

Thermo Scientific Integrated Informatics Solutions for the

Oil & Gas Industry

introduction

Professionals across all aspects of the oil and gas and petrochemicals industry – from lab and IT management and quality control to regulatory affairs and senior management – are more and more faced with the following challenges:

- Safe delivery of quality products on a global basis
- Pressure to standardize processes and harmonize systems for efficiency and cost savings
- A changing regulatory environment and resulting reporting requirements
- Improving quality through the entire supply chain
- Shareholder and management commitment to sustainable processes across the business – reducing energy usage, reducing waste and employing more automation
- Stringent attention to profitability – better utilizing resources, having more harmonized processes, mitigating risks while continuously looking for process improvements



Your data management solutions need to support your efforts to control processes across your entire organization – from exploration and extraction to refining, with rigorous testing and real-time monitoring.

Thermo Scientific Integrated Informatics Solutions can help today's oil and gas and petrochemicals companies deliver the safest products, using the most sustainable process, while delivering superior value to all stakeholders.

This eBook has been developed to give you a comprehensive resource when searching for the laboratory data management solutions that can help your business meet the most pressing business and regulatory challenges. Inside you'll find expert commentary on how Integrated Informatics can help you meet ISO 17025 requirements or manage daily workflow and SOP compliance issues in the lab. You'll also find case studies from some of the largest oil and gas companies in the world, as well as technical product information and other supporting materials.

If your lab is challenged by increasingly complex data management, let us show you the power of Integrated Informatics Solutions.



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The Power of Fully Integrated Informatics

By Ajith Kumar, Senior Business Analyst, Shell, Pearl GTL, Qatar
As seen in *The Analytical Scientist*.

Shell's Pearl GTL brings in the big guns to tackle its vast data-handling requirements with an integrated laboratory information management system.

The Challenge

The unprecedented scale of the world's largest gas to liquids (GTL) plant in Qatar – Pearl GTL – creates a massive business and technology challenge: how can quality be maintained and productivity maximized while managing huge volumes of critical data?

Background

As a senior business analyst for Pearl GTL, I was responsible for managing the laboratory informatics components of a project of unprecedented scale, which required billions of investment dollars and created tens of thousands of jobs during peak construction. Data management was a major priority. To maximize production and allow rapid decisions, we needed consolidated, accurate information available at our fingertips – at all times.





Established by Shell and Qatar Petroleum in 2006, and onstream at the beginning of 2011, Pearl GTL is the world's largest GTL plant and cements Qatar's position as the GTL capital of the world. The GTL process converts natural gas to liquid fuels and other products, including gasoil, naphtha, kerosene, normal-paraffin and lubricants. Pearl GTL captures the full value chain, from offshore development and onshore gas processing to the refining of finished products in one project. The project provides the platform for the growth of an entirely new industry with GTL fuels, in particular by opening up opportunities for new markets.

When it comes to illustrating the enormous scale of the project to build the world's largest GTL plant, the statistics paint an impressive picture. Some two million tons of freight were shipped into a dedicated berth at Ras Laffan port adjacent to the plant site. More than 750,000 cubic meters of concrete were poured during construction. And enough steel was being used during the peak construction period to erect the equivalent of two and a half Eiffel Towers a month.

Initially, my major challenge was finding a resilient software solution that supported all of our stringent data and integration requirements – something that could help drive success from the very beginning.

The Solution

From the start, we knew that we needed a highly sophisticated software solution to manage the interface of a quality control system that receives a constant stream of 34,000 transmitted measurements. These measurements, which include well content, volume, emissions, equipment condition and hundreds of other data points integral to the plant's operation, needed to be mapped onto the data generated by the laboratory operations. In addition to collection and storage, data also needed to be organized, integrated and analyzed constantly to ensure plant safety, product quality, environmental protection and production efficiency. Furthermore, our solution needed to ensure that Pearl GTL's labs remained in compliance with requirements such as ISO 17025, an accreditation that sets an international benchmark for running a testing laboratory. It lays out qualifications for suppliers, training, record-keeping, equipment calibration and much more. In the event of an audit, Pearl GTL would need to quickly retrieve and present data proving compliance.

With so many prerequisites for success, we needed a proven solution: a Laboratory Information Management System (LIMS). The right LIMS should present accurate, unbiased information necessary for maintaining the highest standards of safety, regulatory compliance and environmental commitment – all without sacrificing financial performance. But clearly, given the operation's complexity, not just any LIMS solution would do. In addition to organizing sample results, Pearl GTL's LIMS would need to be fully integrated with the ability to communicate with a variety of other systems, including operations management, batch tracking and enterprise

resource tracking systems. Without such integration, it would be almost impossible to achieve success with a project of this size and scale.

We chose Thermo Scientific's SampleManager LIMS to manage our state-of-the-art testing laboratories, standardizing it across all laboratory equipment and production systems. SampleManager offered unparalleled support for all of Pearl GTL's stringent requirements.

Despite our complex quality, regulatory and interface requirements, we worked with a strong team of people from Thermo Fisher. Rolling out the solution across Pearl GTL was seamless, despite some of the LIMS interfaces that were implemented being the first of their kind in any Shell facility.

One of our principal reasons for choosing SampleManager was its ability to integrate with other systems. At Pearl GTL, the LIMS is integrated with an operations management system (known as OTTER), process historian (OSI PI), an oil movement and batch tracking system, laboratory instruments and other production systems. Now, communication between all systems is seamless and bi-directional. And all information necessary to manage complex sample scheduling and stringent safety, quality and regulatory requirements is readily accessible.

The way SampleManager integrates with PI delivers notable efficiencies for Shell and Qatar Petroleum at Pearl GTL. While some other labs manually send test results to operations, technologists and process engineers, the Pearl GTL laboratory results are available to all relevant parties within the PI system as soon as they are



authorized in SampleManager. If high accuracy sampling data is important to your job, you can access it through the system in real time.

