, a laboratory information system (LIS). We support more than 1500 global customer sites in the life sciences, pharmaceutical, medical device, biobank, food & beverage, consumer packaged goods, oil & gas, genetics/diagnostics, and healthcare industries. Headquartered in Somerset, NJ., with global offices, LabVantage has, for four decades, offered its comprehensive portfolio of products and services to enable customers to innovate faster in the R&D cycle, improve manufactured product quality, achieve accurate record-keeping, and comply with regulatory requirements.

For more information, visit www.labvantage.com.