

# General Requirements for the Competence of Testing and Calibration Laboratories



LabVantage is a great tool to meet the ISO 17025:2005 requirements that can be controlled via software.

## EXECUTIVE SUMMARY

This position paper provides a high-level overview of how LabVantage supports customers in relation to compliance with ISO 17025:2005: “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. A second release was issued in 2005 after it was agreed that it needed to have ISO 17025 quality system words more closely aligned with ISO 9001:2000. As of this writing, the ISO 17025 standard is under review for another update as ISO 17025:2017.

The 17025 standard itself comprises five elements: Scope, Normative References, Terms and Definitions, Management Requirements and Technical Requirements.

The two main sections are Management Requirements and Technical Requirements. Management Requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory and are in line with the ISO 9001:2015 requirements. Technical Requirements includes factors that determine the correctness and reliability of the tests and calibrations performed in laboratory.

## 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 became 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: Organization, Leadership, Quality Policy, Management Review, Document Control, Record Control, Change Control, Risk Management, Improvement, Corrective and Preventive Action, Internal Auditing, External Auditing, External Provider Management, Training, Customer Complaints, Customer Support, Product Development (SDLC), Testing, and Product Release.

## 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 in accordance with the requirements of ISO 9001 that are relevant to calibration and testing activities.

## Achieving Compliance

The testing and calibration laboratory's compliance with ISO 17025:2005 regulations can be achieved with:

- 1) The development and enforcement of policies and procedures, which are unrelated to the LabVantage software.
- 2) The configuration and implementation of LabVantage software to assist the testing and calibration laboratory compliance to the regulations.

In summary, LabVantage can be a great tool to meet the ISO 17025:2005 requirements that can be controlled via software.

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## Detailed Analysis on How LabVantage Can Assist in ISO 17025 Compliance

The following is a detailed analysis of the ISO 17025 regulations and how LabVantage can 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. Requirements that are fully dependent on laboratory procedures, and are therefore outside the LabVantage software, are identified as N/A.

### MANAGEMENT REQUIREMENTS

#### ORGANIZATION

- 4.1 Although compliance with this requirement relates to the organizational structure of the testing laboratory, LabVantage ensures analysts can perform tests and calibrations that they are qualified or trained for. In addition, the organizational structure of the laboratory can be reflected in granting access and permissions over data and functionality, implemented in LabVantage, for example, through roles/job types and departmental security.

#### MANAGEMENT SYSTEM

- 4.2
- Compliance is per the laboratory procedures and are outside the LabVantage software.
  - 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.

## MANAGEMENT REQUIREMENTS

	<b>DOCUMENT CONTROL</b>
4.3	<ul style="list-style-type: none"> <li>Compliance is per the laboratory procedures and are outside the LabVantage software.</li> <li>Nevertheless, LabVantage allows documents and testing procedures to be attached and viewed.</li> </ul>
4.4	<b>REVIEW OF REQUESTS, TENDERS AND CONTRACTS</b> N/A
	<b>SUBCONTRACTING OF TESTS AND CALIBRATIONS</b>
4.5	<ul style="list-style-type: none"> <li>Compliance is per the laboratory procedures and are outside the LabVantage software.</li> <li>Nevertheless, LabVantage may be configured to identify results originating from an in-house or external laboratory.</li> </ul>
	<b>PURCHASING SERVICES AND SUPPLIES</b>
4.6	<ul style="list-style-type: none"> <li>Compliance is per the laboratory procedures and are outside the LabVantage software.</li> <li>Nevertheless, LabVantage can monitor reagents used in the laboratory.</li> </ul>
	<b>SERVICE TO THE CUSTOMER</b>
4.7	N/A
	<b>COMPLAINTS</b>
4.8	N/A
	<b>CONTROL OF NON-CONFORMING TESTING AND/OR CALIBRATION WORK</b>
4.9	LabVantage can create, manage and track non-conformities with the implementation of the CAPA module.
	<b>IMPROVEMENT</b>
4.10	N/A
	<b>CORRECTIVE ACTION</b>
4.11	LabVantage can create, manage and track corrective actions associated with testing and calibrations.
	<b>PREVENTIVE ACTION</b>
4.12	LabVantage can create, manage and track preventive actions associated with testing and calibrations.
	<b>CONTROL OF RECORDS</b>
4.13	LabVantage can manage testing and calibrations data, generate data reports and is 21 CFR Part 11 and Annex 11 compliant for electronic records and signatures. For details please see the 21 CFR Part 11 / Annex 11 Compliance <a href="#">white paper</a> .
	<b>INTERNAL AUDITS</b>
4.14	N/A
	<b>MANAGEMENT REVIEWS</b>
4.15	N/A

