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How LIMS enables compliance with ISO 17025

Driving quality testing and streamlining processes

ThermoFisher SCIENTIFIC

Introduction

Testing is essential to ensure high-quality oil and gas production. During upstream, midstream, and downstream oil and gas processes, composition, purity and contaminants must be tested to guarantee seamless production, trading and distribution.

The presence of difficult matrices, contaminants and sensitivity requirements makes petrochemical analysis challenging. Analytical tools must therefore facilitate accurate and precise assessment of various analytes to control product quality throughout the process.

Standards provide requirements, specifications and guidelines for consistent testing and analysis. The oil and gas industry relies on standards from several regulatory agencies to simplify testing procedures, assure accuracy, and minimize the cost of petroleum and petroleum product transactions, both nationally and internationally. Examples include:

- **Gas Processors Association (GPA) Midstream:** a primary advocate for enhancing the viability of natural gas (NG) and natural gas liquids (NGL) in the US. Their cooperative research programs are utilized worldwide.
- **American Society for Testing and Materials (ASTM):** an international regulatory body with test methods across multiple industries. The ASTM D02 committee focuses on petroleum products, liquid fuels, and lubricants.
- **German Institute for Standardization (DIN):** applies across multiple industries at national and international levels, including petroleum and natural gas products.
- **International Petroleum (IP):** develops and publishes test methods for petroleum and petroleum products
- **European Standard (EN) documents have been ratified by one of three European Standardization Organizations (ESOs):** The European Committee for Standardization (CEN), The European Committee for Electrotechnical Standardization (CENELEC), or The European Telecommunications Standards Institute (ETSI). These documents offer test methods for crude oil, distillates, and lubricants.
- **Universal Oil Products Collections Standards (UOP):** provides guidelines for oil and petroleum products testing and analysis.

The International Organization for Standardization (ISO)[1] is an independent, non-governmental body that brings together experts from around the world to develop and share International Standards. ISO/IEC 17025 general requirements for the competence of testing and calibration laboratories, was developed by laboratory experts for any organization that performs testing, sampling or calibration and wants to demonstrate their ability to deliver reliable results.

In 2017, the standard was updated to provide a more risk-based approach and has an increased focus on information technology, mainly in the use of systems, the provision of electronic test results, and the provision of electronic records. To achieve this, laboratory information management systems (LIMS) are necessary to help manage and control laboratory processes, drive quality testing, and achieve and maintain compliance.

This eBook will outline how Thermo Scientific™ SampleManager™ LIMS software can be applied to help achieve ISO 17025 accreditation and drive accuracy and consistency in testing methods within the oil and gas industry.

1. International Organization for Standardization. Available online: https://www.iso.org/what-we-do.html

Understanding ISO 17025

ISO provides the most used global standards across manufacturing today. Standards provide information on recommended processes, facilitate consistent practice, and give customers confidence in product quality. ISO 17025 is the international reference for testing and calibration laboratories. It is used by organizations to demonstrate that they operate a quality management system and are technically competent to carry out the work that they do.

ISO/IEC 17025:2017 supersedes the 2005 version to match newer standards such as ISO 9001 (quality management), ISO 15189 (quality of medical laboratories) and ISO/IEC 17021-1 (requirements for audit and certification bodies). As modern-day laboratories shift towards the use of information and communication technologies, the standard now recognizes and incorporates the use of these systems and electronic records to aid in the production of electronic results and reports. The updated standard also includes a chapter on risk-based thinking which describes the commonalities with the latest version of ISO 9001:2015, Quality management systems – Requirements. The concept of the Plan-Do-Check-Act cycle is also carried through ISO 17025, ensuring regular testing of tools and processes and monitoring to confirm suitable operation (Figure 1).

Figure 1. The Plan-Do-Check-Act cycle. This cycle can be applied to oil and gas quality control testing.