Other important consumers of lab data within Pearl GTL are users of the oil movement and batch tracking system. When panel operators need to move oil to new tanks in preparation for shipping, for example, they don't need to wait to be notified of test results, and this minimizes demurrage charges for loading delays. As soon as the results are available from the lab, the LIMS notifies operators through the oil movement system.

The LIMS has also enabled Pearl GTL to go paperless, helping us eliminate many human errors common in paper-based laboratories. Human beings can make an average of 3-6 mistakes for every 1,000 lab readings transcribed, so a sampling program the size of Pearl GTL's, could lead to hundreds of errors every day. SampleManager solves this problem by integrating lab instruments that automatically transmit data as soon as final results are produced.

SampleManager aggregates all this data and combines it with information collected from other sampling systems, including technicians in the field, enabling Pearl GTL to collate and present a vast array of data in a logical format for managers to analyze and make fast, effective decisions.

Using the OTTER system, all sample points in the field are marked with radio frequency identification tags. When field operators perform sample rounds, a handheld computer guides them to each sample point and then automatically records the required information, such as

sampling time, and whether the sampling task is routine or non-routine. The LIMS also transmits safety related information, (such as the sample container to be used and special instructions for sampling) to the handheld computers to ensure the wellbeing of staff. As the LIMS is fully integrated with OTTER, the data collected is instantly transferred to SampleManager from the field for analysis by managers or technicians back in the lab, which also saves Pearl GTL an estimated 2,400 working hours per year.

It's interesting to note that all the benefits we achieved by implementing SampleManager are completely transferable to other industries.

Beyond the Solution

The implementation of SampleManager LIMS at Pearl GTL was an enormous accomplishment for both Shell and Thermo Fisher alike. Among the most important benefits of a fully integrated informatics solution is the agility gained in moving assets, reassigning personnel or streamlining production. In essence, the LIMS gives the business the ability to make more timely decisions.

The same principles are echoed in many other industries, for example, downstream of the oil refinery at modern chemical manufacturers. The need for agility is especially true in the production of fine and specialty chemicals, where plants may change over production lines weekly, sometimes even daily. Within these highly flexible environments, laboratories responsible for quality, safety and efficacy of finished products must be equally flexible, which is no simple task.

In the chemical manufacturing lab, LIMS isn't just the first step, it's the most important step towards achieving

the agility required to meet more precise customer demands and more stringent regulatory requirements. Once in place, the business isn't simply capturing and collecting data; it's making that data actionable across the enterprise. With the LIMS enabling this type of data mining, management can move more quickly to respond to market trends or new regulations or to recognize and capitalize on cost-saving or margin growing opportunities.

For businesses to compete in manufacturing, they need to liberate the insights that are too often kept in silos across the site or around the world. Opening up these vast stores of knowledge to the benefit of the enterprise can improve manufacturing technology in new ways. Your laboratories can become real growth drivers for business transformation and enable your business to rapidly capitalize on new growth opportunities and build lasting value, customer loyalty and security for employees. ●

If your lab is challenged by increasingly complex data management, let us show you the power of Integrated Informatics Solutions.



Addressing the Challenges of ISO 17025 Compliance

By Trish Meek, Thermo Fisher Scientific

A Laboratory Information Management System is more than a tool to ensure regulatory compliance: it is an instrument to improve quality.

What if ISO 17025 wasn't a standard, but instead was a technology that automated laboratory best practices? What if following the regulations to the letter – often without even thinking about it – actually led to better overall business performance? In that case, it's likely every business would aggressively deploy that technology.

That technology does indeed exist, and it's commonly known as LIMS, short for a Laboratory Information Management System, an essential data management and enterprise integration tool for managing laboratory workflow, samples, reporting and compliance requirements. And while many in the oil and gas industry think of LIMS as a way to manage important data, it is, in fact, much more than that.

Paula Hollywood of ARC Advisory recently wrote that “hydrocarbon processing laboratories are becoming almost like third-party service laboratories...this means that accreditation with standards such as ISO 17025 is no longer just nice to have, but a necessity to ensure conformance and customer satisfaction.”

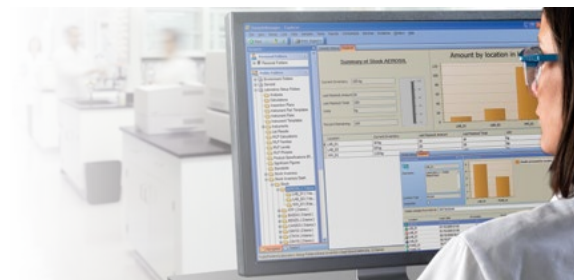
A “necessity for customer satisfaction” doesn't sound anything like onerous regulation. Instead it sounds like a catalyst that is part technology, part discipline and all-encompassing. In other words, when you think of ISO 17025, don't think compliance, think higher-quality product.

But certainly conforming to ISO 17025 standards is time-consuming, costly and technologically complex. It covers everything from contract review to method validation and quality assurance. One does not simply check a few boxes to stay in compliance; if it were that easy it wouldn't be so beneficial in the long run. But getting into compliance – and realizing the benefits of doing so – doesn't need to be overly costly or time-consuming. The rest of this article will explain how this is possible today.

How a designed-for-purpose LIMS supports ISO 17025 compliance

Sections 4 and 5 of ISO 17025 are the primary areas of alignment between regulatory compliance and LIMS functionality. In fact, Thermo Scientific SampleManager is preconfigured for compliance; no additional programming or bolt-on modules are required. For an onsite or third-party laboratory in the oil and gas industry, built in functionality saves time, money and months of aggravation that can be associated with custom software development.

At a glance, sections 4 and 5 of ISO 17025 resemble a list of best practices for any lab. But what's spelled out in each section is more complex than many realize. With so many interdependencies and so much relational data, it's nearly impossible to manage without assistance from software. Sure, some have developed home-grown paper systems that seem intuitive, but ultimately they can't



scale, often contain troublesome, burdensome processes, and can be slow to track down data, especially during an audit.

