How LIMS Facilitates ISO 17025 Certification in Food Testing Labs

confience

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INTRODUCTION

ISO 17025 is the international standard for all organizations performing laboratory activities. It sets out requirements for competence, impartiality, and consistent operation, ensuring the accuracy and reliability of testing and calibration results.

There are many reasons food testing laboratories seek ISO 17025 certification, including to gain a competitive advantage, reduce operational costs, proactively manage risks and/or meet regulatory compliance goals. Obtaining ISO 17025 certification tells prospective clients that the laboratory has a strong commitment to quality, boosts the laboratory's reputation and demonstrates a focus on operational efficiency and management practices. Proof of 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. Many ISO certified laboratories purchase products (raw materials, supplies, and software) and services from other ISO certified firms, which minimizes the need for additional work to qualify the vendor or the products.

Assuring consistent product quality and safety is an ongoing concern in food and beverage manufacturing. Recent, large-scale recalls have increased public concerns about food safety. Without relevant data and process management, manufacturers run the risk of erroneous or unqualified information and the potential for product quality issues that necessitate a recall. To reduce these potential risks, food manufacturers need reliable technologies that facilitate compliance with ISO 17025 and support monitoring for potential contaminants. The latest ISO 17025 standards incorporate the critical points for food safety that are currently part of the Hazard Analysis and Critical Control Points (HACCP) methodology.

Gathering, organizing, and controlling the data that is generated by food testing laboratories can be challenging. Implementing a Laboratory Information Management System (LIMS) can provide the solution to many of these challenges, while facilitating compliance with ISO 17025 regulatory requirements. By incorporating a LIMS into the daily workflow, manufacturers are able to standardize their processes across all facilities and laboratories, and to build Quality Control into a single integrated system.

HOW A LIMS SUPPORTS ISO 17025 COMPLIANCE

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

Sample Handling and Acceptance

Laboratories are required to have a sampling plan and method that addresses all processes a sample is subjected to while in the laboratory's possession. The sampling method includes the selection of samples or sites, sampling plan, and preparation and treatment of samples from a substance, material or product. The laboratory should have procedures specific to the transportation, receipt, handling, protection, storage, retention and disposal/return of test or calibration items.

Laboratories must retain all records of sampling data that form part of the testing or calibration. These records must include unique sample ID, sampling method(s), date/time of sampling, descriptive data (number, amount, name), personnel ID, equipment ID, sample

sites/locations (where relevant), and all deviations, additions to or exclusions from the sampling method and sampling plan.

These features support compliance with *ISO 17025:2017 Section 7.3 – Sampling and Section 7.4 Handling of Test or Calibration Items.*