If any issues are found, processes are required to correct them and continual monitoring would confirm the success of such adjustments. This forms the basis of continual improvement for the organization. Across many of the process-oriented standards, ISO follows a consistent structure; (1) definition and context, (2) organization and leadership, (3) support, (4) operations, and (5) performance monitoring and improvements and its guidance is focused on:

- Resource qualification and control (personnel, instruments, third party laboratories)
- Validated sampling and testing methods
- Accuracy of results including measurement uncertainty
- Traceability of results
- Incidents, deviations - including customer complaints
- Performance evaluation
- Improvements

A systematic and software-driven approach can alleviate lab, process and data management challenges, enabling laboratories to optimize their workflow, increase compliance and improve productivity by integrating

laboratory instruments and equipment in and out of the laboratory. SampleManager LIMS software provides a single user interface that enables standardization and eases compliance across multiple laboratories.

Let's step through how a LIMS, such as SampleManager LIMS software, can be used to achieve and maintain compliance to ISO 17025.

Oil and gas quality control requirements can be set up to comply with ISO 17025 using SampleManager LIMS software. The solution provides consistent practice and control through its preconfigured workflows. Data visualization and reporting provide real-time information and intelligence through Manufacturing Execution Systems (MES) to enable optimized production. Incidents are widely used used to manage deviations and drive continuous improvement.

Where standards provide guidance around testing procedures, analytical methods can be configured in SampleManager LIMS software to comply with ISO, ASTM and environmental regulations. Information on the execution, consistent practice and control can be ensured through the Laboratory Execution System (LES) in SampleManager LIMS software.

ISO 17025 processes in the laboratory map directly to capabilities in SampleManager LIMS software. These processes are the building blocks of the SampleManager LIMS software refinery solution.

Test Methods and Laboratory Execution

Once received into the laboratory, samples are prepared for testing. Methods for preparation and testing are configured using analyses in SampleManager LIMS software, and the full method can be executed using the Laboratory Execution System (LES) to further drive process integrity. The Laboratory Execution System (LES) guides analysts through each step of a method to ensure compliance to the SOP and captures the complete process history (Figure 2). ASTM or other standard methods can be set up in the LES and act as templates for any additional tests that are required (Figure 3).

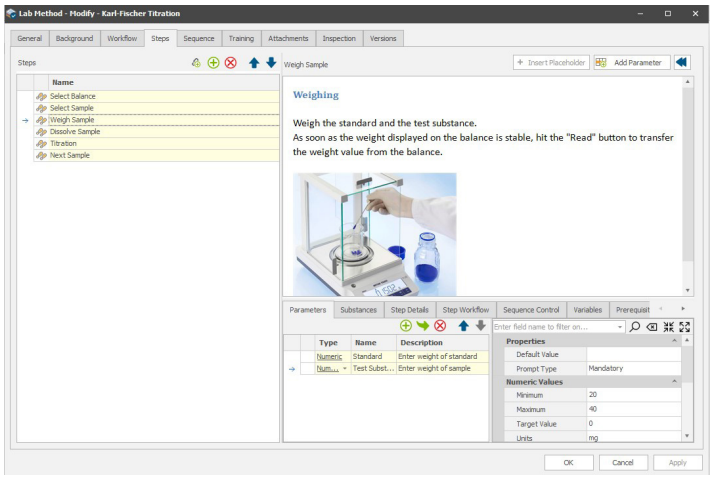


Figure 3. The LES steps users through SOPs using detailed images and instructions.

