

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 ISO 17025 compliance?
- Advantages gained by laboratories by using LIMS to achieve ISO 17025
- Q & A

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

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

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>

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.

ISO 17025 Standards and Regulatory Requirements

Management and Technical Requirements for Laboratories Performing Environmental Analysis

- **Management Requirements**

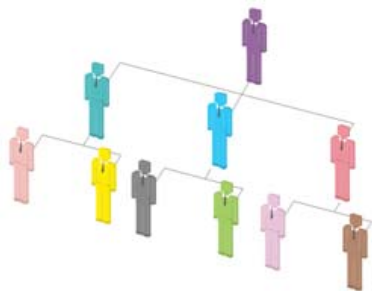
Pertain to the operation and effectiveness of the quality management system within the laboratory

- **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>

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.

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.

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

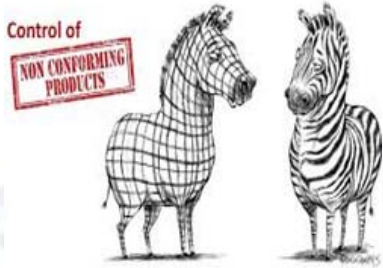
Clarify requests and get customer input for the request they placed. Collect customer feedback.



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.

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.

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.

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

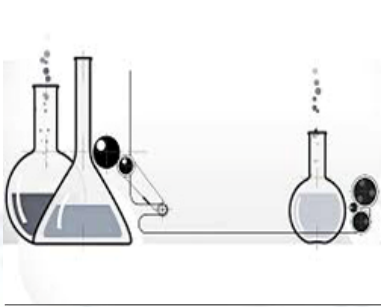
Environmental conditions should not adversely affect the required quality of tests. Equipment should operate within the manufacturer's specifications for humidity and temperature.



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.

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

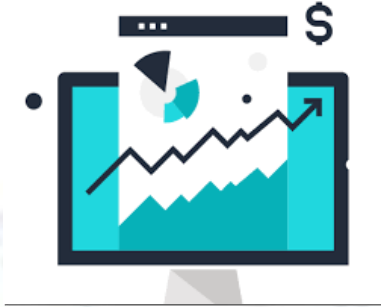
Traceability of equipment to the same standard is a prerequisite for comparability of test and calibration results.



Sampling

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

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.

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

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

The screenshot displays a LIMS software interface with the following components:

- Add Request Information Form:**
 - Catalog Information:** Associated Catalog ID * (CTLG_AirT_1).
 - General Information:** Requested On (27 Jun, 2018), Required On/ Before (11 Jul, 2018), Priority (High), Purpose, Requester, Samples To Be Tested *.
 - Client Information:** Client ID * (Comp_1), Bill To, Ship To.
 - Attachments:** Attachment Information table with columns S. No., Category, File Name, File Size. Two attachments are listed: 'Environmental-Analysis-Request-Form.pdf' (294.381 KB) and 'test_requisition.pdf' (1.079 MB). Buttons for Add, Delete, and Close are present.
- List of Available Data Table:**