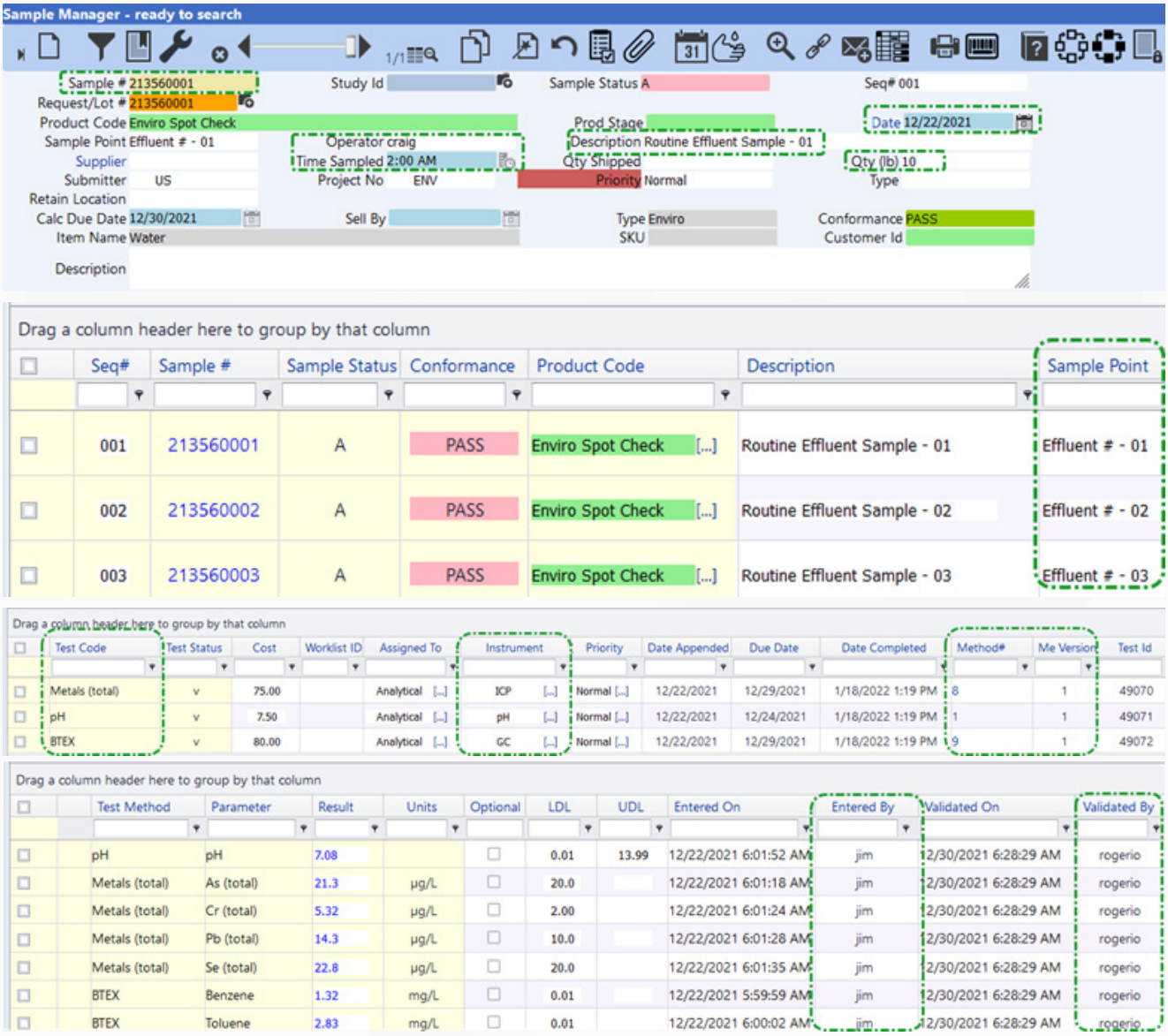

Figure 1 - LIMS Sampling Details

In addition, food laboratories are required to document and maintain essential information associated with the analytical analysis, such as incubator and refrigerator temperature charts, and instrument run files/logs. Data from logbooks, including the unique sample identifier, date/time of the analysis, holding time and any time critical steps included in the analysis such as sample preparations, extractions, or incubations, also must be tracked. A LIMS supports these requirements by capturing and tracking data throughout the sample's active lifetime.

Seq#	Sample #	Sample Status	Conformance	Product Code	Retain Location	Storage Temp (°C)
004	213560004	A	PASS	Enviro Spot Check [...]	Refrigerator # 01[...]	4
003	213560003	A	PASS	Enviro Spot Check [...]	Refrigerator # 01[...]	4
002	213560002	A	PASS	Enviro Spot Check [...]	Refrigerator # 01[...]	4
001	213560001	A	PASS	Enviro Spot Check [...]	Refrigerator # 01[...]	4
005	213560005	A	PASS	Enviro Spot Check [...]	Refrigerator # 01[...]	4

Figure 2 - Temperature Logging

Environmental monitoring and Quality Control (QC) samples are critical to the manufacturing process, and a LIMS can be utilized to link these items to the final (end) product, providing complete traceability. Continuous Control Points (CCPs) can be set up within the LIMS for specific locations, including facilities, storage rooms, and other laboratories. Related samples can then be added to the test schedule and are then associated in the LIMS to the defined specifications for a given CCP. In many instances, the LIMS will support adding these CCPs to a Visual Collection Diagram (Figure 3), allowing users to quickly identify issues in a specific location.

