NEMC

Achieving ISO 17025 Compliance Using LIMS

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Key Talking Points

- Why ISO 17025 accreditation?
- ISO 17025: 2017 standards and regulatory requirements for environmental testing laboratories
- Role of LIMS in ISO 17025 compliance
- How LIMS helps to achieve IS0 17025 compliance?
- Advantages gained by laboratories by using LIMS to achieve ISO 17025
- Q & A

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Why ISO 17025 Accreditation?

It determines the technical competence of laboratories to perform specific types of testing, measurement and calibration

ISO 17025 Accreditation proves a laboratory has:

- An acceptable quality management system in place
- Ability and competence to provide testing and calibration results
- Assures that tests are performed against the international standards (ISO 17025:2017) and results are mutually acceptable between different governmental and regulatory organizations

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Why ISO 17025:2017 Accreditation?

How does this benefit your customers?

- Your customers have assurance that they are choosing a technically competent lab
- Your customers have more confidence in testing results provided by your lab
- Your customers can avoid expensive retesting

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New Edition of ISO/IEC 17025

New Edition of ISO/IEC 17025:2017: Latest Changes

The three Convenors of CASCO working group 44 (CASCO/WG 44) that revised the standard tell us why the new version of ISO/IEC 17025 is so important for laboratories:

Discover the new ISO/IEC 17025:2017

In order to reflect the latest changes in market conditions and technology, the new edition of the standard encompasses the activities and new ways of working of laboratories today. It covers technical changes, vocabulary and developments in IT techniques and takes into consideration the latest version of ISO 9001 on quality management.

https://www.iso.org/news/ref2250.html

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New Edition Changes

- Introduced a new chapter on risk-based thinking. Laboratory must: consider risks associated with lab activities; plan how to address them; and evaluate the effectiveness of these actions.
- Greater flexibility in the guidelines for processes, procedures, documented information, and organizational responsibilities. ISO 17025:2017 section 7.10 Non-conforming Work (previously 4.9) has been made more general.
- Terminology has been updated. For example, a definition for “laboratory” has been added.
- The scope has been revised to cover all laboratory activities. This includes testing, calibration, and the sampling associated with subsequent calibration and testing.

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ISO 17025 Standards and Regulatory Requirements

Management and Technical Requirements for Laboratories Performing Environmental Analysis

- **Management Requirements**

  Pertain to the operation and effectiveness of the quality management system within the laboratory

- **Technical Requirements**

  Address the competence of staff, sampling and testing methodology, equipment, and the quality and reporting of test and calibration results

Reference: ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories
https://www.iso.org/publication/PUB100424.html

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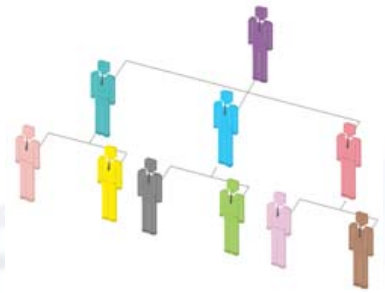
Management Requirements



Organization

Well-defined organizational structure, well-defined responsibilities of the laboratory, the management, and key personnel.

Document Control

Ensure that all documents related to the management system are uniquely identified created, approved, and issued. Changes to documents should follow the same review process.

Management System

Defined policies, standard organization procedures and work instructions to ensure the quality of test results, quality manual with policy statements.

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Management Requirements

Review of Requests, Tenders, and Contracts

Review of requirements of requests, tenders and contracts to ensure that the laboratory has the technical capability and resources to meet the customer request.

Purchasing Services and Supplies

Ensure that services and supplies delivered by third parties do not adversely impact the quality and effectiveness of laboratory operations.

Subcontracting of Tests and Calibrations

Ensure that tests and calibrations subcontracted to third parties are performed according to the same quality standards.

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Management Requirements

Complaints

Resolution of complaints received from customers. Records of complaints and all steps taken when resolving the complaint should be maintained.

Service to the Customer

Clarify requests and get customer input for the request they placed. Collect customer feedback.

Continuous Improvement

Suggestions for improvements should be taken from audit reports, analysis of data, customer complaints and suggestions, corrective and preventive actions, and management reviews.