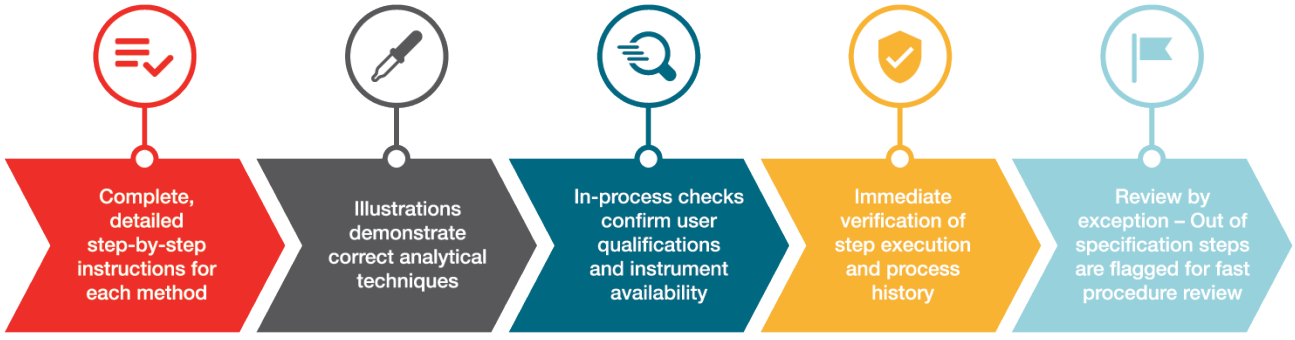


Figure 2. The benefits of the Laboratory Execution System (LES) in SampleManager LIMS software.

How SampleManager LIMS software can be configured to achieve compliance to ISO 17025

Sections 1–3 cover the scope, references and terms of the standard. Section 4 details the general requirements of the laboratory while section 5 details structural elements. Section 6–8 in the standard can be supported by implementing a LIMS.

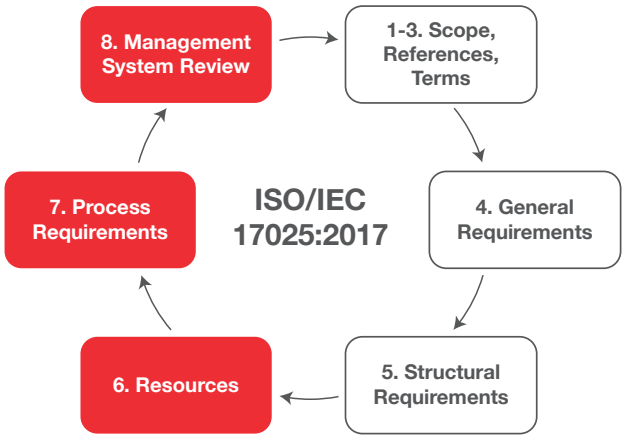


Figure 4. The eight sections of ISO 17025. Highlighted areas show that the LIMS is a critical component of sections 6-8.

Preconfigured Processes in SampleManager LIMS software

SampleManager LIMS software has functionality that is designed to support oil and gas testing laboratories. These features are developed under an ISO 9001:2017 compliant quality system (Table 1). Customers can leverage the testing done in the product release process as part of their risk-based assessment.

SampleManager LIMS software utilizes workflows to manage testing. This unique capability enables users to quickly

Table 1. A list of the software capabilities available in SampleManager LIMS software and the ISO 17025 section that each one relates to.

SampleManager LIMS software capabilities	ISO 17025 Reference
Resource compliance	6.2
Equipment use and availability	6.4
Instrument calibration	6.4
Reagents and stocks	6.4
Metrological traceability	6.5
Externally provided product and services	6.6
Test methods	7.2
Sampling	7.3
Handling of calibrated items	7.4
Technical records	7.5
Evaluation of measurement uncertainty	7.6
Ensuring validated results	7.7
Reporting results	7.8
Complaints	7.9
Non-conforming work	7.10
Control of data	7.11

build workflows which map to actual laboratory processes, automating decisions and actions and reducing the need for user intervention. Labs can easily adapt to new methods and process changes while simplifying initial system configuration, deployment and ongoing maintenance.

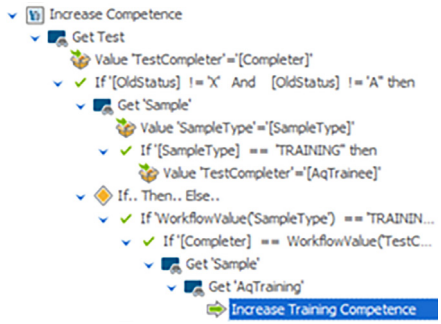


Figure 5. Users can quickly build workflows which map to actual laboratory processes.