An integrated data management system, such as Thermo Scientific SampleManager LIMS, is designed to mitigate complexity, easing compliance within oil and gas laboratories and, most important, exposing previously unrecognized opportunities for performance improvement. Next we'll look at several key ISO 17025 sections, specifically management requirements and technical requirements, and discuss how LIMS is purpose-built to align with each section.

Management requirements

4.1 Organization and management

Labs must not only meet standards within their own facilities, they are responsible for compliance at third-party facilities and temporary facilities – such as field-based labs – as well. This not only strengthens compliance, but also it establishes a quality benchmark to which all laboratory practices and data must conform. To manage this level of complexity without disrupting daily activity, a LIMS must use a web services architecture that is both secure and extensible.

Proper security controls are especially important for external laboratories – and those doing business with them – because proprietary, confidential data is continuously stored and accessible. A proven LIMS will address this by providing group security, which limits access to specific projects or clients, and by providing native browser encryption (SSL) for web access.

4.2 Quality system

Quality and consistency are merely concepts unless policies, systems and programs are documented and reinforced. ISO 17025 not only calls for documentation of quality systems and procedures, it requires that it be communicated to, understood by, available to and implemented by appropriate personnel. The LIMS system can be the conduit for quality system documentation and reinforcement. Not only can relevant quality information be stored within the LIMS – or easily accessible through the LIMS via an intranet, but labs can also insert hyperlinks on landing pages and dashboards within the LIMS as just-in-time reminders to staff of quality system requirements.

4.3 Document control

Document control is an important component of a quality system. All documents generated internally or externally must be indexed and available on-demand. This includes any document type, including drawings, manuals and methods. The LIMS can store relevant documents in nearly any standard format as an attachment, making compliance with document control a natural extension of routine laboratory work.

4.4 Review of request, tender or contract

An oil and gas laboratory must demonstrate that it has the requisite experience, capabilities and resources to meet the requirements of the client (whether internal or external). This ensures that the laboratory is actually capable of meeting its promise to provide quality results. Because the LIMS offers a system-wide view of resources, methods, instrument calibration, etc., it plays an important role in the contract review process. SampleManager LIMS, for example, pulls in data from



operator loading reports to provide real-time insight into operator workload and possible resource conflicts. This avoids post-contract surprises that could trigger a compliance audit or, much worse, jeopardize a customer relationship.

Once work is complete, the LIMS also plays an important role in matching final delivery and pricing to scope of work. The LIMS tracks the handling of surface and subsurface oil and gas samples at all stages of the extraction and refining process from their delivery into the lab to the return of results to the customer. Everything is documented, ensuring full compliance and providing a record trail useful in ongoing quality control and efficiency analysis.



4.5 Subcontracting of tests and calibrations

Testing overflow is common, but cannot be handled haphazardly. ISO 17025 requires that laboratories are able to demonstrate that any subcontractor is competent to perform the activities in question, and that it is also in compliance with the standards. A lab must therefore maintain an up-to-date register of all subcontractors, including its precise area of expertise and an assessment of past performance and testing results. When using a LIMS, all this information, including current certification statuses, is stored within comprehensive supplier tables for fast, universal access.

4.6 Purchasing services and supplies

Laboratories are responsible for the quality of all services and supplies that affect the quality of tests or calibrations. Specific procedures must be in place for the purchase, receiving and storage of all supplies and consumables, and failure to verify and document compliance with a stored consumable constitutes non-compliance. Using a paper-based process, compliance is nearly impossible. With a LIMS, however, all supplier statuses, including reagents and other consumables, are easily managed using supplier management entry screens that feed into real-time reports and dashboards.

4.8 Complaints

ISO 17025 requires that laboratories have policies and procedures in place to resolve complaints. This includes a full record of investigations and corrective actions taken, if necessary. With a LIMS, all this information is easily captured and stored within an incident summary, ensuring compliance and providing an historical record for avoiding such issues in the future. In SampleManager LIMS, this incident management capability can also be used to assign and track actions due to non-conforming work, which is addressed in section 4.9 of ISO 17025.

4.11 Preventative action

ISO 17025 includes provisions for prevention as well as complaint resolution. This is one of the places where the regulations align with the LIMS best practices capabilities. Several tools within SampleManager, for example, help proactively identify issues before they become serious or systemic. In addition, Analytical Quality Control functionality can detect problems with running analyses, and the data feeds into a built-in Statistical Quality Control (SQC) package to proactively monitor analyses, identify trends and highlight potential issues.

Technical requirements

The technical requirements section addresses the myriad of factors that influence the correctness and reliability of laboratory tests and calibrations. These factors range from personnel to equipment and handling.

5.2 Personnel

ISO 17025 requires that laboratory management take full responsibility for the ongoing competency of all staff at all stages of testing and analysis. For this, a LIMS is particularly useful, not only for compliance, but also for ensuring that staff remain properly trained and certified. In SampleManager LIMS, for example, the system's operator training functionality sets specific user input restrictions so that only personnel who are certified on particular instruments, analyses or preparations can enter or modify data associated with these items. These rules and requirements can change as staff turnover, as requirements change or based on updated training results.

5.4 Test and calibration methods including sampling

Using appropriate methods and procedures for tests and calibration is as much about best practices as it is compliance. ISO 17025 requires that labs have easily accessible instructions for operation and handling of instruments and test samples, that all methods are appropriate and compliant/current and that personnel have the requisite experience to use the method. Calibration standards need to be fully tracked throughout their lifetime, so the LIMS stores up-to-date inventory and preparation records, usage and expiry data. The system also stores a full audit trail of any modifications, and labs can implement electronic signature controls for added security when standards are authorized for use.



SampleManager LIMS also supports validation of methods, required under section 5.4.5. This critical function for any oil and gas laboratory is addressed through AQC worksheets that enable analytical QA/QC support. This is done through a batch system that augments QA operations by including spiked samples, recoveries and surrogate support in the analytical sequence. Once the lab determines analysis parameters, the results for both analytical and standard samples are stored in the LIMS for future compliance reporting.