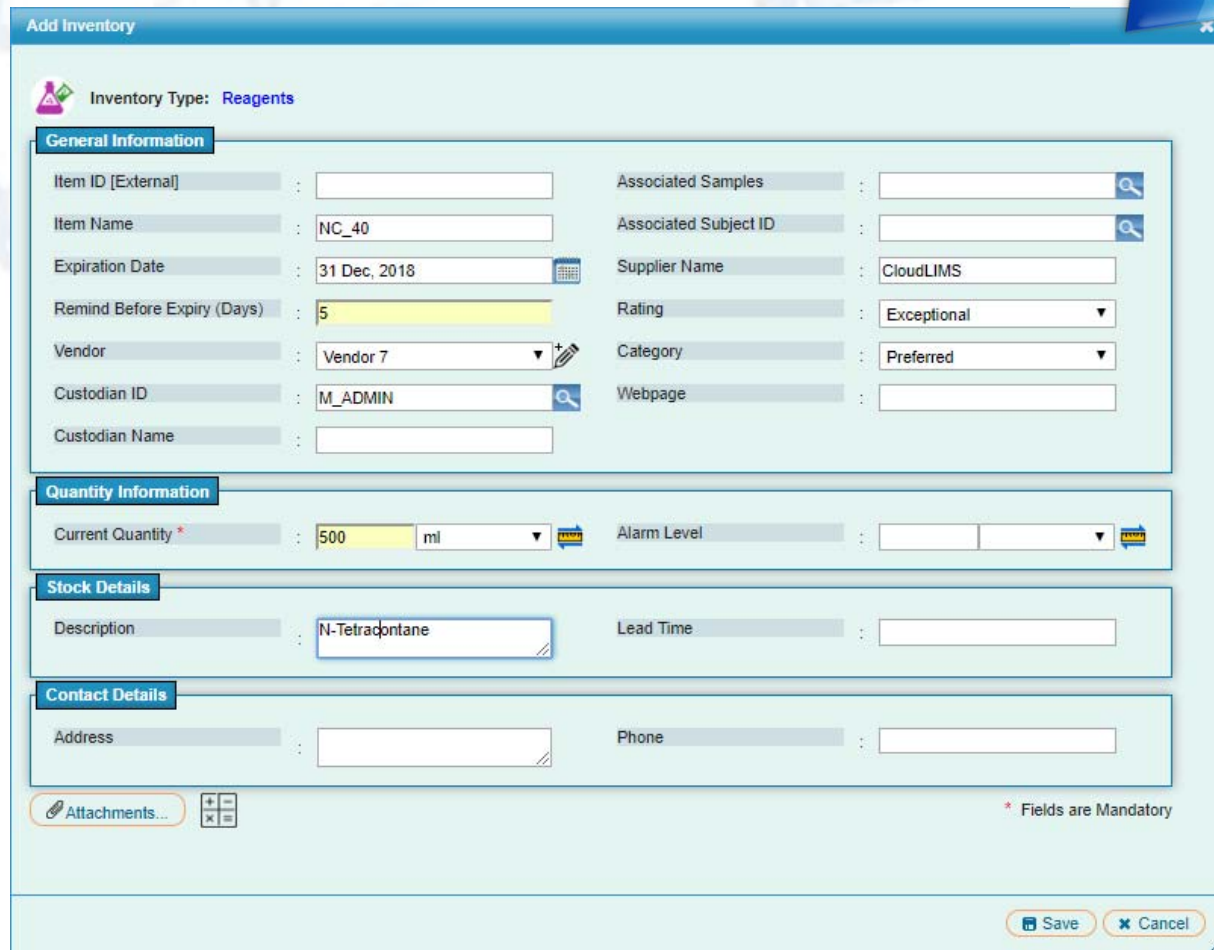
Select	Catalog ID	Name	Contents/ Unit	Unit Price	Currency	Catalog ID [External]	Test Group
<input type="radio"/>	CTLG_AirT_1	Asbestos Bulk Testing	1 Unit	110	USD		Air Testing
<input type="radio"/>	CTLG_AirT_2	Asbestos Air Testing	1 Unit	115	USD		Air Testing
<input type="radio"/>	CTLG_AirT_3	Mold Bulk Testing	1 Unit	120	USD		Air Testing
<input type="radio"/>	CTLG_AirT_4	Mold Air Testing	1 Unit	120	USD		Air Testing
<input type="radio"/>	CTLG_AirT_5	Lead Air Testing	1 Unit	125	USD		Air Testing
<input type="radio"/>	CTLG_AirT_6	Lead Bulk Testing	1 Unit	125	USD		Air Testing
<input type="radio"/>	CTLG_AirT_7	TEM	1 Unit	130	USD		Air Testing

Buttons: Submit, Cancel, Clear Selection, Select, Cancel.

How LIMS Helps to Achieve ISO 17025 Compliance?

PURCHASING SERVICES & SUPPLIES

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



Add Inventory

Inventory Type: **Reagents**

General Information

Item ID [External]	:	<input type="text"/>	Associated Samples	:	<input type="text"/>
Item Name	:	<input type="text" value="NC_40"/>	Associated Subject ID	:	<input type="text"/>
Expiration Date	:	<input type="text" value="31 Dec, 2018"/>	Supplier Name	:	<input type="text" value="CloudLIMS"/>
Remind Before Expiry (Days)	:	<input type="text" value="5"/>	Rating	:	<input type="text" value="Exceptional"/>
Vendor	:	<input type="text" value="Vendor 7"/>	Category	:	<input type="text" value="Preferred"/>
Custodian ID	:	<input type="text" value="M_ADMIN"/>	Webpage	:	<input type="text"/>
Custodian Name	:	<input type="text"/>			

Quantity Information

Current Quantity *	:	<input type="text" value="500"/> ml	Alarm Level	:	<input type="text"/>
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Stock Details

Description	:	<input type="text" value="N-Tetracontane"/>	Lead Time	:	<input type="text"/>
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Contact Details

Address	:	<input type="text"/>	Phone	:	<input type="text"/>
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Attachments...