Complete laboratory processes are mapped during the implementation of SampleManager LIMS software. Each process can be broken down into reusable pieces that can be applied across testing and process workflows (Figure 5). SampleManager LIMS software is used widely in the oil and gas industry. By using the preconfigured capabilities in the LIMS designed for testing, organizations can reduce project risk and expedite implementation, leading to a faster time to value.

Section 6.2 - Personnel

Resource competence can be simplified through the LIMS by managing training records and roles as shown below. SampleManager LIMS software checks training

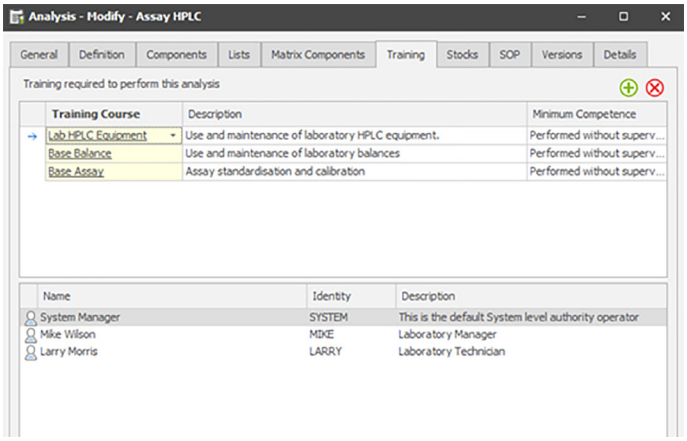


Figure 6. Training records outline the SOPs, instruments and equipment an analyst is authorized to use.

records to ensure that only operators trained to use required instruments and equipment and to run the SOPs are allowed to execute the tests (Figure 6).

Section 6.4 - Equipment

The use of equipment is controlled through SampleManager LIMS software instrument records (Figure 7), so that only instruments that are verified as in service and calibrated can be used.

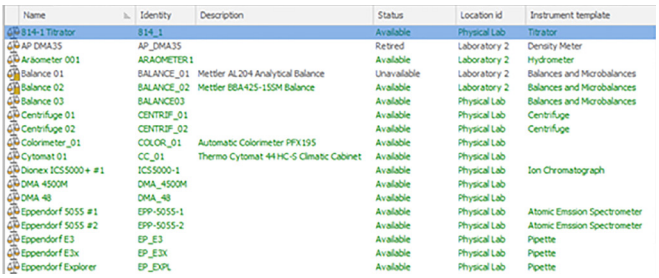


Figure 7. Instrument records allow the user to see if the instruments are authorized to be used.

Section 7.3 - Sampling

In oil and gas industry testing, there are two distinct sample lifecycles: environmental monitoring and quality control (QC) samples. To manage environmental monitoring, SampleManager LIMS software is used to set up sampling points around a plant or any other area where testing is required (Figure 8). These sample points are set up in SampleManager LIMS software's automated Sample Point Scheduler. When samples are logged into the LIMS, each sample is associated with the test limits for each analysis as defined in the specification. These limits can be set according to local or national requirements, results are checked against these limits on entry and immediately flagged if they are out of specification. Incidents can automatically alert stakeholders or request retesting.

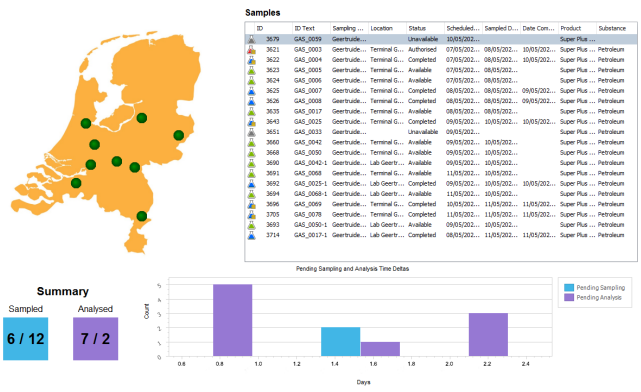


Figure 8. LIMS visualization tools for hazard analysis, this figure shows air contamination results by sample point in SampleManager LIMS software.

