



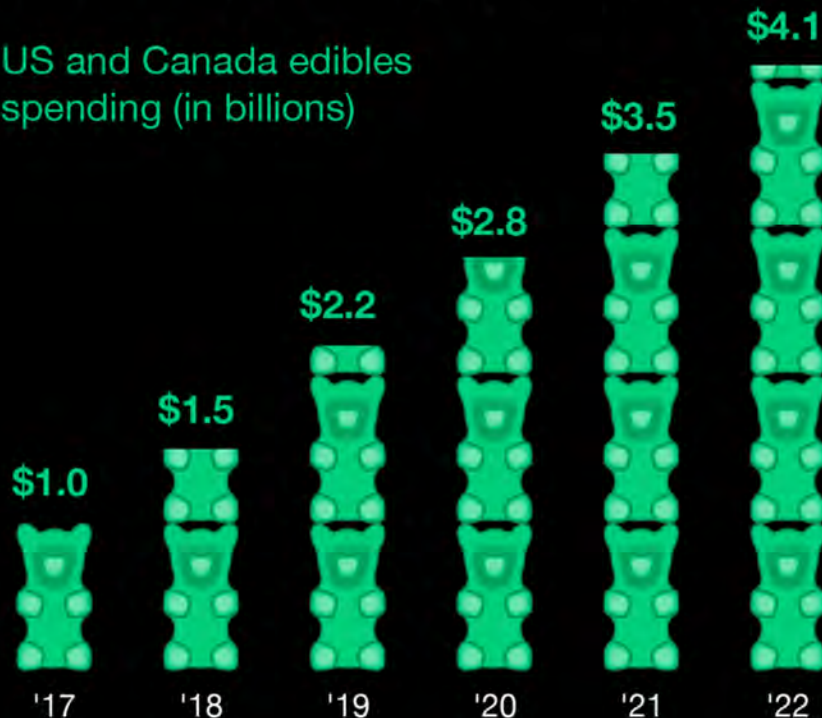
# Preparing for an ISO 17025 Audit: What to expect from a LIMS?

Arun Apte  
Chief Executive Officer, CloudLIMS.com

# Market Share: Cannabis-infused Edibles

## Edibles spending getting higher

US and Canada edibles  
spending (in billions)



SOURCE: Cannabis Intelligence Briefing

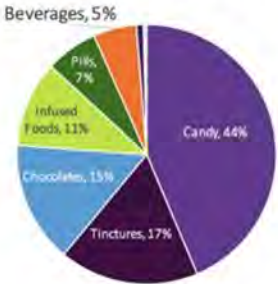
YAHOO!  
FINANCE

CloudLIMS  
Empowering Labs

# Market Share: Cannabis-infused Beverages & Edibles

Cannabis Beverages: a small, yet growing portion of Edibles

2018 YTD Tracked Edible Sales: \$612M\* (15% of total sales)



## 2022 TOTAL US

BDS Analytics' Projections

Edibles: \$3.4B  
Beverages: \$374M\*\*



\*BDS Analytics Retail Sales Tracking Data: AZ, CA, CO, OR

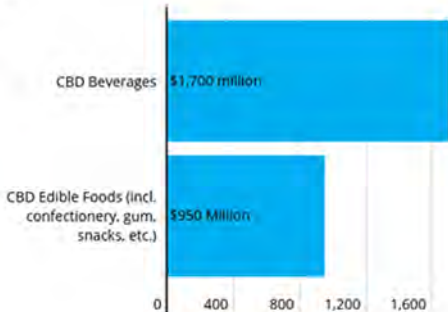
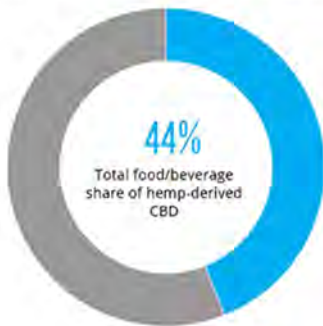
\*\*Beverage projection is preliminary and may change in the coming months with additional research and modeling

©2019 BDS Analytics



## THE U.S. EDIBLE CBD LANDSCAPE IN 2025 (PREDICTION)

Total food / beverage share of hemp-derived CBD





# AGENDA

**“ISO/IEC 17025 serves as a pillar to any global food testing laboratory to boost its market competency and credibility - a market projected to grow from \$17.0 billion in 2018 to \$24.6 billion by 2023”, per a report published by MarketsandMarkets.**

WHAT

is ISO 17025  
Accreditation?

WHY

does my lab  
need it?

HOW

do I achieve it?