5.5 Equipment

ISO 17025 makes it clear that all equipment must meet the required performance parameters for its stated use. The requirements relate to sample preparation, testing, processing and analysis, and this also extends to equipment that is outside the labs permanent control. To accomplish this, the LIMS maintains comprehensive records for each instrument as well as each of its components and complete calibration history and status. Having this information in hand means that it is possible to identify the exact instrument configuration deployed at any point in time to test a particular sample.

5.7 - 5.9 Sampling plan, handling and transport, assuring the quality of test and calibration results

ISO 17025 requires that labs have defined procedures for sampling plans, handling and transportation of samples, as well as the management of calibration items and for ensuring the quality of results. Although these procedures can be complex and time-consuming without a system of record, with LIMS it's possible to create a sampling plan from a template that automates many of the necessary

steps. To address handling requirements, for example, each laboratory sample has a unique identifier, which is combined with a full lifecycle – from receipt to disposal – that can be tracked through the LIMS. Hierarchical definitions allow real-life physical locations to be mapped, and the assignment of materials, samples and equipment to be tracked and audited. For monitoring the quality of results for tests and/or calibrations, the LIMS automates established statistical Analytical Quality Control techniques to ensure the reliability of the process and equipment being deployed.

5.10 Reporting the results

No laboratory would dispute the ISO 17025 requirement that each test or calibration it carries out should be reported accurately, clearly, unambiguously and objectively. That would be a best practice. But this is easier said than done, and nearly impossible without software. A LIMS provides a powerful and flexible reporting tool that generates multiple reports from data stored within the system (in the case of SampleManager LIMS, data stored in external databases is accessible too). The reports, which can be customized as needed, are designed with oil and gas laboratories in mind. The system is preconfigured for rapid, cost-effective implementation.

Conclusion

ISO 17025 compliance in the oil and gas industry isn't easy, especially in labs still using paper-based processes, but for those labs that take a comprehensive approach the benefits are significant. Compliance processes can be part of an integrated program that improves overall multi-facility performance and profitability. ARC Advisory is more direct, stating that "Compliance with ISO 17025 demonstrates a commitment to quality and provides customers the assurance that the laboratory's management and technical requirements adhere to globally accepted best practices."

So whether an oil and gas laboratory starts with regulation as its impetus or simply wants to improve quality, the end result with LIMS is the same: an integrated system that can deliver the best of both worlds. And, with systems such as SampleManager LIMS pre-configured for the industry, getting up-and-running on the road to compliance and higher performance is only a log-in screen away. ●

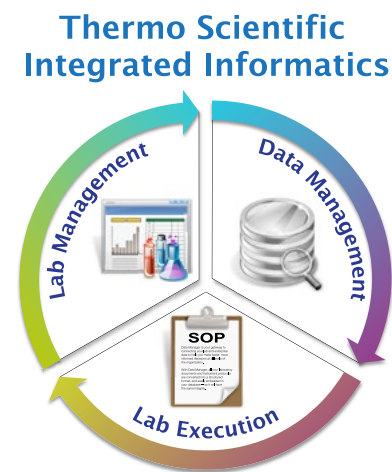
Take Your Lab Informatics to Another Level With SampleManager LIMS

SampleManager LIMS puts decision-making where it belongs – in the hands of users who can make logical choices about workflow, instrument integration and data reporting for management metrics and regulatory requirements. New workflow capabilities in SampleManager LIMS allow lab managers to easily model their processes in the LIMS – so that as your laboratory's needs evolve, workflows can be modified to change with them.

SampleManager LIMS delivers:

- Configurable workflow and extended lifecycle features
- Simplified sample login and user-friendly search syntax
- Complete control over methods and SOPs with Lab Execution System (LES)
- Raw data storage and retrieval with Scientific Data Management System (SDMS)
- Enterprise-level Instrument Integration with Integration Manager

For more information about the benefits of SampleManager LIMS, please visit www.thermoscientific.com/SM11 or email us at marketing.informatics@thermofisher.com



Thermo Scientific Lab Execution System Helps Scientists Go Paperless

Analytical and QA/QC labs, under ever-increasing pressure to improve time to market, ensure compliance and realize cost savings, now have an all-inclusive informatics solution that gives them complete control over their methods and standard operating procedures (SOPs) without having to purchase, integrate and validate software from multiple vendors. Trish Meek, Director of Product Strategy for Informatics at Thermo Fisher Scientific, explains how the new solution helps get scientists closer to the paperless lab.

Engineering Defensibility

By Jeanne Mensingh, Thermo Fisher Scientific Partner

Jeanne Mensingh, president and founder of Labtopia Solutions, a Thermo Fisher Scientific Partner, explains how LNG labs can use data management tools to improve the reliability of their results and strengthen the business they serve.

Laboratory data is critical to every part of the LNG industry. From soil sample data for upstream exploration to purity data used downstream to ensure product quality, LNG professionals rely heavily on timely, accurate and well-organized sample data.

These data must be reliable and defensible. Fortunately, many laboratories adhere to strict protocols to ensure data accuracy – they can ill afford to have decision-makers question what they're seeing. The real challenge for these labs isn't data quality; instead, it's the ability to prove data quality as efficiently as possible. In a word, the lab's findings must be defensible: based on proven processes and robust supporting data.

This data-driven approach to lab data reliability is nothing new: ISO 17025, the international standard for testing and calibration laboratory competence, has mandated comprehensive data collection and management for 15 years. What has changed are the software solutions that labs can deploy to meet this challenge.