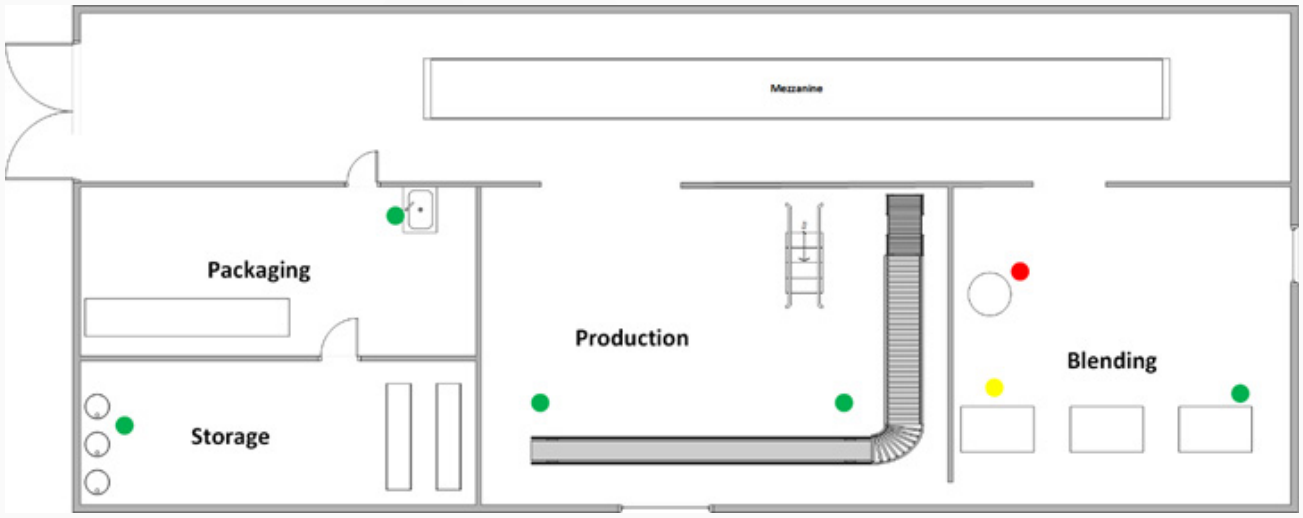

Figure 3 - Visual Collection Diagram

As an added enhancement, the LIMS can be integrated with a wireless environmental monitoring solution that collects temperature, light, humidity, and pressure readings, and transmits these to a web portal. This information is then imported into the LIMS. If there is an issue with the readings falling outside of range, an email can automatically be spawned, or a text message sent to a cell phone to alert the responsible party. This helps to ensure valuable inventory, products and samples are not compromised and further supports ISO 17025 regulatory compliance.

Figure 4 – LIMS Enhancement - Wireless Environmental Monitoring Solution

These features support compliance with *ISO 17025:2017 Section 6.3 Facilities and Environmental Conditions.*

Equipment Maintenance and Calibration

ISO 17025 requires verification that the instrument conforms to specified requirements and is capable of achieving the measurement accuracy or/or measurement uncertainty required to produce valid results. Equipment must be calibrated both routinely and any time the accuracy or uncertainty affects the validity of the result.

Records of equipment and any calibration and maintenance performed, must be maintained. This includes evidence that the instrument conforms with specific requirements, calibration/ maintenance dates, results of calibration, schedule of future calibrations and any accompanying documentation.

A LIMS provides the ability to capture this information in a single system, rather than on multiple paper forms, and offers integrated functionality that allows users to define and closely monitor each of the instruments that are used for analyzing samples. A LIMS supports scheduling of maintenance and calibration, attachment of associated documents, and a record that is easily accessible and traceable (Figure 5). It can also be configured to prevent an instrument that is out of calibration from being utilized, or to require calibration each time the instrument is used.