**So, let's understand the nuances of the  
ISO 17025 Accreditation!**

WHAT

# What exactly is the ISO 17025 Accreditation?

- It is the single most important standard for calibration and testing laboratories around the world.
- It demonstrates that a lab operates to a global standard and has passed a rigorous examination of methods, facilities and staff.
- It also assures that the testing laboratory is capable of producing data that is accurate, traceable and reproducible.





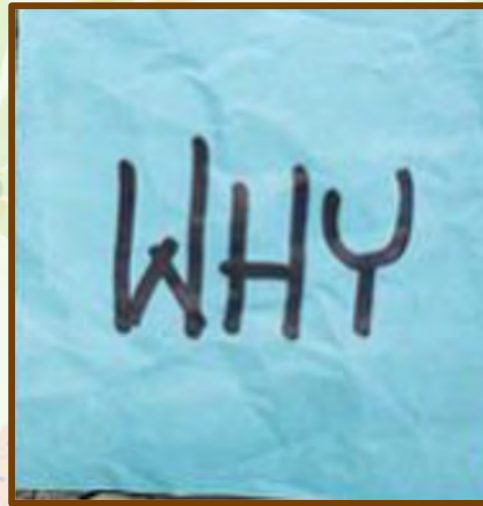
# What's New in ISO/IEC 17025:2017



## Risk Based Thinking

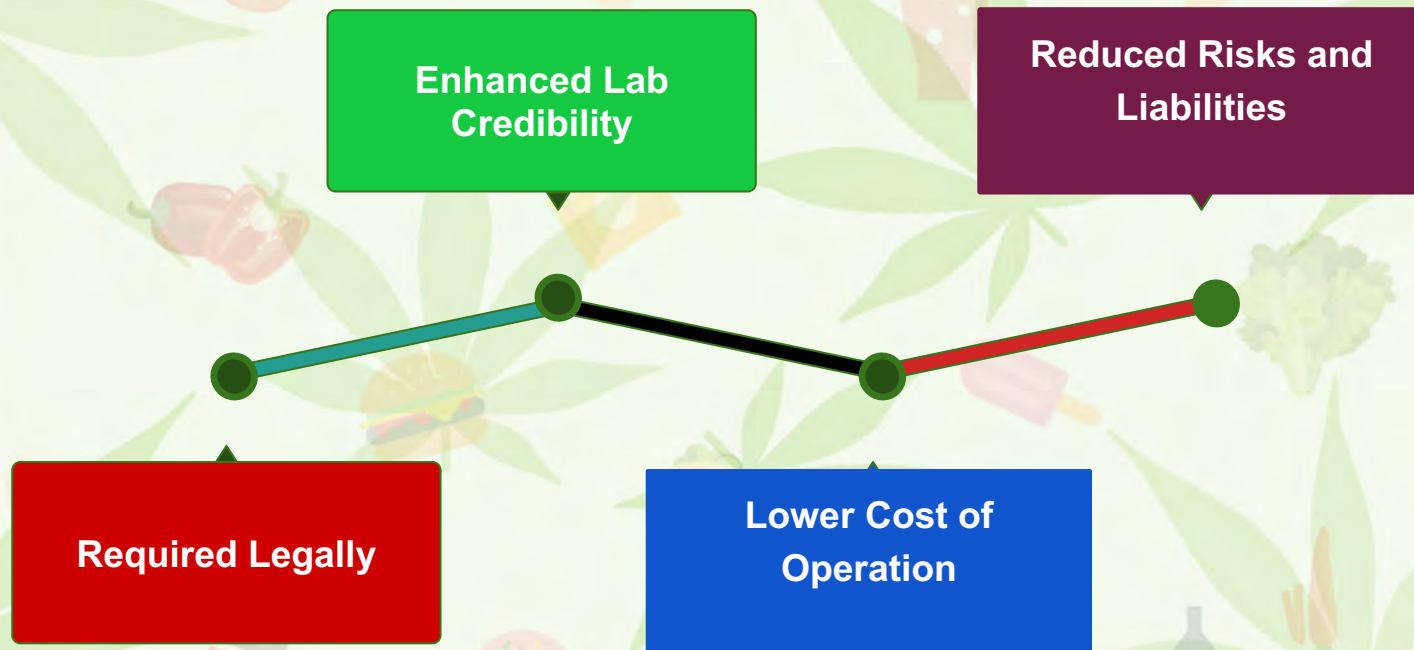


**Have you been curious to know why is ISO 17025 Accreditation so important?**





# Why IEC/ISO 17025 Accreditation?



# Why? FSMA Mandates ISO 17025 for F&B Labs

“FDA publishes a long-delayed rule detailing the use of laboratory oversight for food testing.”