## TECHNICAL REQUIREMENTS

5.1	<b>GENERAL</b> N/A
5.2	<b>PERSONNEL</b> <ul style="list-style-type: none"><li>• LabVantage ensures analysts can perform tests and calibrations that they are qualified or trained for based on the task and date of training. Analyst certification component allows the tracking of training, certifications and their expiration dates.</li><li>• Specific roles and job functions are assigned to each user to authorize or prevent the execution of certain tasks and activities.</li></ul>
5.3	<b>ACCOMMODATION AND ENVIRONMENTAL CONDITIONS</b> <ul style="list-style-type: none"><li>• 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.</li><li>• The scheduler functionality defines routine schedules to take environmental samples.</li></ul>
5.4	<b>TEST AND CALIBRATION METHODS AND METHOD VALIDATION</b> <p>LabVantage can:</p> <ul style="list-style-type: none"><li>• Store procedures for the sampling, handling, transport, storage and preparation of items to be tested.</li><li>• Document and manage any deviation from the standard procedure as a CAPA.</li><li>• Define the testing and calibration methods based on the customer requirements and needs.</li><li>• Ensure the latest version of international, regional or nation standards are used by allowing only the current approved version in the software to be used.</li><li>• Record test results at the time of generation.</li><li>• Identify detections limits, limits of sensitivity and linearity. Limit of reproducibility and robustness.</li><li>• Define and validate calculations as part of method approval.</li><li>• Perform statistical process control.</li><li>• Interface to instruments.</li></ul>

## TECHNICAL REQUIREMENTS

### EQUIPMENT

LabVantage can:

- Define the equipment and instruments needed to perform testing and calibrations.
- Ensure the equipment has been calibrated or validated to meet the laboratory specifications prior to use or placed in service.
- Ensure that authorized people can use the equipment.
- View equipment use and maintenance instructions / procedures.
- Retain equipment calibration records with the necessary information, including 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 the calibration, overloading, mishandling, shown to be defective or provide out of specification results until fully repaired.
- 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 prior to return to service.
- Intermediate calibration checks are recorded to maintain confidence of the equipment as per defined procedures.

### MEASUREMENT TRACEABILITY

LabVantage can:

- Ensure equipment used for tests and calibrations are calibrated and maintained prior to being put into service.
- Trace calibration of equipment to International System of Units (SI), NIST and other standards.

### 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.

## TECHNICAL REQUIREMENTS

### HANDLING OF TEST AND CALIBRATION ITEMS

LabVantage can:

- Protect the integrity of the test or calibration samples.
  - Implement barcodes to track samples and ease of data entry.
- 5.8
- Uniquely identify all samples throughout the life of the item, so one 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 and that are associated with the sample.

### ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

LabVantage can:

- Make available trending of results 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.
- 5.9

### REPORTING THE 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 and unambiguous and objective method in accordance with any specific instructions in the test / calibration methods.
  - 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 / non-compliance to requirements / specifications and any other information that is captured in the software.
- 5.10
- Deviations from the test methods, a statement of compliance / non-compliance, statement on the uncertainty of measurement, comments, sampling date, unambiguous identification of the material sampled, sampling location, sampling plan, any environmental conditions impacting sampling.
  - Environmental conditions during the calibration, statement of compliance or non-compliance with metrological specifications, traceability of measurements, calibration results prior to and post 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 and to minimize the misunderstanding or misuse.
  - Amendments to the test report or calibration certificate after issuance and a unique report or certificate identification.

## Additional Requirements

### Objective Evidence of Laboratory Utilization of PJLA's Accreditation Symbol Must Be Included in the Package

Test reports or calibration certificates can be configured to include:

- The PJLA logo, company logo, any other certification logos, that are readable in size, and in color.
- A statement that the laboratory is ISO/IEC 17025:2005 certified, utilizing the ILAC criteria or any other statement.
- Be printed on company letterhead or watermarked paper.

#### SUBCONTRACTED TESTS OR CALIBRATIONS

- N/A

#### CALIBRATION LABELS ON EQUIPMENT

- Calibration labels can be configured to include the PJLA accreditation symbol or any other logos or symbols, the accreditation laboratory, equipment identification, date of current calibration and cross reference to calibration certificates.

#### PL-1 PROFICIENCY TESTING REQUIREMENTS FOR APPLICANT AND ACCREDITED LABORATORIES

- Proficiency Testing (PT), and any corrective actions, may be documented in LabVantage via a plan, schedule or individual testing.

#### PL-2 MEASUREMENT TRACEABILITY POLICY

- N/A

#### PL-3 POLICY ON MEASUREMENT UNCERTAINTY FOR CALIBRATION AND TESTING LABORATORIES

- N/A

#### SURVEILLANCE OF PREVIOUS NON-CONFORMITIES AND CORRECTIVE ACTION

- Although compliance to this requirement is addressed per the laboratory procedures, LabVantage can capture, manage, and verify the effectiveness of remediations to resolve the non-conformity.



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#### ABOUT LABVANTAGE SOLUTIONS

LabVantage is a multinational enterprise software provider with over 35 years of experience in laboratory informatics, including laboratory information management systems (LIMS), electronic laboratory notebooks (ELN), and laboratory execution systems (LES). It has ongoing relationships with more than 750 clients supporting more than 1500 sites working in the life science, pharmaceutical, medical device, biobank, food & beverage, CPG, oil & gas, genetics/diagnostics, and healthcare industries. Headquartered in Somerset, N.J., with 450 employees, LabVantage offers a comprehensive portfolio of products and services that enable companies to innovate faster in the R&D cycle, improve manufactured product quality, achieve accurate record-keeping, and comply with regulatory requirements. The LabVantage platform is highly configurable, purpose-built, and 100% web-based to support hundreds of concurrent users and seamlessly interface with instruments and other enterprise systems.

**For more information, visit [www.labvantage.com](http://www.labvantage.com).**