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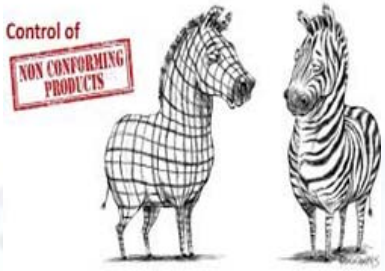
Management Requirements



Control of Nonconforming Testing and/or Calibration Work

Ensure that nonconforming test and calibration results are adequately followed up and that corrections are initiated.

Corrective and Preventive Action

Corrective actions can be triggered through nonconforming tests or other work, customer complaints, internal or external audits, management reviews, and observations by staff.

Procedure to identify potential sources of nonconformities and define preventive actions to prevent occurrence of these nonconformities.

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Management Requirements

Control of Records

Procedures for identification, collection, indexing, storage, retrieval, and disposal of records.

Records should be stored such that their security, confidentiality, quality and integrity are ensured.

Management Reviews

Schedule and procedure for periodic management reviews.

Internal Audits

Procedure and a schedule for internal audits. Internal audits can either cover the whole laboratory and all elements of the quality system at one specific period of time or can be divided into several subsections.

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Technical Requirements

Personnel

Only competent personnel should perform testing and calibrations Management should define and maintain tasks, job descriptions, and required skills for each job.

Accommodation and Environmental Conditions

Environmental conditions should not adversely affect the required quality of tests. Equipment should operate within the manufacturer's specifications for humidity and temperature.

Test and Calibration Methods & Method Validation

Test methods and procedures should be used within their scope. The laboratory should have up-to-date instructions on the use of methods and equipment.

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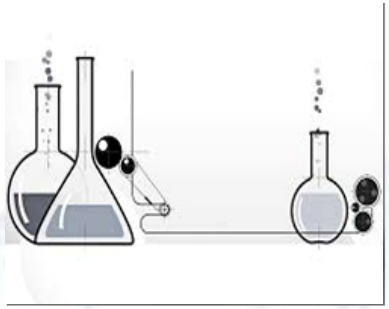
Technical Requirements



Equipment

Equipment that is performing well and properly maintained is a prerequisite for the ongoing accuracy of test and calibration results.

Measurement Traceability

Traceability of equipment to the same standard is a prerequisite for comparability of test and calibration results.

Sampling

Ensure that statistically relevant representative samples are taken and that all information on the sample and the sampling procedure is recorded and documented.

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Technical Requirements

Reporting of Results

Test/calibration results should be reported in such a way that it has clarity and accuracy, but it also has very detailed requirements on the contents.

Assuring the Quality of Test and Calibration Results

Ensure the quality of results on an ongoing basis through, for example, regular analysis of quality control samples or participation of proficiency-testing programs.

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Role of LIMS in ISO 17025 Compliance

There are many areas in which a LIMS supports and promotes ISO 17025 compliance

- Sample handling
- Managing and maintaining SOPs (standard operating procedures)
- Managing all test methods, and all documents pertaining to quality
- Equipment maintenance and calibration
- Quality assurance of test results
- COAs (Certificate of Analysis), and CoCs
- Data integrity audits