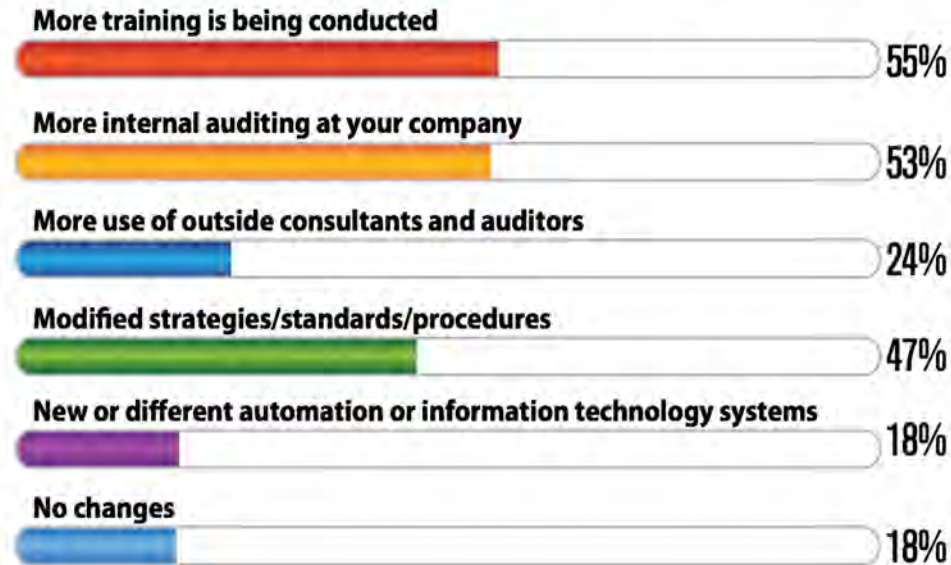
Essential elements of the Food Safety Modernization Act (FSMA) Rule:

- To demonstrate appropriate validation methods
- To pass proficiency testing
- To comply with the international standard **ISO/IEC 17025:2017**