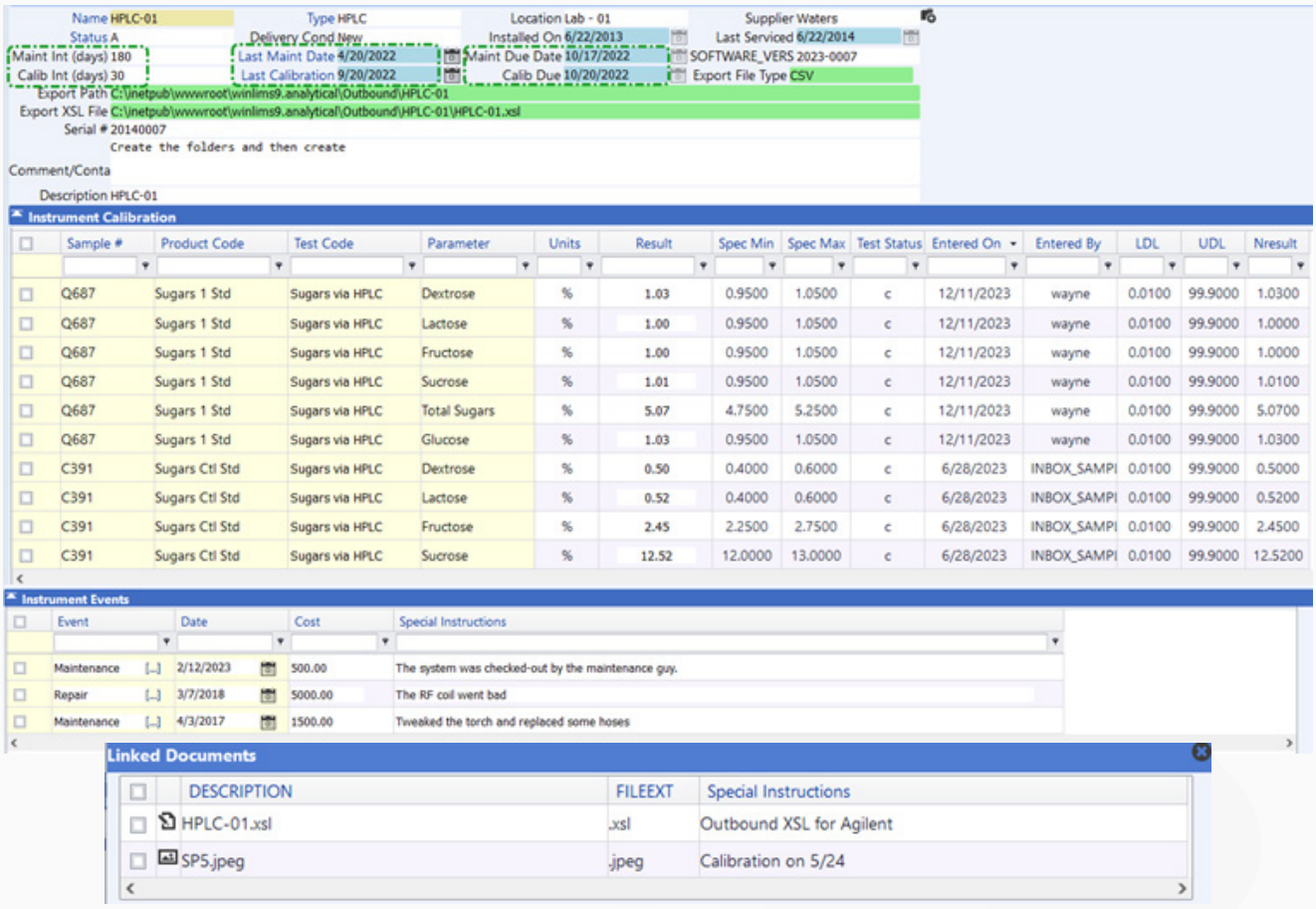

Figure 5 – Instrument Maintenance and Calibration Record in LIMS

In addition, users can record results from all calibration and Quality Control (QC) samples that were run on each instrument to monitor both usage and performance. QC Charts (Figure 6) can be generated to provide a clear, graphic illustration of instrument performance, detecting trends allowing the lab to proactively address and prevent instrument-related issues. All results data and assigned analysis methods are referenced to the instrument, for full traceability.

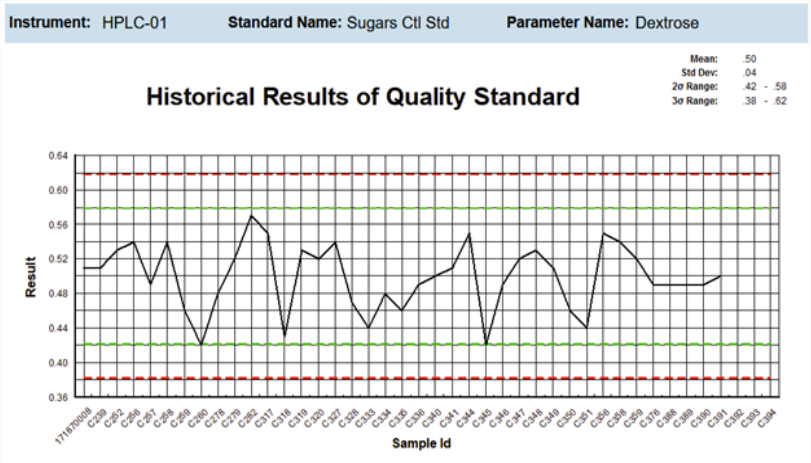

Figure 6 - Instrument QC Chart

These features support compliance with *ISO 17025:2017 Section 6.4 Equipment (Maintenance and Calibration) and Section 6.5 Metrological Traceability.*

Document Management

Laboratories are required to manage and maintain standard operating procedures (SOPs) that accurately reflect all phases of current laboratory activities such as assessing data integrity, taking corrective actions, handling customer complaints, managing all test methods, and managing all documents pertaining to quality.

A LIMS can act as a repository for all the required documentation, reducing the need for paper in the laboratory, ensuring that the most current version of the document is accessible to laboratory staff and allowing documents to be versioned for historical reference.

This includes linking SOPs (Figure 7) to an analytical method so analysts can view the SOP as they are doing the procedure, helping to ensure that no steps are omitted. Analysts only have access to the most current version of the document, thereby preventing the use of outdated procedures.