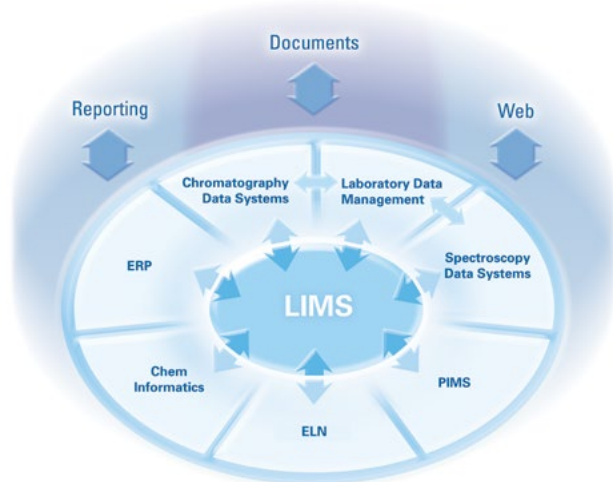
The importance of data management

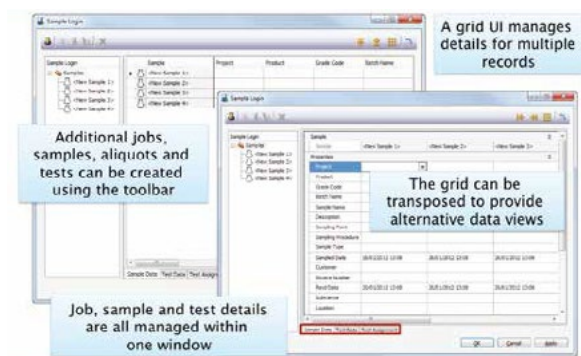
A laboratory test result doesn't exist in a vacuum: even a common gas chromatography result is the sum of many complementary parts, from supplier shipment data and staff training records to carrier gas and reagent quality checks. Ideally, all of these data work together to prevent errors and make results more defensible.

Historically, defending data has been a time- and labor-intensive process. Lab employees had to collect data from dozens of different sources – including handwritten notes – to build a case in support of a disputed result. Even today, many labs spend as many as ten hours a week manually collecting and managing data. This represents a lot of time spent on manual and labor intensive tasks that could be better spent on more important or revenue-generating activities. Time spent on these manual tasks represents a significant opportunity cost.

Fortunately, comprehensive data management software makes it much easier for today's labs to defend their data. Laboratory Information Management Systems (LIMS), first introduced in the 1980s as basic sample management and data reporting tools, have today grown into comprehensive platforms that gather, monitor and manage all laboratory data and records. They also serve as the integration point for all lab instrumentation and can also link to enterprise systems such as PIMS, MES and SAP. Having all these data well-organized and readily available makes the process of defending lab results much easier, allowing lab employees to focus on productive work and assuring management that the data they're relying on for key business metrics are defensible.

Gas chromatography, a common analytical technique in LNG laboratories, serves as a useful example of the sheer volume of data necessary to support the validity of a single lab result. A LIMS allows lab employees to





Multi Sample Login

easily access these data when and how they need them, ensuring the reliability and defensibility of all test results.

Case study: Gas Chromatography

Gas Chromatography (GC) is used to determine the composition of a liquid or gaseous sample. It works by vaporizing a sample and then sending the resulting gas through a coiled tube, called a column, filled with an inert carrier gas. The sample's constituent gases are slowed down by the carrier gas as they pass through the column; each constituent gas is slowed to a different degree depending on its molecular structure. By measuring the time it takes each constituent molecule to reach a detector at the other end of the column as well as the volume of each constituent, lab professionals can determine the composition of the sample as a whole.

The goal here is not to provide an in-depth explanation of GC, but rather to make clear the enormous number of variables that can influence a GC result. Everything

from technical errors, such as using the wrong column or improperly calibrating an instrument, to staff management errors, like improper training or manual data entry inaccuracies, can render a lab result indefensible.

To defend their results, labs must account for all the variables and provide evidence that they were executed properly. A LIMS makes this much easier by automating the entire data collection and reporting process.

Technical quality

Technical quality data include all variables involved in producing an accurate result from an instrument. These data are different than those related to employee performance, which primarily concern the lab staff's competency and adherence to Standard Operating Procedures (SOPs).

For GC analysis for the LNG industry, relevant technical quality data would include reference material certificates, records of approved suppliers, maintenance records and more. A LIMS provides an entire suite of capabilities for managing these data.

Suppliers

Labs require many consumables to operate GC analyzers. Rather than retest all of these consumables as they arrive at the facility, most labs find it easier to build a network of trusted suppliers. These suppliers likely have a well-earned reputation for quality which they can support with their own laboratory data.

A LIMS can automate supplier data management by associating materials with a supplier as they enter the facility. If a technician needs to defend the results from a

test, they can reference the LIMS database to verify that all consumables used were from approved suppliers. If they are, they can partially rule out consumables as a fail point.

Consumable quality

Verifying that a consumable comes from an approved vendor is only part of the equation. Consumables can also go out of specification during storage or use. Fortunately, a LIMS can help solve this problem as well: lab administrators can configure the LIMS to trigger periodic consumable quality checks. Together with verification of supplier data, this capability can help labs avoid the inadvertent use of out-of-specification consumables.

Instrument maintenance and calibration

GC analyzers must be regularly maintained and calibrated to deliver accurate results. To defend their results, labs must also be able to demonstrate adherence to proper maintenance procedures. This is another area where a LIMS excels. Lab managers can organize and retrieve records by instrument, time period and even staff member, allowing them to demonstrate that the instrument in question is adhering to a pre-defined schedule. Verifying this would be much more time-consuming and error-prone in a paper-based environment.

A LIMS adds additional value for calibrations that require certified reference materials. In addition to tracking the calibration itself, the LIMS can store reference material certificates that demonstrate the quality of the materials used.



Staff performance

In addition to instrument error, lab results can also be invalidated by human error. Human errors in the lab originate from issues in one of three broad categories: training, process and data management. A defensible lab result must be able to demonstrate that the lab staff that produced it did not inadvertently make errors in any of these areas.