QC samples are taken at various stages of the process. QC sample login can be automated using the Sample Point Scheduler, event driven, may be manually logged or automated through enterprise manufacturing systems. The rules that control sampling and sampling procedures are set up in the workflow.

What are sample plans?
Sample plans are set up with manufacturing and the sample lifecycle starts when it is taken in production and sent to the laboratory for analysis.

Login plans and testing in SampleManager LIMS software control the sample entry using templates. This enables the sample to be uniquely identified, labelled and assigned specific tests based on rules. The next step in the lifecycle is to receive the sample into the laboratory for testing.

Section 7.4 – Handling of Test or Calibrated Items

SampleManager LIMS software Instrument Calibration and Maintenance functionalities can be used to manage calibration schedules for instruments and equipment (Figure 9). In the event of calibration or QA check failure, an incident can be raised to ensure the issue is resolved satisfactorily.

Section 7.5 - Technical Records

SampleManager LIMS software enables records to be made and kept, preserving data integrity throughout lab processes. Data is reviewed and any changes made are fully recorded though version control and are traceable in the audit history.

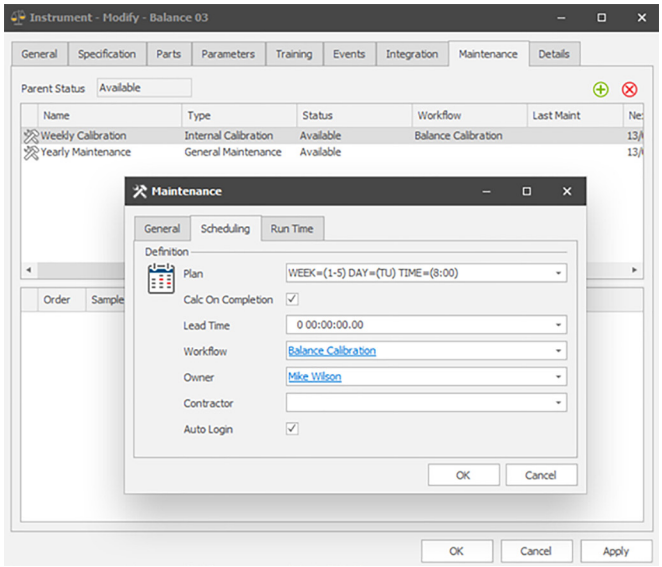


Figure 9. Instrument and equipment calibration schedules.

Section 7.6 - Evaluation of Measurement Uncertainty

Measurement uncertainty factors can be assessed for each analysis and the resultant SOP updates made in the Laboratory Execution System to drive improved control of testing. SampleManager LIMS software's Statistical Quality Control (SQC) module provides the capability to monitor day to day processes over time, and ensure they are within statistical control measures (Figure 10). Trend rules, used to distinguish between variations due to sporadic or inherent causes in manufacturing processes, are applied to create charts with multiple options available to fit business needs.

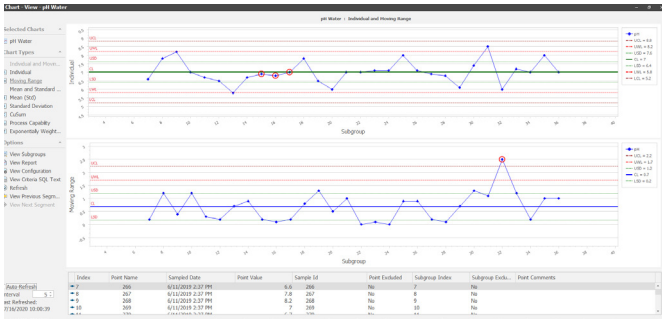


Figure 10. The Statistical Quality Control (SQC) module.

The SQC tool allows the user to define trends based on certain criteria for use in charts. Within SQC, the trend editor allows the user to build their own trend analyses based on a series of rules. Trend rules can then be tied into SampleManager LIMS software workflows to trigger actions based on statistical results, for example if a process appears to be going out of statistical control, an alert can automatically be sent to a process or operations manager.