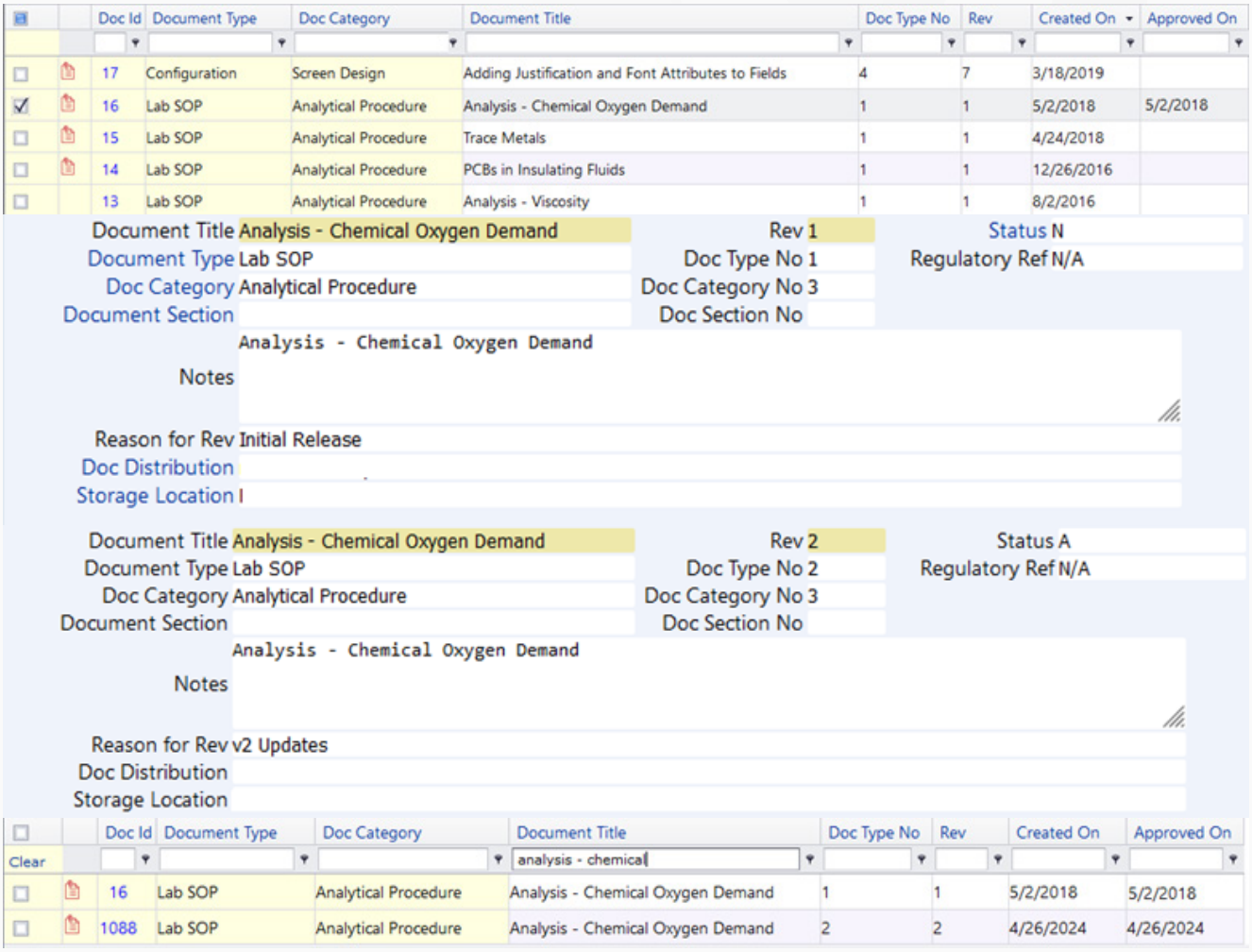

Figure 7 – Tracking and Versioning SOPs for Analytical Methods in a LIMS

Administrative Records, Demonstration of Capability

All laboratory personnel that may influence laboratory activities must be competent to perform the required work and follow the appropriate processes. Laboratories must document this competence to include employee education, qualification, training, technical knowledge, skills and expertise. Competency must be demonstrated for the use of every Method an analyst is responsible for conducting.

Laboratories are required to manage and maintain the following information on an analyst working in the laboratory:

A LIMS enhances the ability to track and manage this information, allowing for attachments to personnel records and creation of laboratory defined trainings. Defined training may include the training type/category, topic (description), instructor(s), method reference (if applicable), whether it is required training, scoring range and recurrence requirements.

Personnel training records may contain the course/training name, trainer, date started/completed, score, date of certification, date of expiration, etc.

Additionally, a LIMS can be configured to limit the methods the analyst may perform, or to prevent the analyst from entering results for a specific method if their certification has expired or they do not have documented training for that method. A LIMS also allows for automated alerts when an analyst is due for recertification, minimizing the risk that the training will expire.