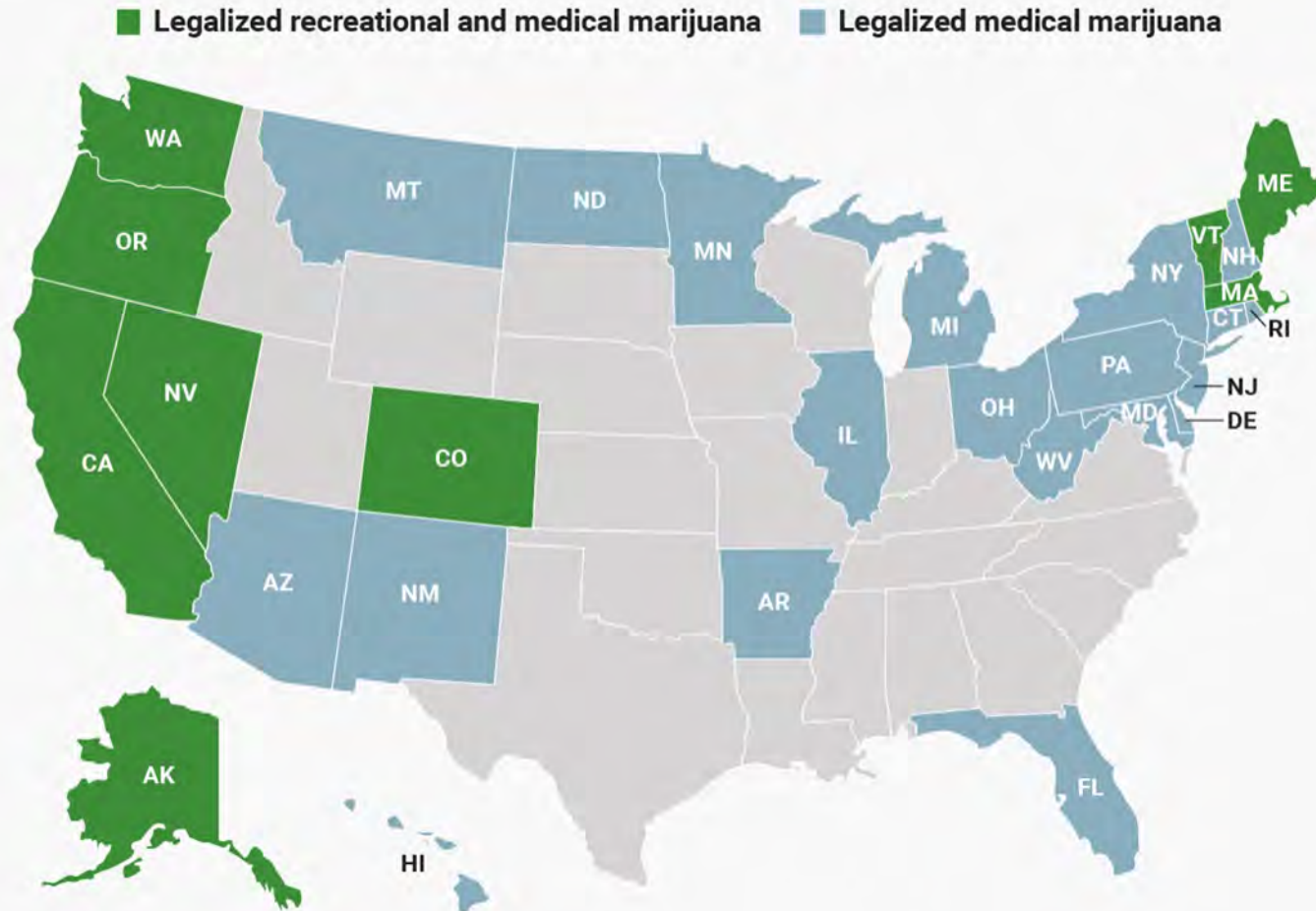


FDA FOOD SAFETY  
MODERNIZATION ACT

## Effects of FSMA on food and packaging safety



## Why? Legally Required in Many States





# Why? Lab Credibility to Manufacturers



# Why? Reduces Operational Costs



**RESULTS  
ACCURACY**



**PRODUCTIVITY**



**QUALITY**



**LOWER COSTS**

# Why? Increases Defensibility



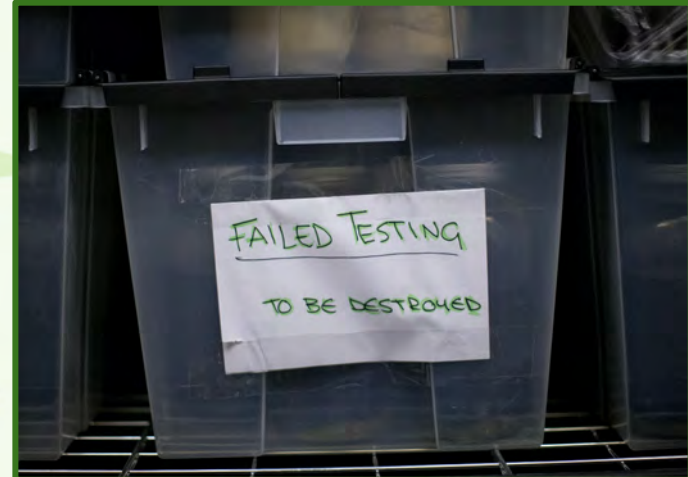


***“The story of a lab that learned the criticality  
of the ISO 17025 Accreditation the hard  
way...”***

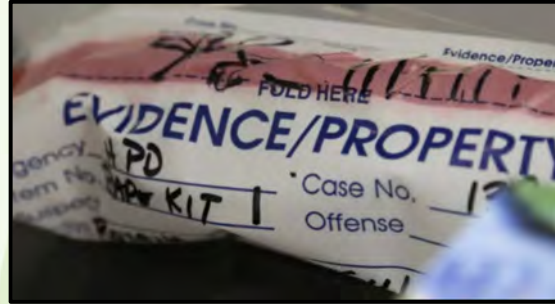
# CA-based Cannabis Lab Accidentally Lost its License!

**“A California cannabis testing lab reported incorrect pesticide test results for months.”**

- Internal audits weren't conducted
- Reports for hundreds of batches of cannabis went out to growers
- BCC made a surprise inspection at the lab
- License revoked



# What if the Lab had been 17025 accredited?



- Regular internal audits ensure the lab's operations, testing methods, results accuracy, staff training etc. are up to the mark. A LIMS facilitates such activities.
- Keeping track of the equipment's calibration and maintenance cycles/status further enables accurate testing
- Quality Assurance and Quality Control processes - measurement traceability



**So, let's walk through the process of achieving  
the ISO 17025 Accreditation for your lab!**

How

# How? ISO/IEC 17025 General Requirements

This clause includes impartiality and confidentiality, whereby the laboratory activities are to take into account impartiality and safeguard the confidentiality of all the information obtained during the execution of laboratory activities.