Section 7.7 - Ensuring Validity of Results

In the event that control charts indicate a process is moving out of control, incidents can be raised in SampleManager LIMS software to investigate and address the issue. Incidents can outline and drive any corrective action which needs to occur. KPIs related to incidents can be tracked in the LIMS to demonstrate testing performance.

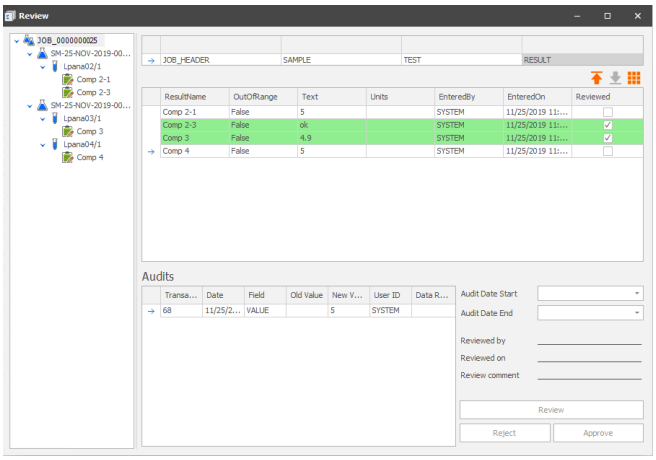
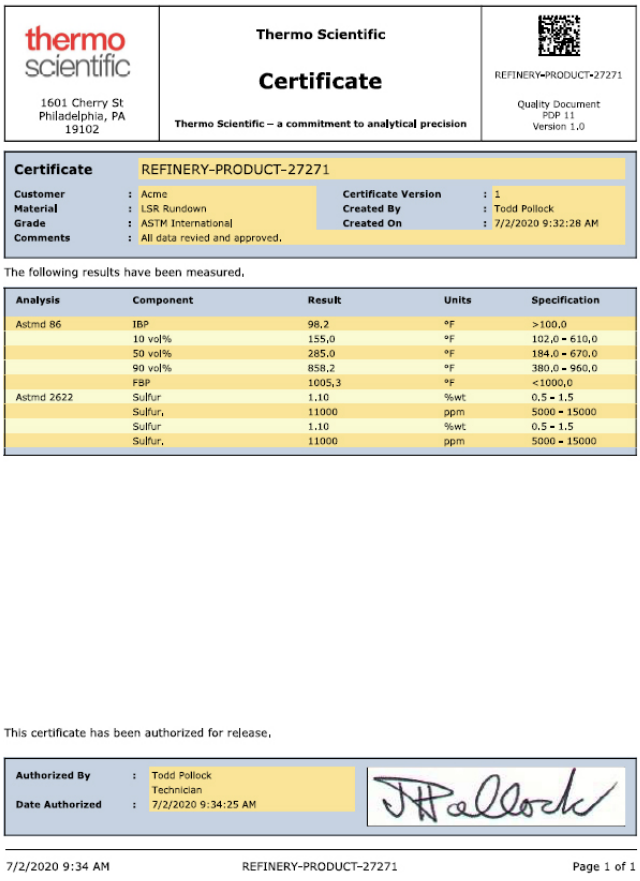


Figure 11. The Review and Approval module in SampleManager LIMS software.

Section 7.8 – Reporting Results

The SampleManager LIMS software review and approval process can be configured to include peer review at the results level, supervisor test review, and QA sample review as well as the review of meta data (Figure 11). Certificates of Analysis (CoAs) are a critical deliverable for laboratories (Figure 12). LIMS makes it easy to generate CoAs. Any details stored in the LIMS can be included. Amendments are subject to version control and are fully tracked in the audit trail. Statements of conformity or opinion can be included specific to the results to which they apply. Calibration details including those around measurement uncertainty, conditions and any relevant repairs or adjustments can be added to certificates where required.