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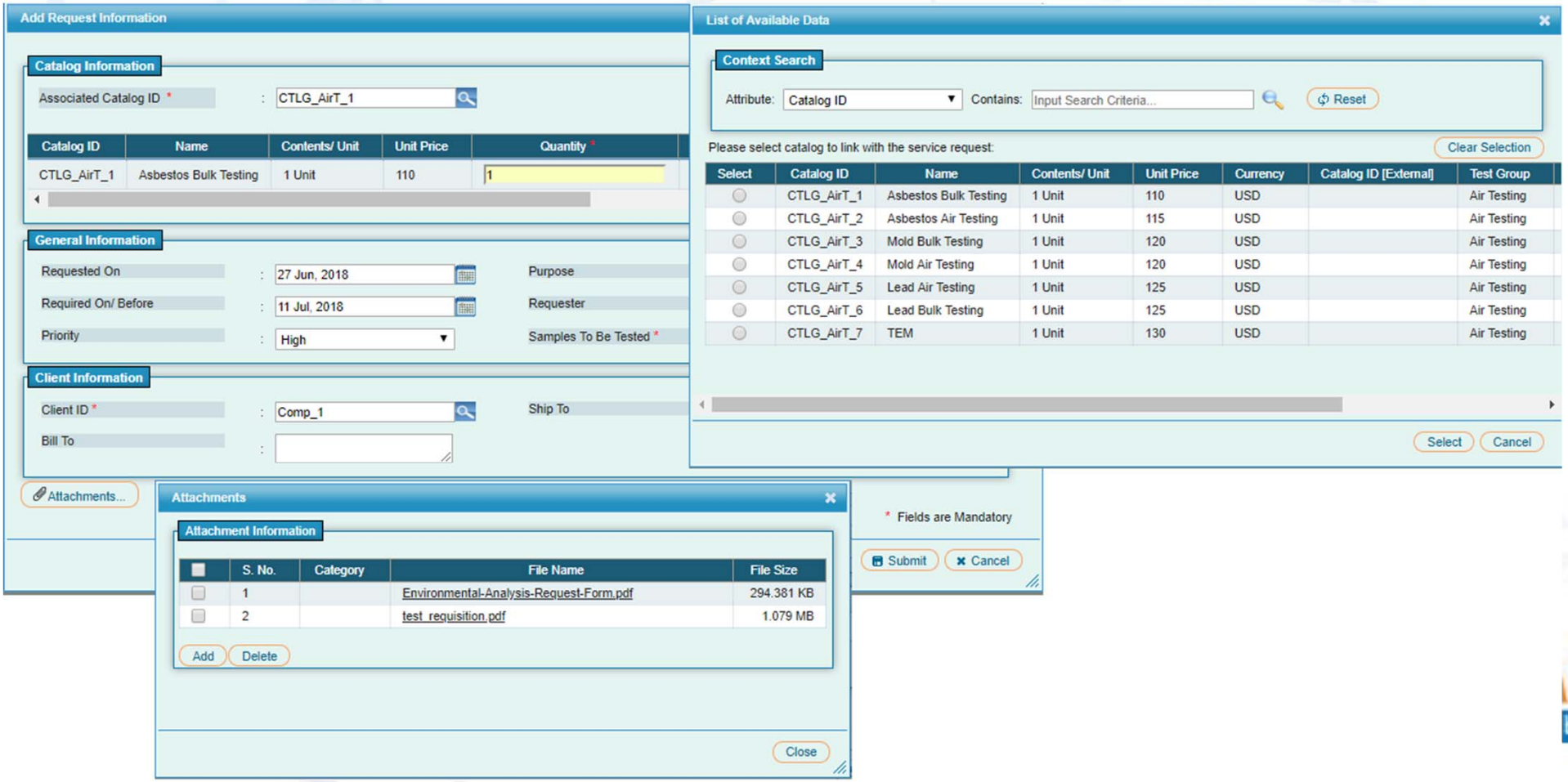
How LIMS Helps to Achieve ISO 17025 Compliance?

REVIEW OF REQUEST & CONTRACTS

- Review of client request
- Agreed statement of work to be performed
- Attachments as a evidence of request