## Confidentiality of Information



# User Access: Secure Confidential Data

Provide full/limited/no access to different user groups to maintain confidentiality of information

The screenshot shows the CloudLIMS Enterprise interface. At the top, the header bar includes the 'CloudLIMS Enterprise' logo, the user 'Master Admin', and the last login time 'Aug 28 2019 03:36:39 PM'. Below the header, the 'Documents' section is visible, showing a tree view of folders and files. A 'User Access Permission' dialog box is open, displaying the 'Properties' for 'Folder 1'. The dialog box has a table with columns 'Users Allowed' and 'Users Permission'. The table lists four users: M\_ADMIN (Full Access), USR\_1 (No Access), USR\_2 (View Only), and USR\_3 (No Access). There are checkboxes for each user to toggle their access. Below the table, there is a checkbox for 'Apply Permissions to Sub-Folders and Documents' which is checked. A note at the bottom of the dialog box states: 'Note: Unselect the groups to remove access.' On the right side of the dialog box, there are several input fields for dates and times, including '11 Apr, 2019', '10:29:30 PM', and '02 Apr, 2019'. At the bottom right of the dialog box, there are 'Update' and 'Cancel' buttons.

CloudLIMS Enterprise

Master Admin  
Last Login: Aug 28 2019 03:36:39 PM

Documents

Expand All Collapse All Clear Selection

Folder 1

The Difference Between Digital Signatures and Electron

Folder 1.1

sentinelcannatonic.pdf

MicroBio\_img\_006.jpg

SOP

SOPv5.pdf

Folder 1

Properties

General Information

Folder ID \*

Title \*

Folder ID [External]

Type

Custodian

User Access Permission

Selected Document/Folder ID: FLDR\_1 Type: Folder

Users Allowed	Users Permission
<input checked="" type="checkbox"/> M_ADMIN	Full Access
<input type="checkbox"/> USR_1	No Access
<input checked="" type="checkbox"/> USR_2	View Only
<input type="checkbox"/> USR_3	No Access

☒ Apply Permissions to Sub-Folders and Documents

Note: Unselect the groups to remove access.

Update Cancel

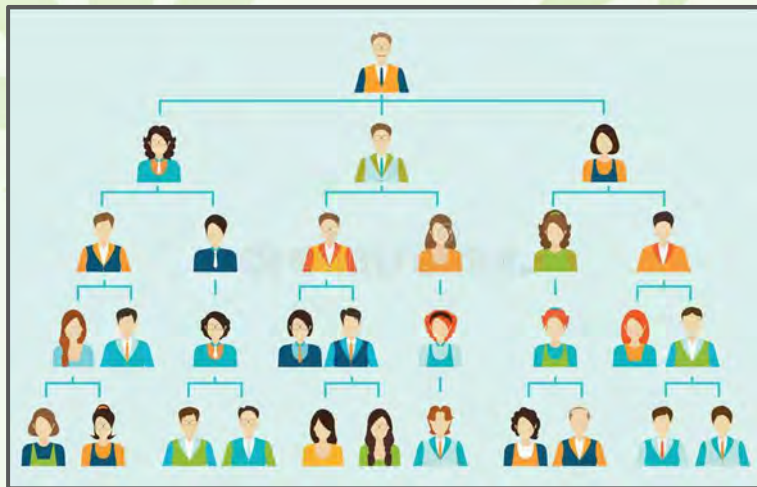
\* Fields are Mar



# How? ISO/IEC 17025 Structural Requirements

This clause represents the legal entity that defines and documents the range of laboratory activities. Additionally, it identifies the management, the laboratory activities, the organization and management structure, the responsibility, authority and interrelationships of all personnel.

## Organizational Structure



# Organizational Structure: Role Based Permission Level to Staff

Users can be granted/revoked accesses to/from various functionalities based on their designation in the organization's hierarchy

The screenshot displays the 'Assign Rights' window in the CloudLIMS Enterprise application. The window is titled 'Assign Rights' and shows a table of permissions for various user roles. The roles are: Manager, PI, Technician, SM, Lab Incharge, and Visitor. The permissions are organized into two main categories: 'Subjects' and 'Samples'.

**Subjects Permissions:**

Functionality	Manager	PI	Technician	SM	Lab Incharge	Visitor
View	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Create	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Edit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Delete	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Restricted Attributes View	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Restricted Attachments View	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Samples Permissions:**

Functionality	Manager	PI	Technician	SM	Lab Incharge	Visitor
View	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Create	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Edit	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Delete Permanently	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cart	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Transfer	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dispose	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Restore	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Update Barcode	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Restricted Attributes View	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Restricted Attachments View	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The interface includes a sidebar with navigation icons, a top navigation bar with 'Application Settings > User Accounts', and a bottom status bar with 'Update' and 'Cancel' buttons. The top right corner shows the user 'Master Admin' and the last login time 'Aug 26 2019 03:07:25 PM'.