Staff training

New lab staff typically undergo initial training on the unique processes within their new work environment. Regular retraining is necessary as processes change. Training for each employee must be closely monitored to ensure that they're up-to-date; otherwise, results from

any part of an analytical process in which they participate could be questioned. Maintaining these accurate and up-to-date staff competency records is an onerous process that can be simplified by storing all personnel training records within the LIMS.

Process quality assurance

Human error is one of the most common causes of failure in any process: small errors in the execution of a GC analysis can render a result invalid. To prevent this, labs must be able to comprehensively monitor the execution of laboratory processes and reference them to individual results.

A LIMS achieves this by storing and automating SOPs to walk staff members through each process. As staff progress through the steps of an SOP they mark their progress in the system, creating records to document that they executed everything correctly. Process errors can be reported to a lab manager in real-time, allowing them to correct problems before erroneous results are even reported. In fact, multiple SOPs and workflows can be stored in the LIMS so that changeover for production can be done in the most efficient manner possible.

Data entry and transcription

Manual data entry errors made by staff can significantly affect lab results. Even if a process is nearly entirely automated, a single manual data entry error can make the result indefensible. A LIMS helps alleviate data entry concerns by automatically collecting and aggregating lab instrument data. A vendor-agnostic LIMS is particularly important, as it's capable of interfacing with a broad range of instruments from multiple vendors.



Standard Dashboards

Conclusion: complete traceability

The areas covered here are not an exhaustive list of variables involved in GC analyses. But they do demonstrate the point – there are many ways for a single experiment to go astray and lead to a disputed result. Defending results is about more than simply verifying inputs and outputs; it's about documenting complicated processes rigorously at every step.

A LIMS can provide complete visibility into processes and the staff that execute them. Moreover, it can direct processes in a manner consistent with SOP. This complete traceability – from materials supplied to training and instrument calibration – significantly streamlines laboratory operations and provides critical data defensibility. ●

ISO 14001 and LIMS: **Combining Laboratory Environmental Management with Operational Efficiency**



By Trish Meek, Thermo Fisher Scientific

Many expect there to be a conflict between meeting environmental targets and improving a company's bottom line, but managed carefully they can both improve operational efficiency.



Businesses around the world are realizing that environmental responsibility and profitability don't have to be at odds: in fact, effective environmental management can often encourage operational efficiency.

This is true in laboratories as well, but some laboratory managers still believe that practicing environmental stewardship automatically means higher costs. Experience has shown otherwise: labs that choose to take a rigorous, disciplined approach to environmental management usually realize efficiency gains in the form of reduced energy use, more efficient use of consumables, diminished waste production, disposal costs and more. This makes sense: waste – including the environmental externalities of running a lab – is almost always a sign that inefficiency exists somewhere in an operation.

The family of ISO 14000 standards have been in place across many industries for more than 15 years, and for laboratories they provide a useful non-technical framework for successfully reducing waste and environmental impact. ISO 14001, the primary standard in the 14000 family, outlines a set of guidelines for establishing an effective Environmental Management System (EMS). An EMS is a management framework that helps decision-makers, including those attached to a lab or labs, establish environmental goals and set up a positive feedback loop that enables ever-improving environmental performance and, by extension, greater laboratory efficiency.

The feedback loop is at the heart of the ISO 14001 standard. At its core is a five-step process: first, lab management must commit to environmental goals that are reasonable for their organization. Next, they must plan how to achieve those goals over a set period of time (often a quarter or a fiscal year). Step three is implementation: once a specific plan has been made, management must present it to staff and ensure that they're capable of executing their new workflows.

After the plan is in place, the final two steps begin. In the evaluation phase, the lab must continuously monitor all operations and collect data on the performance of its plan. Finally, the review phase is a chance for lab management to go over the data collected in the evaluation step and look for ways to improve upon their original plan for the next operating period – which, naturally, leads back to the policy step. Environmental management improvement in terms of laboratory operations can have a number of targets, such as instrument running costs, waste solvent disposal, and may have their root cause in long established working practices.

The importance of information management

An effective, fully-compliant EMS is built on being able to measure the effects of changes – essentially being able to compare the before and after stages of each five step iteration. In fact, it requires labs to manage additional, more granular, data so that the lab environmental performance can be appropriately measured allowing management to evaluate the success of implemented changes. This creates new complexities that make better information management a priority for any lab in the process of establishing an EMS.

For many labs, the ideal solution for managing all this information is already in place: the Laboratory Information Management System (LIMS). Among many other things, a LIMS is commonly used for management and reporting of sample data; however, it can be equally effective for the collecting, organizing and reporting of performance data, which are all critical aspects of a successful EMS. As the LIMS tracks the lifecycle of a sample as it passes through the lab, it also gathers metrics about the laboratory operations, for example, the usage of stock solvent for a preparation, the time taken to analyze the sample using an instrument and so on. This data can be used to collate actionable information as we shall see later.

Planning

Once a lab commits to establishing an EMS, it must identify and catalogue the environmental aspects of its operations, which ISO 14001 defines as any items or processes that can have negative impacts on the environment. Once all impacts are catalogued,

management sets what are called objectives and targets. Objectives establish what must be accomplished, such as “reduce the usage of hazardous solvents,” while targets are measurable outcomes that are related to an objective. For the objective to reduce solvent use, for example, a lab might set a target such as “reduce total solvent waste for disposal by 15 percent before June 2015.”

A LIMS makes EMS planning easier by enabling lab management to build a map of the lab, which includes all instruments and testing protocols having a proportionately higher environmental impact. This allows the lab to identify the low hanging fruit for process improvements or protocol changes to meet the environmental targets that have been set.

Implementation

Once the plan is set and the lab is working towards its new environmental goals, new processes and methods must be rolled out to relevant lab workers. Implementation comprises three important steps: providing training to employees on their new environmentally friendly protocols, instituting data capture processes for environmental metrics, and management review of the results of the new process. LIMS provides critical support for each of these steps.