Maintaining this information in a single location provides laboratories with a single source of

information that may be used towards generating a fully defensible record for laboratory audits, and/or production of documentation during adverse outcomes or for legal purposes.

These features support compliance with *ISO 17025:2017 Section 6.2 Personnel.*

Reference Standards and Materials

Because the references and standards that laboratories use in their analytical measurements affect the correctness of the result, laboratories must have a system and procedures to manage and track the calibration and testing of their reference standards. Documentation that standards were calibrated by a body that can prove traceability must be provided. Although most standards are purchased from companies that specialize in the creation of reference standards, there are some standards that laboratories create internally that can also be traced and tracked in the LIMS. The LIMS can be used to ensure that only suitable products and services are utilized within the laboratory.

Most LIMS allow for the creation, receipt, tracking, and management of all products (Figure 8 and Figure 9) and inventory (Figure 10 and Figure 11) items. This documents the reference material identification, lot numbers, expiration date, supplier, and vendor, and links the standard to all tests in which it was used.

Receip	Chemical Name	Supplier Name	Lot#	Expiration Date	Received On	Units	Amt Received	Amount Accepte	Received By	Storage Locat
1	Concentrated Hydrochloric Acid	Fischer Scientific	151201.01	11/30/2015	1/18/2016	mL	5000.00	1000.00	jeff	Storage Shelf# 01
2	Concentrated Nitric Acid	Fischer Scientific	151202.01	11/29/2016	11/22/2015	mL	5000.00	5000.00	jeff	Storage Shelf# 01
3	DI Water	Fischer Scientific	151202.02	12/31/2015	11/30/2015	mL	10000.00	10000.00	matt	Storage Shelf# 02
4	Acetic Acid Buffered Solution	EM Sciences	151215.01	1/28/2016	12/22/2015	mL	5000.00	4660.00	jim	Storage Shelf# 03
5	Concentrated Sulfuric Acid	Spectrum Chemical	151212.01	11/29/2016	12/28/2015	mL	10000.00	10000.00	jeff	Storage Shelf# 01
6	Concentrated Hydrochloric Acid	Spectrum Chemical	151204.01	1/1/2017	12/15/2015	mL	5000.00	5000.00	jeff	Storage Shelf# 02
7	Acetonitrile	EM Sciences	151221.01	1/2/2017	1/27/2016	mL	10000.00	9530.00	craig	Storage Shelf# 02
8	Glacial Acetic Acid	Sigma-Aldrich	160101.01	12/31/2015	1/6/2016	mL	5000.00	5000.00	jim	Storage Shelf# 02
9	Dibasic Potassium Phosphate	EM Sciences	160912.01	1/19/2017	9/18/2016	mL	500.00	500.00	matt	Storage Shelf# 02
10	1N Potassium Hydroxide	Sigma-Aldrich	160105.01	1/2/2018	1/7/2016	mL	5000.00	4865.00	wayne	Storage Shelf# 03

Figure 8 - Product Tracking

Figure 9 - Product Detail

Item	Current Qty	Reorder Qty	Item I	Inventory Units
Sulfuric Acid	2450.00	500.00	1122	mL
Alpha-Copaene	2375.00	500.00	50	mL
Potassium Phosphate Dibasic	2000.00	500.00	92	mg
Petri Film	2000.00	100.00	1125	
Potassium Chloride	1999.75	500.00	1117	mg
Ammonium Chloride	1924.75	500.00	95	mg
Acetone	1900.00	1000.00	1134	mL
Magnesium sulfate heptahydrate	1600.00	500.00	96	mg
1-Octenylsuccinic Anhydride	1500.00	500.00	66	mL
Alpha-Pinene	1455.00	500.00	6	mL

Figure 10 - Inventory Tracking

Item Acetonitrile		CAS Number 75-05-8	Molecular Wt 41.05
Physical State Liquid	Melting Point	Boiling Point 81.60	Flash Point 2.00
Solubility	Specific Gravity 7810.00	pH	Odor Sweetish
Current Qty 22732.50	Inventory Units mL	Reorder Qty 500.00	Status Active
HMIS Fire	HMIS Health	HMIS Reactivity	HMIS Protection
NFPA Flammability	NFPA Health	NFPA Reactivity	NFPA Hazard
Formula C2H3N			
MSDS URL https://fscimage.fishersci.com/msds/00170.htm			

Additional Info

Retention (days)

Figure 11 - Inventory Detail

DESCRIPTION	FILEEXT	Special Instructions
COA-ACE-M11LA1-10 210727-21309.pdf	.pdf	

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Figure 12 – Laboratory Reference COA

A LIMS can also tie a test and methods with the associated instruments, products, and inventory items and associate all related QC and results for full traceability.