# How? ISO/IEC 17025 Resource Requirements

This clause highlights the importance of the provision of the resources such as the personnel, facilities and environmental conditions, equipment, metrological traceability, and the externally provided products and services used to support the operation of the laboratory.

## Personnel



## Purchasing Services & Supplies





# Personnel: Staff & Training

Manage staff and training records and mark their competency

CloudLIMS Enterprise

Master Admin  
Last Login: Jan 25 2019 04:44:54 PM

Training

Training Type: chromatography

Show 50 entries

First

Previous

1

Next

	Training ID	Title	Training ID [External]	Trainer	Training Status	Associated Staff	Total Associated Staff	Venue	Type	View Competency	Training Start Date	Training End Date
1	TR_CHR_1	Ion exchange chromatography	Chroma_1	T.P Singh	Scheduled	<a href="#">View</a>	1	Grapes Room	chromatography	<a href="#">Link</a>	10 Feb, 2019	15 Feb, 2019
2	TR_CHR_2	Paper chromatography	Chroma_2	G.P.S Raghava	Conducted	<a href="#">View</a>	5	Conf- Hall-1	chromatography	<a href="#">Link</a>	20 Oct, 2018	29 Oct, 2018
3	TR_CHR_3	Gas chromatography	Chroma_3	Dr. Bhatnagar	In progress	<a href="#">View</a>	28	Apple Room	chromatography	<a href="#">Link</a>	11 Feb, 2019	29 Feb, 2019
4	TR_CHR_4	Thin-layer chromatography	Chroma_4	Andrew Lynn	Conducted	<a href="#">View</a>	44	Auditorium	chromatography	<a href="#">Link</a>	17 Aug, 2018	17 Sep, 2018

View Competency

Training ID: TR\_CHR\_2

Training ID [External]: Chroma\_2

Training Type: Chromatography

Title: Paper Chromatography

Competency Results for TR\_CHR\_2

Participants

	#	Staff ID	First Name	Last Name	Attended	Certified	Competent
<input type="checkbox"/>	1	Stf_1	Maxim	Gilbert	Yes	Yes	Yes
<input type="checkbox"/>	2	Stf_2	Sania	Fernandis	Yes	Yes	Yes
<input type="checkbox"/>	3	Stf_7	Christina	Paul	Yes	No	No
<input type="checkbox"/>	4	Stf_13	Tim	Yan	No	No	No
<input type="checkbox"/>	5	Stf_15	Jack	lynn	Yes	Yes	Yes

S



# Purchasing Services & Supplies

Accurate barcode labeling of reagents and maintaining their stocks

The screenshot displays the CloudLIMS Enterprise Lab Inventory interface. At the top, the header includes the CloudLIMS Enterprise logo, the user 'Master Admin', and the last login time 'Jul 02 2019 05:55:58 PM'. Below the header, the 'Lab Inventory' section is active, showing a filter for 'Inventory Type: Reagents'. A table lists four reagents: Methanol, Ethanol, Acetone, and Hydrochloric acid. The table columns include Item ID, Item ID [External], Item Name, Barcode ID, Barcode Image, Expiration Date, Vendor, Current Quantity, Current Quantity-Unit, Alarm Level, Custodian ID, Expired status, Type, Custodian Name, and Associated Samples Count. The Hydrochloric acid entry is highlighted in red, indicating an expiration date of 31 Mar, 2019. The interface also features a sidebar with various icons and a bottom status bar showing 'Showing 1 to 4 of 4 entries'.

CloudLIMS Enterprise

Master Admin  
Last Login: Jul 02 2019 05:55:58 PM

Lab Inventory

Inventory Type: Reagents

Show 50 entries

	Item ID	Item ID [External]	Item Name	Barcode ID	Barcode Image	Expiration Date	Vendor	Current Quantity	Current Quantity-Unit	Alarm Level	Custodian ID	Expired	Type	Custodian Name	Associated Samples Count
1	Reagents_4	Methanol		Reagents_4				10	units		M_ADMIN	No	Reagents		1
2	Reagents_3	Ethanol		Reagents_3				5	ml		M_ADMIN	No	Reagents		
3	Reagents_2	Acetone		Reagents_2				0	ml		M_ADMIN	No	Reagents		1
4	Reagents_1	Hydrochloric acid				31 Mar, 2019		0	ml		M_ADMIN	No	Reagents		