The first step, employee training, benefits from the way a LIMS can fully automate the assignment of Standard Operating Procedures (SOPs) for lab technicians, creating a paperless training environment. New workflows and procedures are clearly outlined based on roles and responsibilities, ensuring that each technician knows precisely what they must do as a part of the lab achieving



its EMS goals. Additionally, the LIMS can enforce that users must have completed a specific training course prior to being able to access protocols stored within the LIMS. And, during any audit to demonstrate ISO 14001 compliance, the LIMS has automatically captured the employee training progress and history.

A LIMS also plays a vital role in communicating environmental management parameters to staff. Real time dashboards can be used to display environmental quality parameters, alerts based upon critical parameter levels can be sent to relevant decision-makers inside and outside the lab. This dramatically reduces response times and improves EMS performance. What's more, early response can also mitigate damage to instruments, equipment or product if an environmental impact rises to the level of hazard.

When environmental incidents are surfaced, the LIMS is designed to help employees solve them. The LIMS stores Incident Protocols that detail exactly what employees must do if problems occur. Little time is wasted between notification and response because the LIMS notifies each employee precisely what to do and when.

Evaluation

Evaluation is the longest and most data-intensive step in the EMS process: a compliant lab must continuously monitor all affected lab operations throughout the operating period. Once again, this is where LIMS can play a significant role. It is, after all, designed to automatically collect and manage large, diversified sets of data and make them easily usable for laboratory decision-makers.

A LIMS can serve as a central repository for collecting data from all instruments in the lab (a LIMS such as Thermo Scientific SampleManager can collect data from any manufacturer's instrument). Having a single place to store and retrieve information enables analysis of performance trends, monitoring of key performance indicators defined by the EMS and periodic internal audits to ensure that goals are being met.

The ability to securely store, recall and analyze such a volume of data, including digital information in high-resolution formats, is critical to the next step of the process: management review.

Management review

At the end of a predefined operational period (often a quarter or fiscal year), ISO 14001 requires that lab management meet to review the progress of their EMS goals. A LIMS can simplify this review significantly. Because all data is organized within the LIMS and preconfigured for streamlined access and review, lab management can quickly assess progress against previously defined goals. Management can drill down into details – all the way to the instrument configuration, solvent usage, etc. – as necessary.

As EMS goals are met, management can set new goals, further improving environmental performance based on hard data gathered from the prior period. A flexible LIMS allows management to easily update the system for new objectives and targets, including revising SOPs and other automated procedures to guide employees through what's required of them in the forthcoming period.

(Re)commitment

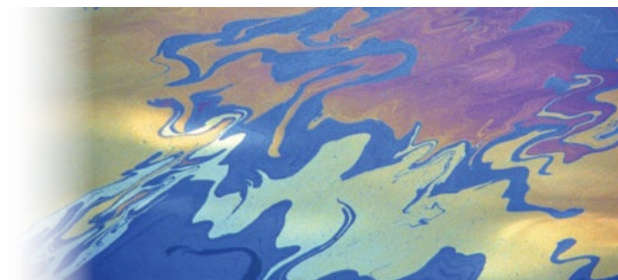
After each period, management must reaffirm its commitment to ISO 14001 compliance by reviewing the results of their EMS with an independent (ISO) or governmental (EPA) auditing body. Just as a LIMS simplifies EMS performance review for management, so too does it streamline external reporting of the laboratory's environmental performance. The LIMS can generate reports for each period that are tailored to the requirements of external auditors. This not only ensures a thorough, well-documented review, it also shows auditors that a rigorous system is in place for achieving results over the next period.

Conclusion

Combining the environmental management capabilities of an ISO 14001-compliant EMS with the operational efficiency power of a LIMS has the potential to transform laboratory operations to be more environmentally friendly. By simultaneously reducing process waste, identifying improvement opportunities and implementing a lab-wide data management system, labs can significantly enhance their productivity and environmental responsibility. As more and more companies realize the benefits of ISO 14001 compliance and institute their own environmental management systems, the role of the LIMS in ensuring EMS excellence in the laboratory will only increase. ●



LIMS Compliance for Better Quality and Performance



By Trish Meek, Thermo Fisher Scientific

Too often, businesses think of government regulation, standards and oversight as burdensome, onerous and, some would say, even gratuitous. If businesses can instead think of standards, such as ISO 17025, as checklists for running a credible, high-quality lab, tremendous benefits are possible. This article explores how an integrated data management solution, such as a Laboratory Information Management System (LIMS) can help oil and gas companies adhere to ISO 17025 standards and how that can actually be a catalyst for better overall performance.

According to a recent “ARC View” piece by ARC Advisory Group, “hydrocarbon processing laboratories are becoming almost like third-party service laboratories.”

The author of the piece, Paula Hollywood, goes on to say that “this means that accreditation with standards such as ISO 17025 is no longer just nice to have, but a necessity to ensure conformance and customer satisfaction.” The key here is customer satisfaction, whether that customer is internal or external, in the case of a true third-party laboratory. Compliance, in other words, is not the ultimate goal of LIMS; delivering higher quality product and customer satisfaction are.

So how do LIMS and regulations such as ISO 17025 align and or complement one another? Fundamentally, ISO 17025 overlaps with LIMS in 12 key areas, outlined in the following sections of the standard:

- 4.4. Review of requests and contracts
- 4.6. Purchasing services and supplies
- 4.8. Complaints
- 4.9. Control of non-conforming testing
- 4.10. Corrective action
- 4.11. Preventative action
- 4.12. Records
- 5.2.5. Training and authorization of personnel
- 5.4.5. Validation of methods
- 5.5. Equipment
- 5.9. Assuring the quality of test results
- 5.10. Reporting results

At quick glance, you’ll see that each of these areas touches on an aspect of lab business that should already have best practices to which all staff adhere. But hewing to best practices philosophically is much different – and infinitely less complex – than capturing, managing and reporting on the “hows, whens, whos and whats” related to following the standards.