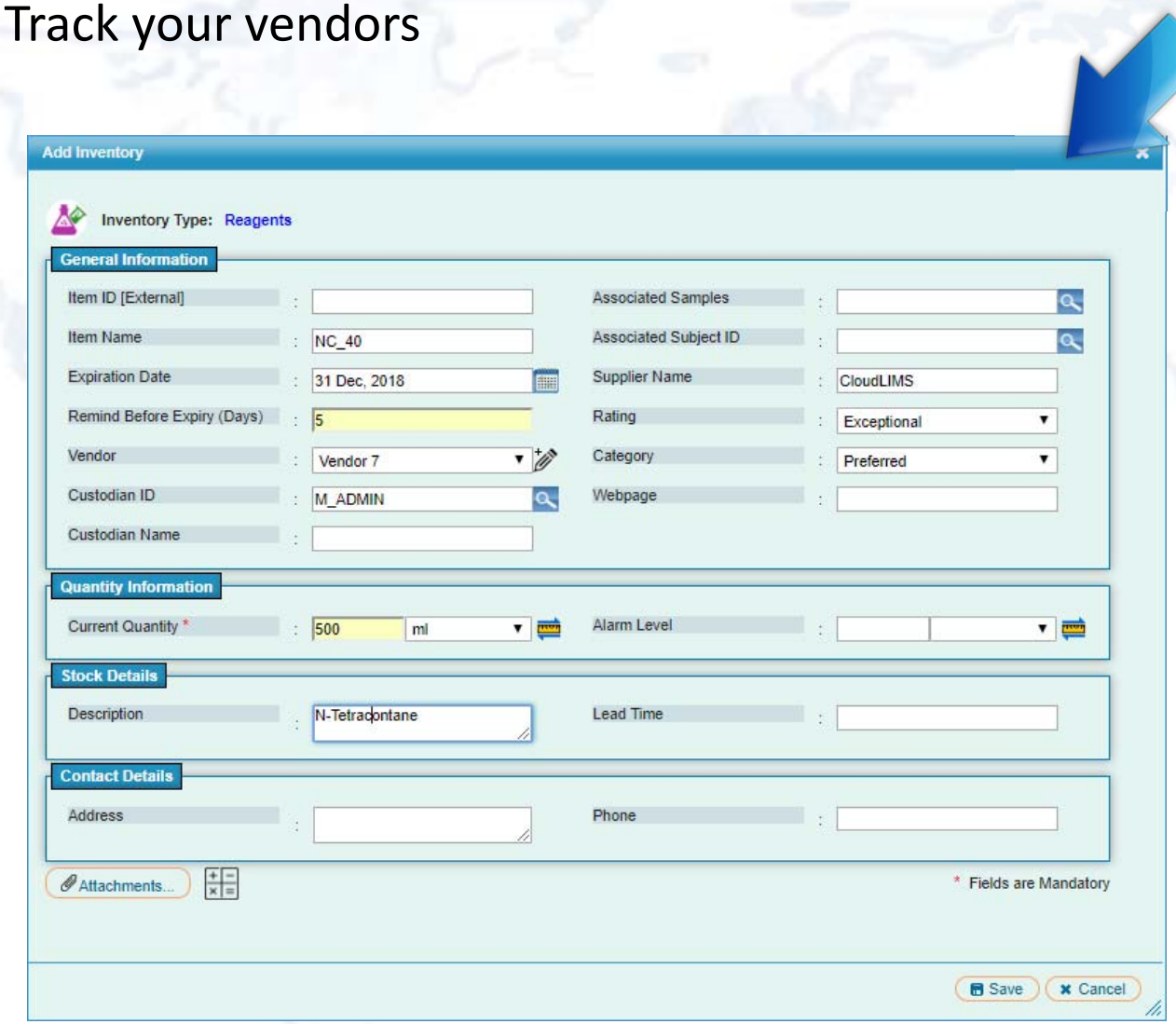
Test Request



How LIMS Helps to Achieve ISO 17025 Compliance?