Showing 1 to 4 of 4 entries

# Purchasing Services & Supplies

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

**Result Entries**

Test ID:  Test Type:  Test Group:  Test Code:

**Associated Inventories**

#	Inventory	Reagents	Quantity	Unit
1	Reagents_2	Reagents	<input type="text" value="0"/>	<input type="text" value="ml"/>
2	Reagents_3	Reagents	<input type="text" value="0"/>	<input type="text" value="ml"/>
3	Reagents_4	Reagents	<input type="text" value="2"/>	<input type="text" value="units"/>

**Associated Samples**

#	Sample ID	Sample ID [External]	Sample Status	Sample Type	Associated Analytes	QC Sample?
1	EDBL_13	EDBL_1	Under Testing	Edibles	<input type="text" value="cbd* cbda* cbg* cbn* thca* thc"/>	

Flagging Sets:

**Test Results For Sample ID: EDBL\_13**

☐ Update Quantity to be Deducted:  Total Consumed:  ml Current Quantity:  ml

**Test Analyte Runs**

Test Runs:

#	Analyte Group	Analyte Name *	lod	loq	Amount (%)	Amount (g)
1	cannabinoids	cbd	<input type="text" value="0.03"/>	<input type="text" value="0.04"/>	<input type="text" value="3"/>	Error
2	cannabinoids	cbda	<input type="text" value="0.1"/>	<input type="text" value="0.1"/>	<input type="text" value="10"/>	Error
3	cannabinoids	cbg	<input type="text" value="0.08"/>	<input type="text" value="0.01"/>	<input type="text" value="8"/>	Error
4	cannabinoids	cbn	<input type="text" value="0.06"/>	<input type="text" value="0.07"/>	<input type="text" value="6"/>	Error

**Turnaround Time Status**

Sample Testing Start Date:  Turnaround Time Threshold:

Save Results Cancel

# How? ISO/IEC 17025 Process Requirements

**Review of Requests,  
Tenders, & Contracts**



**Equipment**



**Reporting of Results**



**Test and Calibration Methods  
& Method Validation**



**Measurement  
Traceability**



**Ensuring the Quality of Test  
and Calibration Results**





# Review of Requests, Tenders, & Contracts

All details related to a service requested by a client can be seen along with the ability to accept, reject and assign the task pertaining to a request

The screenshot displays the CloudLIMS Enterprise web application. At the top, the header includes the logo, user name (Master Admin), and last login time (Aug 26 2019 03:07:25 PM). The main navigation bar shows 'Home', 'Dashboard', 'Tasks', 'Alerts (31)', and 'Audit Trail'. The 'Tasks' tab is active, showing a list of 18 tasks. Each task row includes an 'Action' column with 'Accept | Reject' buttons, a 'Task ID' (e.g., TSK\_49), a status icon (green checkmark), and an 'Assign' button. A modal window titled 'Add Request Information' is open, showing details for a request. The modal is divided into sections: General Information, Client Information, Catalog Information, and Cannabinoid Test. The 'General Information' section shows 'Requested On' (30 Aug, 2019), 'Required On/ Before' (24 Sep, 2019), 'Priority' (High), 'Purpose' (Analgesic Formulation), and 'Requester' (Sam). The 'Client Information' section shows 'Client ID' (GROWER\_5), 'Ship To' (28610 Highway 290 East, Suite F, Cypress, TX 77455, United States), and 'Bill To' (same address). The 'Catalog Information' section shows 'Associated Catalog ID' (CTLG\_HEMP\_TESTING\_7). The 'Cannabinoid Test' section shows 'Catalog ID [External]' (CANNA\_001), 'Catalog Price' (50), 'Quantity' (2), 'Currency' (USD), and 'Total Price' (100). Below this is a table with columns: #, Test Group, Test Code, Analytes, Description, and Associate Samples. The table has one row: 1, Cannablis Testing, Cannabinoids, Link, Cannabinoid Profiling, and EDBL\_1. The modal also has an 'Attachments...' section and 'Submit' and 'Cancel' buttons. On the right side of the modal, there is a 'Status Changed' dropdown menu with a list of users (SR\_2\_M\_ADMIN, M\_ADMIN) and a 'Last' button.