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Certificate

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Quality Document
PDP 11
Version 1.0

Certificate	REFINERY-PRODUCT-27271		
Customer	: Acme	Certificate Version	: 1
Material	: LSR Rundown	Created By	: Todd Pollock
Grade	: ASTM International	Created On	: 7/2/2020 9:32:28 AM
Comments	: All data revied and approved.		

The following results have been measured.

Analysis	Component	Result	Units	Specification
Astmd 86	IBP	98.2	°F	>100.0
	10 vol%	155.0	°F	102.0 - 610.0
	50 vol%	285.0	°F	184.0 - 670.0
	90 vol%	858.2	°F	380.0 - 960.0
	FBP	1005.3	°F	<1000.0
Astmd 2622	Sulfur	1.10	%wt	0.5 - 1.5
	Sulfur,	11000	ppm	5000 - 15000
	Sulfur	1.10	%wt	0.5 - 1.5
	Sulfur,	11000	ppm	5000 - 15000

This certificate has been authorized for release.

Authorized By	:	Todd Pollock Technician
Date Authorized	:	7/2/2020 9:34:25 AM

7/2/2020 9:34 AM REFINERY-PRODUCT-27271 Page 1 of 1

Figure 12. The Certificate of Analysis created using SampleManager LIMS software.

Section 7.9 - Complaints

Customer complaints can be handled in SampleManager LIMS software using incidents to manage each case. Data surrounding the complaint can be analyzed and recorded in the incident record, which can be used to create and provide a full report.

Section 7.10 - Non-Conforming Work

Any incidents of non-conforming work are managed using incidents functionality in SampleManager LIMS software (Figure 13). Data surrounding the non-conformance is recorded along with any decisions around corrective action to resolve the issue.

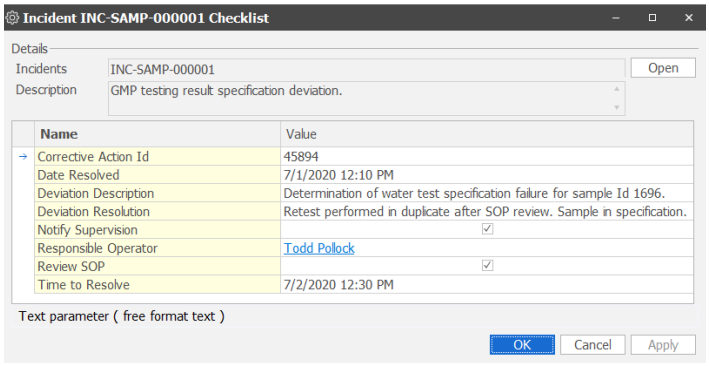

Figure 13. Incidents are used to manage non-conformances.

Section 7.11 - Control of Data and Information Management

SampleManager LIMS software provides analysts with all the data and information required to perform their tasks. Deployment includes validation to confirm that the system operates as specified and any calculations, data transfers and interfaces are all Operationally Qualified. The system is protected against unauthorized access, tampering or loss. Data and information integrity is supported throughout. External support of SampleManager LIMS software conforms to the ISO 17025 standard, and instruction manuals and guides are provided in electronic format.

Section 8 - Management System Requirements

The records for many of the management system actions below are maintained and controlled in SampleManager LIMS, LES and SDMS (Scientific Data Management System) software.

Data and statistical analysis can be performed to assess:

1. Resource performance
2. Training
3. Non-conformance by category
4. Complaints
5. Process usage

Any processes performed using the LES will provide statistical analysis such as frequency of use, average time to execute, etc. This information can be used with any related non-conformances data to indicate process effectiveness and help identify opportunities for process improvement.

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Summary

ISO 17025 outlines practices for the operation of laboratories to ensure reliable testing and quality results. SampleManager LIMS software can be configured to achieve and maintain compliance to ISO 17025, and many oil and gas organizations rely on preconfigured industry-standard workflows in the LIMS to drive efficiency, quality and productivity throughout their processes.

Additionally, SampleManager LIMS software can be configured to 21 CFR Part 11 requirements, enabling fully compliant electronic record, document, and signature control.

Find out more at **thermofisher.com/samplemanager**

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