PURCHASING SERVICES & SUPPLIES

- Track your inventory stocks such as standards, reagents
- Track your vendors



Lab Supplies

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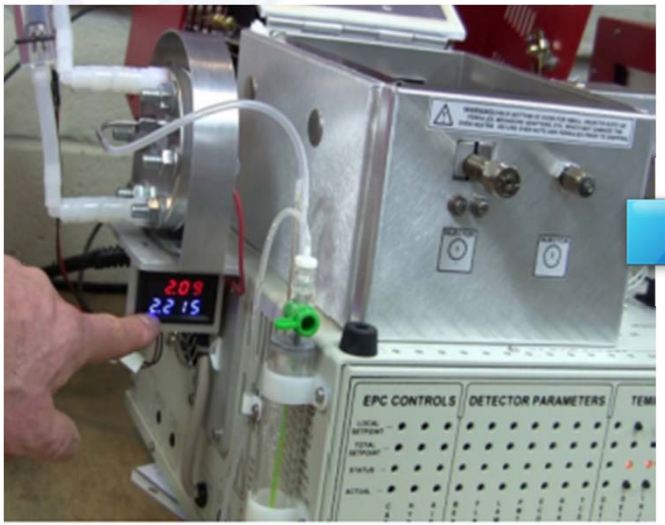
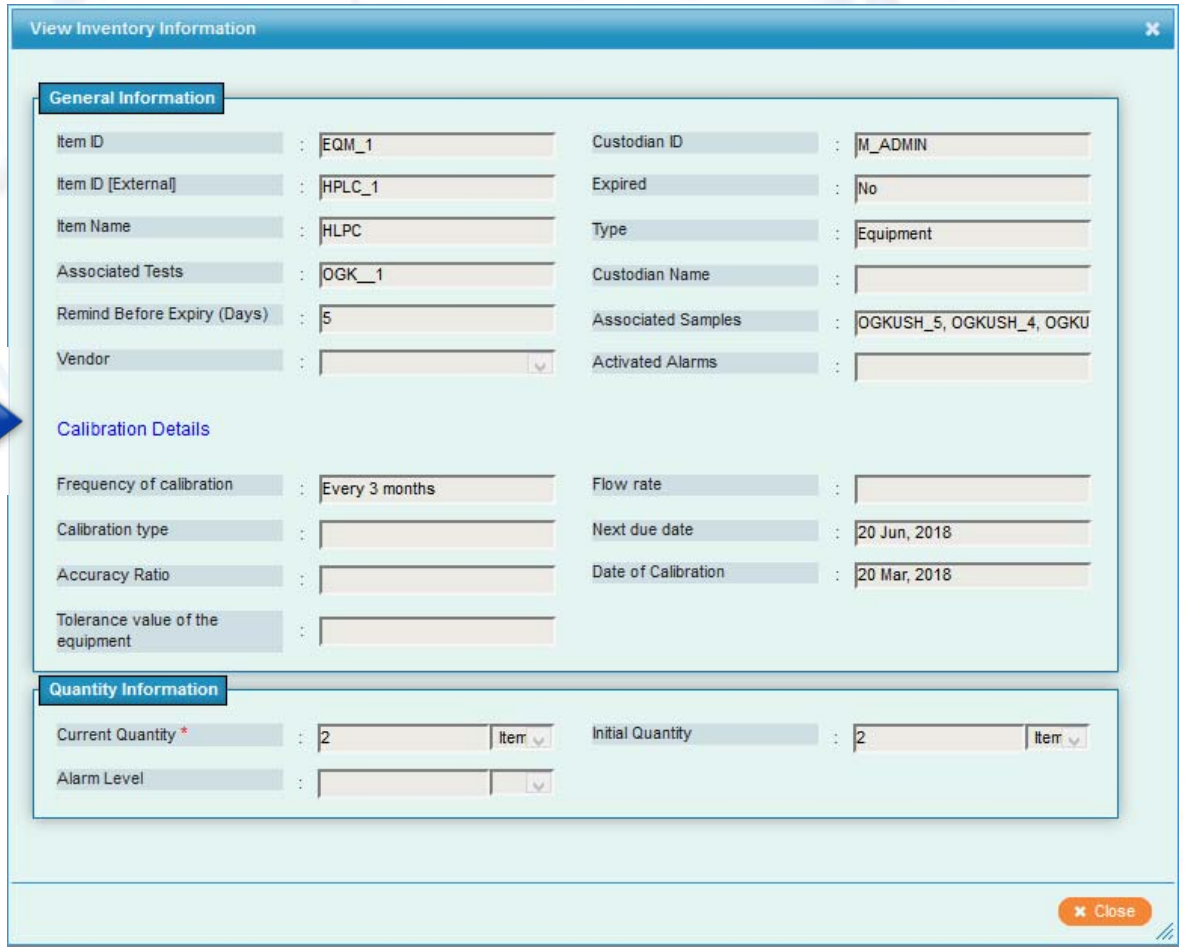
How LIMS Helps to Achieve IS0 17025 Compliance?

EQUIPMENT MAINTENANCE AND CALIBRATION PROGRAM

- Track your equipment
- Track equipment history
- Track calibration details and link to Test via equipment