CloudLIMS Enterprise

Master Admin  
Last Login: Aug 26 2019 03:07:25 PM

Home

Dashboard Tasks Alerts (31) Audit Trail

From To Show Delete Assign Request for Processing

Show 50 entries

Action	Task ID	Status	Task As
Accept   Reject	TSK_49	✓	Assign 1
Accept   Reject	TSK_48	✓	Assign 1
Accept   Reject	TSK_47	✓	Assign 1
Accept   Reject	TSK_46	✓	Assign 1
Accept   Reject	TSK_45	✓	Assign 1
Accept   Reject	TSK_44	✓	Assign 1
Accept   Reject	TSK_24	✓	Assign 1
Accept   Reject	TSK_43	✓	Assign 1
Accept   Reject	TSK_42	✓	Assign 1
Accept   Reject	TSK_35	✓	Assign 1
Accept   Reject	TSK_41	✓	Assign 1
Accept   Reject	TSK_33	✓	Assign 1
Accept   Reject	TSK_40	✓	Assign 1
Accept   Reject	TSK_38	✓	Assign 1
Accept   Reject	TSK_38	✓	Assign 1
Accept   Reject	TSK_11	✓	Assign 1
Accept   Reject	TSK_37	✓	Assign 1
Accept   Reject	TSK_36	✓	Assign 1

**Add Request Information**

**General Information**

Requested On : 30 Aug, 2019 Purpose : Analgesic Formulation  
Required On/ Before : 24 Sep, 2019 Requester : Sam  
Priority : High

**Client Information**

Client ID \* : GROWER\_5 Ship To : 28610 Highway 290 East, Suite F, Cypress, TX 77455, United States  
Bill To : 28610 Highway 290 East, Suite F, Cypress, TX 77455, United States

**Catalog Information**

Associated Catalog ID \* : CTLG\_HEMP\_TESTING\_7

**Cannabinoid Test**

Catalog ID [External] : CANNA\_001 Catalog ID : CTLG\_HEMP\_TESTING\_7 Currency : USD  
Catalog Price : 50 Quantity \* : 2 Total Price : 100

#	Test Group	Test Code	Analytes	Description	Associate Samples
1	Cannablis Testing	Cannabinoids	Link	Cannabinoid Profiling	EDBL_1

Attachments...

\* Fields are Mandatory

Submit Cancel

Status Changed

SR\_2\_M\_ADMIN  
SR\_2\_M\_ADMIN  
SR\_2\_M\_ADMIN  
SR\_2\_M\_ADMIN  
SR\_2\_M\_ADMIN  
SR\_2\_M\_ADMIN  
M\_ADMIN  
SR\_2\_M\_ADMIN  
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M\_ADMIN

loudLIMS  
empowering Labs



# Validate Test Results

Configure a test validation process, send multiple results for validation, select a verifier, track the validation status, thereby assuring the final test results

The screenshot displays the CloudLIMS Enterprise web application interface. At the top, the header includes the 'CloudLIMS Enterprise' logo, user information for 'Master Admin' (Last Login: Jul 03 2019 11:40:47 AM), and navigation icons for settings, notifications, and search. The main content area is titled 'Test' and features a toolbar with various icons. Below the toolbar, a table lists test entries with columns for Test ID, Test Name, Technician ID, Type, and Sample. The table shows three entries, all for 'Cannabis Testing\_Cannabinoids' performed by 'M\_ADMIN'. A 'Validate Test Results' dialog box is open in the center, containing a 'Test Results Validation' section with 'Test Validation Status' set to 'Approved' and 'Validation Remarks' set to 'Tests approved'. The dialog also has 'Save' and 'Cancel' buttons. In the background, a table with columns 'Name', 'Chain of Custody', 'Associated Samples', 'Test Chronology', 'Next Test', and 'Prev' is visible, showing associated samples EDBL\_1, EDBL\_2, and EDBL\_4.

CloudLIMS Enterprise

Master Admin  
Last Login: Jul 03 2019 11:40:47 AM

Test

Test Group: Cannabis Testing Test Code: Cannabinoids

Show 50 entries

Test ID	Test Name	Technician ID	Type	Sample
1	CANN_2	M_ADMIN	Cannabis Testing_Cannabinoids	EDBL_1
2	CANN_1	M_ADMIN	Cannabis Testing_Cannabinoids	EDBL_2
3	CANN_1	M_ADMIN	Cannabis Testing_Cannabinoids	EDBL_3

Showing 1 to 3 of 3 entries

**Validate Test Results**

**Test Results Validation**

Test Validation Status : ☒ Approved ☐ Rejected

Validation Remarks : Tests approved

Save Cancel

Name	Chain of Custody	Associated Samples	Test Chronology	Next Test	Prev
n		EDBL_1	<a href="#">Link</a>		
n		EDBL_2	<a href="#">Link</a>		
n		EDBL_4	<a href="#">Link</a>		