These features support compliance with *ISO 17025:2017 Section 6.5 Metrological Traceability and Section 6.6 Externally Provided Products and Services.*

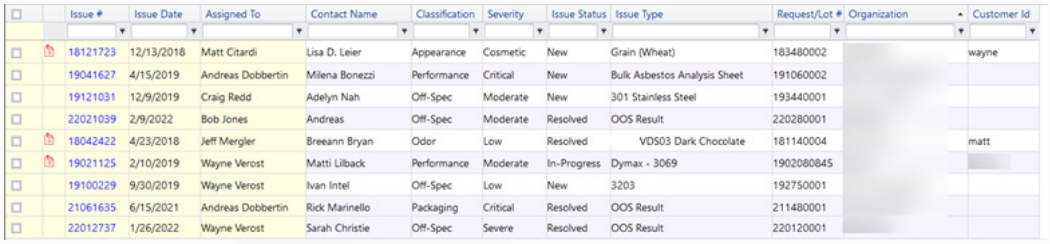
Corrective and Preventative Actions

A significant concern for food manufacturers is addressing quality issues, ideally before they become problems. It is imperative for the laboratory to document any non-conforming work and develop preventative or corrective action plans (CAPAs) to minimize the risk of recurrence.

When a non-conformity occurs, laboratories are required to take action to control and correct it, as well as to address any associated consequences. They must evaluate the need for action through review and analysis, determination of causation, and identification of any similar non-conformities or instances where they could occur.

CAPA records can be created to track the activities involved with initiation, investigation, and resolution of such actions. A CAPA can be assigned to a customer/vendor or contact, and associated with a sample, request/lot#, batch, product, or parameter or another item. Supporting documentation may also be attached to facilitate the CAPA process.

A LIMS allows laboratories to create and track the activities involved with the initiation, investigation and resolution of these items, and to monitor the effectiveness of the actions and/or identify any similar issues in the future. These records are then retained as evidence.



Issue #	Issue Date	Assigned To	Contact Name	Classification	Severity	Issue Status	Issue Type	Request/Lot #	Organization	Customer Id
18121723	12/13/2018	Matt Citardi	Lisa D. Leier	Appearance	Cosmetic	New	Grain (Wheat)	183480002		wayne
19041627	4/15/2019	Andreas Dobbertin	Milena Bonezzi	Performance	Critical	New	Bulk Asbestos Analysis Sheet	191060002		
19121031	12/9/2019	Craig Redd	Adelyn Nah	Off-Spec	Moderate	New	301 Stainless Steel	193440001		
22021039	2/9/2022	Bob Jones	Andreas	Off-Spec	Moderate	Resolved	OOS Result	220280001		
18042422	4/23/2018	Jeff Mergler	Breeann Bryan	Odor	Low	Resolved	VDS03 Dark Chocolate	181140004		matt
19021125	2/10/2019	Wayne Verost	Matti Lilback	Performance	Moderate	In-Progress	Dymax - 3069	1902080845		
19100229	9/30/2019	Wayne Verost	Ivan Intel	Off-Spec	Low	New	3203	192750001		
21061635	6/15/2021	Andreas Dobbertin	Rick Marinello	Packaging	Critical	Resolved	OOS Result	211480001		
22012737	1/26/2022	Wayne Verost	Sarah Christie	Off-Spec	Severe	Resolved	OOS Result	220120001		

Figure 13 - CAPA Tracking

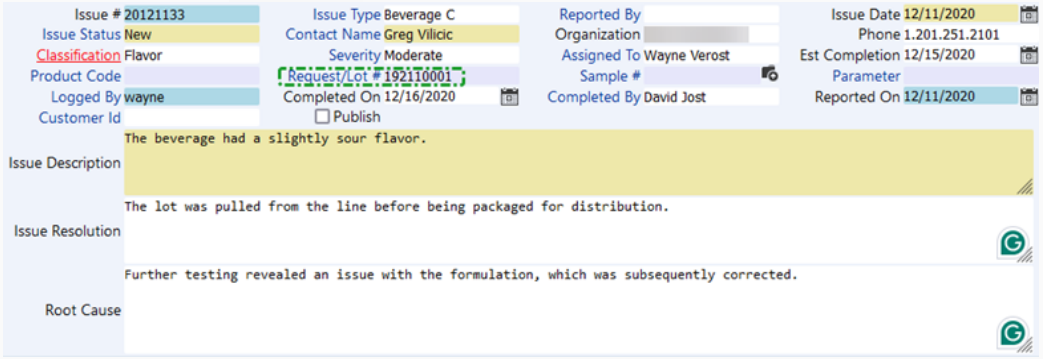


Figure 14 - CAPA Detail

These features support compliance with *ISO 17025:2017 Section 8.7 Corrective Actions.*

Data Integrity

Another area where LIMS can provide significant benefits is around data integrity, the degree to which a collection of data is complete, consistent and accurate throughout the data lifecycle. Data integrity is directly tied to the principals of ALCOA +.