Equipment Maintenance & Calibration



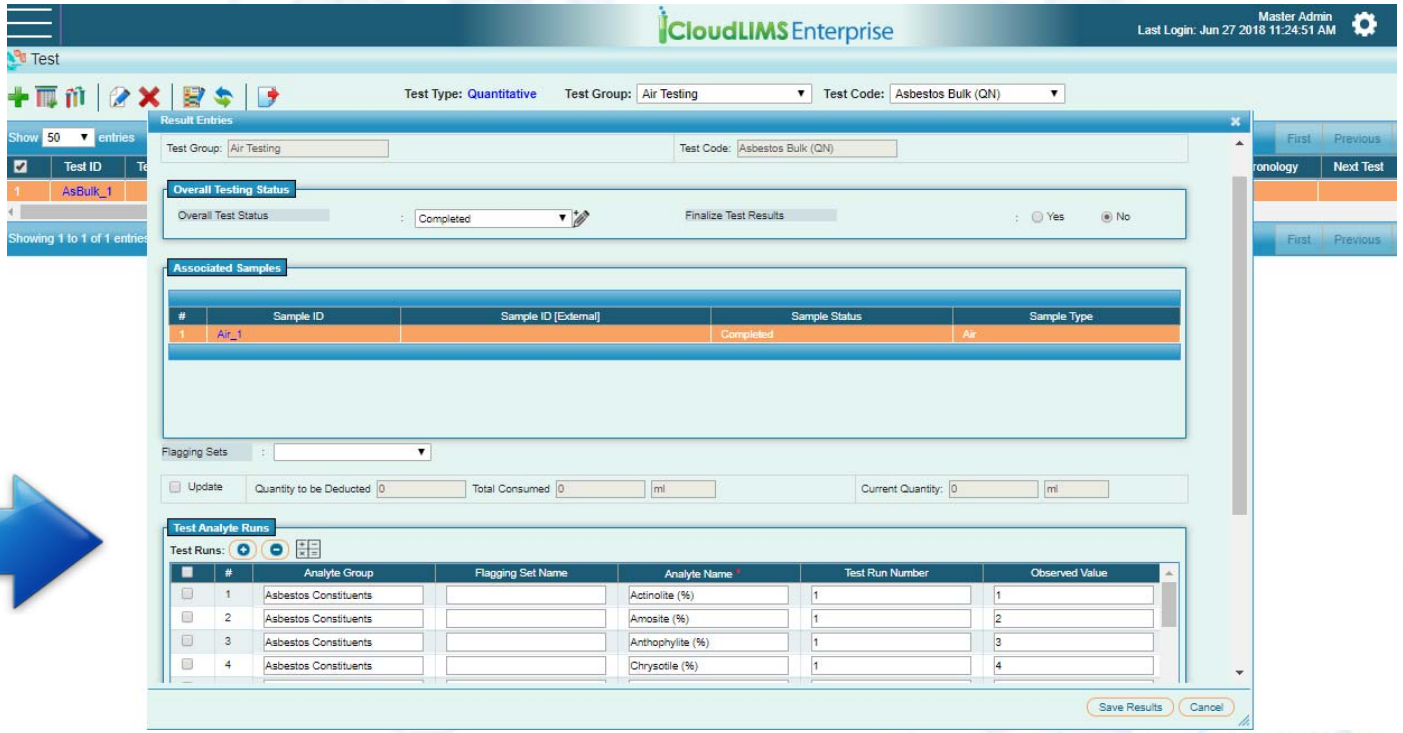
How LIMS Helps to Achieve IS0 17025 Compliance?

TEST DATA & COC

- Manage test results
- Manage the test COC to track the analyst performing test
- Validate test results

Parameter	Asbestos concentration	Temperature	Wind speed	Air humidity
Asbestos concentration (Pearson correlation)	1	−0.950**	0.670**	0.988**
Significant (two-tailed)		0.000	0.000	0.000
n	33	33	33	33