* Fields are Mandatory



Lab Supplies

How LIMS Helps to Achieve ISO 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

View Inventory Information

General Information

Item ID	: EQM_1	Custodian ID	: M_ADMIN
Item ID [External]	: HPLC_1	Expired	: No
Item Name	: HPLC	Type	: Equipment
Associated Tests	: OGK_1	Custodian Name	:
Remind Before Expiry (Days)	: 5	Associated Samples	: OGKUSH_5, OGKUSH_4, OGKU
Vendor	:	Activated Alarms	:

Calibration Details

Frequency of calibration	: Every 3 months	Flow rate	:
Calibration type	:	Next due date	: 20 Jun, 2018
Accuracy Ratio	:	Date of Calibration	: 20 Mar, 2018
Tolerance value of the equipment	:		

Quantity Information

Current Quantity *	: 2	Item	:	Initial Quantity	: 2	Item	:
Alarm Level	:		:				:

Close

How LIMS Helps to Achieve ISO 17025 Compliance?

TEST DATA & COC

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



Test Data

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

CloudLIMS Enterprise

Master Admin
Last Login: Jun 27 2018 11:24:51 AM

Test Type: Quantitative Test Group: Air Testing Test Code: Asbestos Bulk (QN)

Result Entries

Test Group: Air Testing Test Code: Asbestos Bulk (QN)

Overall Testing Status

Overall Test Status: Completed Finalize Test Results: Yes No

Associated Samples

#	Sample ID	Sample ID [External]	Sample Status	Sample Type
1	Air_1		Completed	Air

Flagging Sets: Update Quantity to be Deducted: 0 Total Consumed: 0 ml Current Quantity: 0 ml

Test Analyte Runs

#	Analyte Group	Flagging Set Name	Analyte Name	Test Run Number	Observed Value
1	Asbestos Constituents		Actinolite (%)	1	1
2	Asbestos Constituents		Amosite (%)	1	2
3	Asbestos Constituents		Anthophyllite (%)	1	3
4	Asbestos Constituents		Chrysotile (%)	1	4

Save Results Cancel

How LIMS Helps to Achieve ISO 17025 Compliance?

INSTRUMENT INTEGRATION

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



Instrument Integration

CloudLIMS Empowering Labs **CloudLIMS Enterprise**

Application Settings > User Accounts

User Role: Assign Rights LDAP Configuration API Actions: Generate API Token API Attribute Template

Internal Users (Including Master Admin) - Current: 2 Maximum Allowed: 11

Show 50 entries

	User ID	User ID [External]	Username	Salutation	First Name	Last Name	Hospital/ Institution	User Group	Designation	Employment M
1	USR_1		Thomas	Dr.	Thomas	Jefferson	CloudLIMS	Admin Group		
2	M_ADMIN		madmin		Master Admin		CloudLIMS	Admin Group		

Showing 1 to 2 of 2 entries

Generate API Token

Generate API Token

User ID * : M_ADMIN

Api Permissions : R/W

Token * : bU5IYDG8E2z00N12h07gUEb6y [Generate Token](#)

[Save](#) [Close](#)

Select Attribute for API Template

Attribute Template

Module Type : Client (All)

Attribute Template : Associated Samples, Associated Sample Count

Template Name : Cannabis Samples

[Save](#) [Close](#)

How LIMS Helps to Achieve ISO 17025 Compliance?

RECORDS MANAGEMENT

Maintain SOP Documents Electronically



Maintain SOP

Edit Test

General Information

Test ID *	: OGK_1	Code	: OGK
Test Name	: Cannabinoid Testing	Method	:
Created By	: M_ADMIN	Associated Samples	: OGKUSH_5, OGKUSH_4, OGKUSH_3
Description	: Cannabinoid Analysis	Associated Inventories	: EQM_1
Completion Date	: 23 Mar, 2018	Associated Request ID	:
Created On	: 21 Mar, 2018	Associated Samples [External ID]	: 16040GA0089.1649, 16040GA0089.1650
Type	: Cannabis_OGK	Test ID [External]	:
Group	: Cannabis		

Overall Testing Status

Overall Test Status : Completed ☐ Test validated : ☒ Yes ☐ No

Custodial Information

Technician ID : M_ADMIN
Technician Name : Master Admin

Test Details

Processing Notes :
Container Type :
Synonyms :

Attachments

Attachment Information

<input checked="" type="checkbox"/>	S. No.	Category	File Name	File Size
<input checked="" type="checkbox"/>	1		SOP Sample Preparation.pdf	110.803 KB
<input checked="" type="checkbox"/>	2		SOP Instrument calibration.pdf	110.803 KB
<input checked="" type="checkbox"/>	3		SOP Employee training.pdf	110.803 KB

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

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>

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

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

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

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

Thank You

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