- Attributable — Who performed an action & when?
- Legible — Can you read the data file & written entries throughout the life cycle?
- Contemporaneous — Documented at the time of the activity.
- Original — Original record or a certified copy.
- Accurate — No errors or editing without documented amendments.
  - Complete – All data including any test, repeat or reanalysis performed.
  - Consistent – The data's sequence of events should be in the expected sequence of operations and appropriately date or time stamped to demonstrate the data are contemporaneous.
  - Enduring – Recorded in laboratory notebooks or validated systems.
  - Available – Can be accessed for review and audit or inspection over the lifetime of the record.

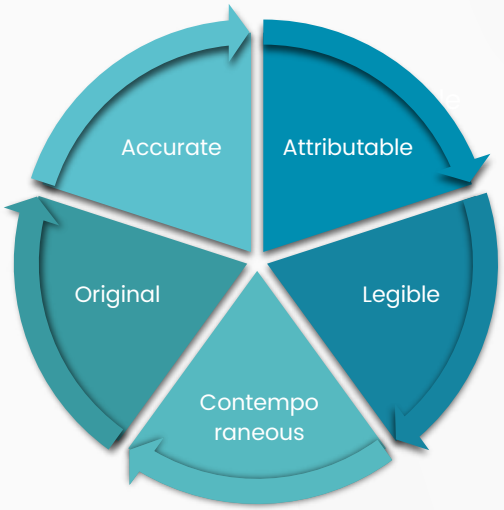


Figure 15 - ALCOA Principles

A LIMS ensures that only users with an active user name and password are able to log in to the LIMS, and only those with appropriate permissions have the ability to access, enter, update and/or add data (Figure 16).

Data Integrity is a critical part of *ISO 17025:2017 Section 7.11 Control of Data and Information Management.*

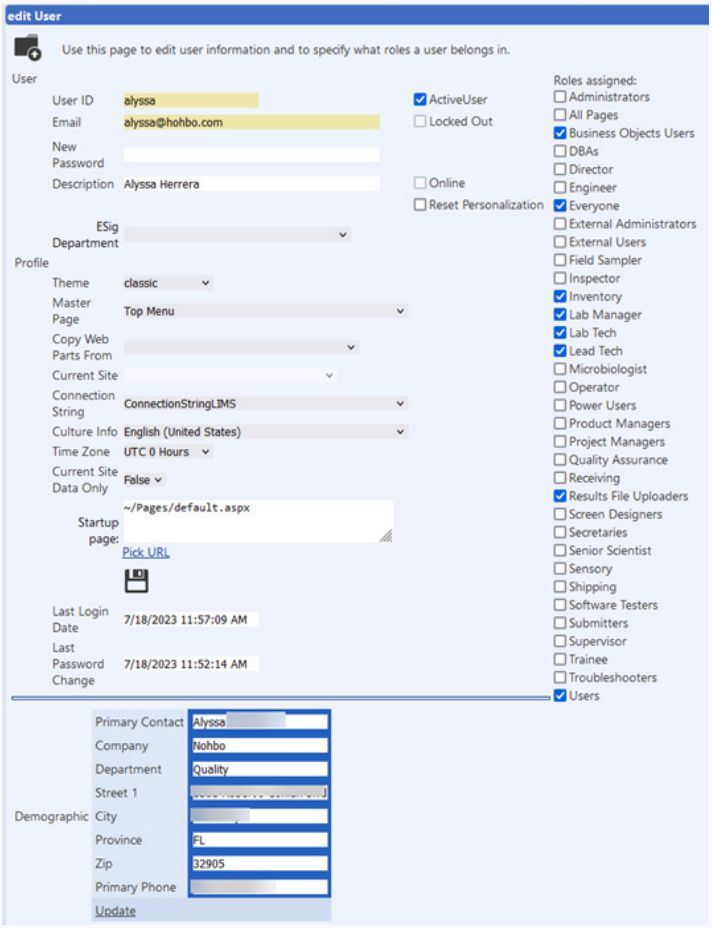


Figure 16 - Users and Roles

CONCLUSION

ISO 17025 identifies the high technical competence and management system requirements that guarantee test results and calibrations are consistently accurate. This increased regulatory focus is driving food testing laboratories to leverage a LIMS and automate their laboratory operations to keep their laboratory compliant through automation, which improves efficiency, productivity, and data quality.