**Correlation is significant at the 0.01 level



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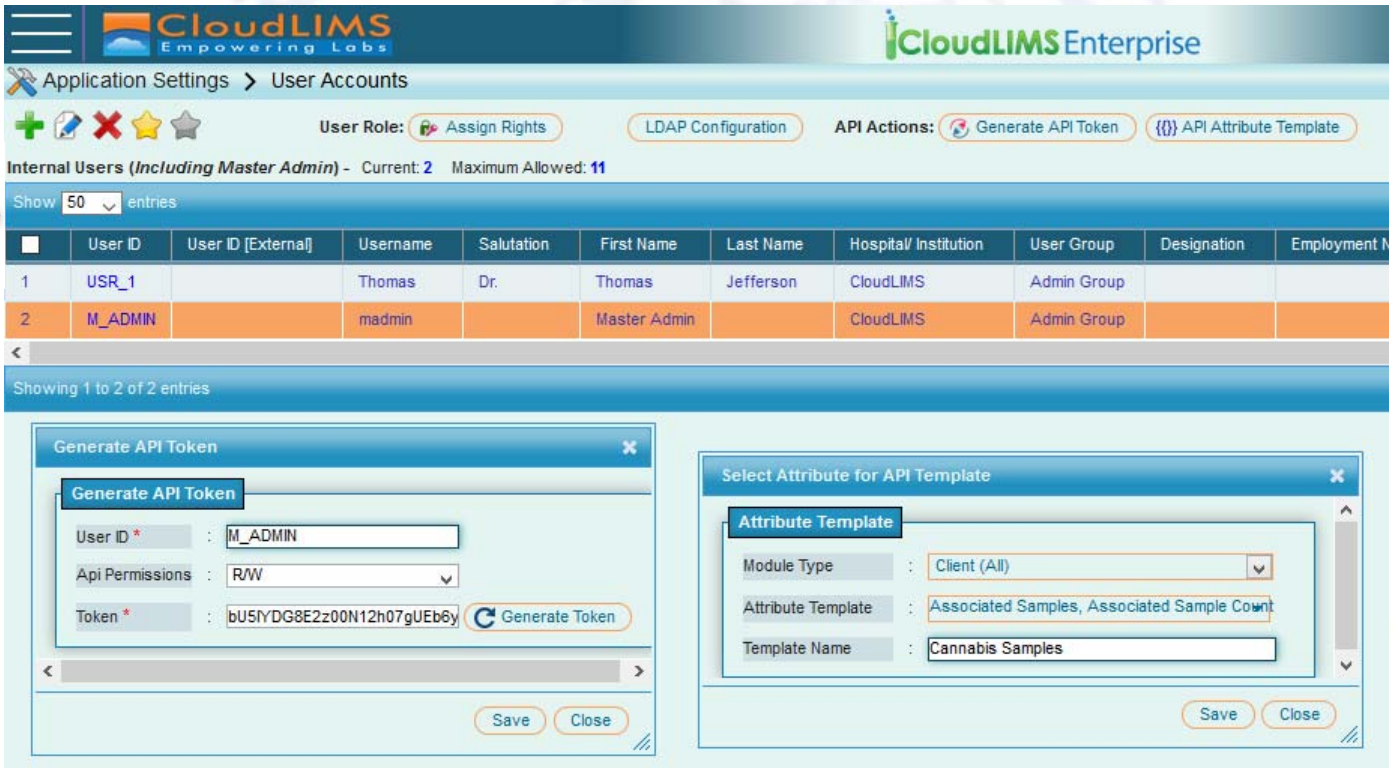
How LIMS Helps to Achieve ISO 17025 Compliance?

INSTRUMENT INTEGRATION

Integrate LIMS with Analytical Instruments for Seamless Data Transfer and Data Integrity

Instrument Integration



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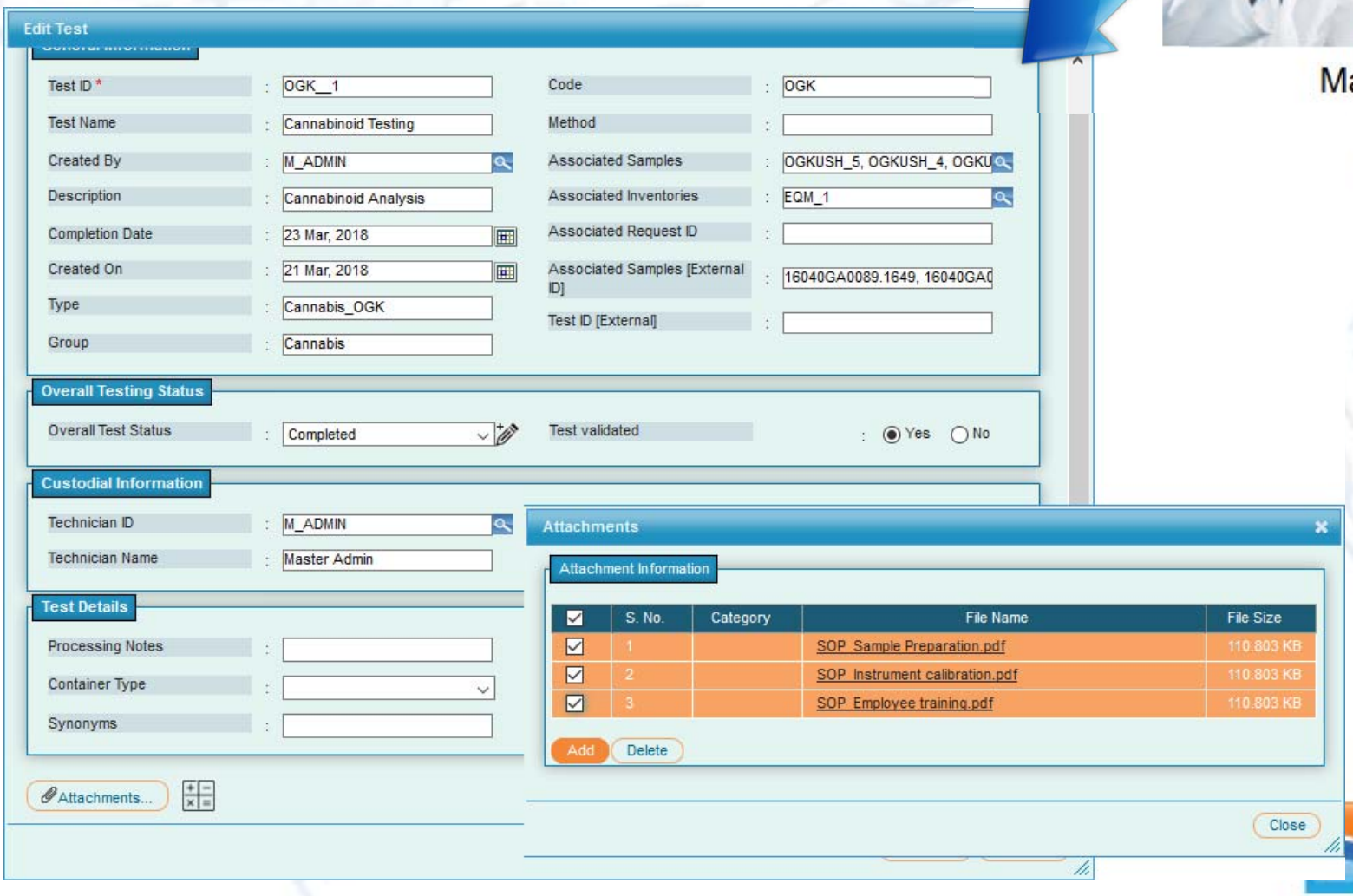
How LIMS Helps to Achieve ISO 17025 Compliance?

RECORDS MANAGEMENT

Maintain SOP Documents Electronically

Maintain SOP



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A2LA Environmental Testing Accreditation

A2LA Environmental Testing Accreditation Program serves following testing bodies to meet the needs of federal and state government agencies

- Air
- Drinking water
- Non-potable water
- Solids
- Tissue
- Asbestos
- Radiochemistry
- Environmental lead
- Microbiology

Environmental Testing

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A2LA Environmental Testing Accreditation Program Requirements

- ISO/IEC 17025 general requirements for the accreditation of testing and calibration laboratories
- Specific program requirements for all environmental testing laboratories, which include industry-specific requirements from the National Environmental Laboratory Accreditation Program (NELAC) standard
- Optional requirements for the accreditation of field work
- A2LA also offers additional requirements for laboratories performing tests in the field (i.e., at other than a permanent laboratory site)

Reference: https://www.a2la.org/accreditation/environmental-testing

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Benefits of using LIMS to Support ISO 17025

Enhance reputation, gain a competitive advantage

- Increased technical competency over other testing labs
- Enhanced the reliability and credibility of the measurement results
- Increased trust of customers in your lab

Before LIMS

After LIMS

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Benefits of using LIMS to Support ISO 17025

Improved quality and productivity

- Reduction in paper and manual process
- Management of all documents electronically

Before LIMS

After LIMS

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Benefits of using LIMS to Support ISO 17025

Reduce operational costs

- Improve operational performance of the laboratory with standardized processes using LIMS
- Speed up the reporting and auditing of quality control

Before LIMS

After LIMS

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Benefits of using LIMS to Support ISO 17025

Assuring strong commitment to quality, operational efficiency and management practices, to their prospective clients

- ISO 17025 Certification eliminates the need for independent supplier audits, because the quality, capability and expertise of the laboratory have been verified by external auditors.

Before LIMS

After LIMS

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Thank You

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