A proven integrated data management system, such as Thermo Scientific SampleManager LIMS, is designed to mitigate complexity by automatically connecting those pieces, easing compliance within oil and gas laboratories and, most important, exposing previously unrecognized opportunities for performance improvement. Let’s explore how LIMS can help turn compliance into opportunity.





Getting on the same page

Sections 4.4 and 4.6 of ISO 17025 address a fundamental best practice in any business, getting on the same page with the client, whether that client is internal or external. Which tests are being performed, how samples must be handled, what supplies must be used, which suppliers are approved, etc. vary greatly from client to client and situation to situation, and loose adherence has potentially costly consequences, especially when it comes to resolving any disputes. The requirement to track this information and produce proof during an audit may seem onerous, but in reality it's simply good business. So the fact that a LIMS removes the "it's too time-consuming" objection, all that remains are the business benefits.

Rooting out inefficiency

In a complex industry such as oil and gas, we learn to expect the unexpected. Sections 4.8 through 4.10 address formal processes for managing incidents, not to simply assign blame, but instead to rapidly fix the issue and avoid future occurrence. The "Incident Management" functionality in LIMS includes templates for different incident types, defines required actions and documents the response through successful closure. Through LIMS, the laboratory can not only accelerate response to incidents and resulting complaints, but it has an always-learning database that is constantly rooting out inefficiency and risk.

An ounce of prevention

Section 4.11 requires laboratories to identify potential sources of non-conformance. This can expose analytical processes that are "heading out of control," even those that are still technically "in spec." Without a system to identify this, such as LIMS Statistical Quality Control (SQC) and Analytical Quality Control (AQC) worksheets and charts, it's nearly impossible for laboratory personnel to spot possible issues.

SQC/AQC charts are also valuable tools for validating methods (see section 5.4.5) and ensuring the quality of test results. Many believe that section 5.4.5 is actually one of the strongest parts of ISO 17025. Having access to at-a-glance charts to use as early warning systems and visual performance monitors provides benefits far beyond compliance.

A proactive oil and gas laboratory can spot data trends related to nitrogen, methane or propane content, for example, using LIMS as a tool to monitor for quality and possible environmental or safety impact. AQC worksheets cover initialization checks, calibration checks, interference checks, matrix spikes, duplications and other information that can expose patterns, including specific patterns for which the laboratory requires warning.

Good news to report

The most burdensome part of reporting is compiling the data. With a LIMS, however, access controls ensure that each step, each access is authorized, documented and stored. Appropriate files, notes and external links accompany each instance of access, creating an audit

trail that is easily accessed and reviewed. Once again, ISO 17025 compliance may dictate the institution of access controls and accompanying documentation, but the wisdom of capturing this information for performance assessment is undeniable. Without LIMS it would be a burden for sure; with LIMS it's a best practice.

Well equipped

A complex oil and gas laboratory maintains a technology inventory comprised of instrumentation, spare parts, consumables and complementary lab equipment. ISO 17025 requires that labs maintain comprehensive records for each piece of equipment and that proper calibration must be documented. This can be especially burdensome, especially in larger labs and/or labs that have relationships with satellite or partner labs upstream and downstream. But with LIMS as a system of record, burden becomes benefit and stakeholders in the business can begin accessing information that informs efficiency, performance and capital equipment decisions for the laboratory enterprise-wide.

Oil and gas laboratories must address difficult analytical challenges as the industry seeks to deploy new exploration, extraction and processing technologies. ISO 17025 addresses the use of new or non-standard methods and provides a framework for capturing all related information. This means that the consumer of the results can be sure that best practices were used in generating that information and the lab can be confident that new methods can be developed and reproduced successfully.



SampleManager LIMS is used to manage Sakhalin's lab workflow and reporting on samples, as well as data management of environmental monitoring throughout operations.

Sakhalin II

Sakhalin II, the world's largest integrated oil and gas development project, proves that no requirements – or environmental conditions – are too harsh for LIMS. The project also shows how ISO 17025 compliance and the pursuit of product quality go hand-in-hand.

The ultra-modern laboratory onsite at Sakhalin II provides round-the-clock testing of both onshore and offshore feeds, environmental and safety monitoring and water quality control and analysis. While ISO 17025 regulations require steps such as validation of analytical methods, instrument calibration and security controls, with LIMS there is so much more the laboratory can do.

The Sakhalin II laboratory manages a rigorous daily sample schedule within LIMS, including analysis of gases for nitrogen, methane, ethane, propane and

butane, as well as quantification of hydrogen sulphide, CO₂, mercaptans, carbonyl sulphide (COS) and total sulphur content. The same system that ensures real-time compliance also drives quality control, from calculating the density and gross heating value of each cargo to issue certificates of quality.

In such a complex operation, the LIMS becomes more than a compliance tool. In a facility such as the Sakhalin II laboratory, LIMS can replace inefficient and risky paper-based processes with highly integrated automatic data capture and transfer that eliminates errors caused by manual processes. Not only is data available to regulators in a timely fashion, it's available to decision-makers making data-driven business decisions that impact product quality and overall profitability.

Conclusion

Oil and gas companies can think of regulations such as ISO 17025 as burdens or catalysts. Before LIMS – before it was possible to run a paperless lab – compliance was indeed time-consuming and costly. Now, however, compliance processes can be part of an integrated program that improves overall multi-facility and performance and profitability. As the ARC View suggests, “Compliance with ISO 17025 demonstrates a commitment to quality and provides customers the assurance that the laboratory's management and technical requirements adhere to globally accepted best practices. The documentation produced by SampleManager LIMS confers credibility in testing practices and data quality to customers and regulatory authorities.” So whether a laboratory in the oil and gas industry starts with the regulation as impetus or simply wants to improve quality, the end result with LIMS is the same: an integrated system that can deliver the best of both worlds. ●



Additional **Resources**

Technical Bulletins



Handy Web Links

Customer Case Study:

Sakhalin Energy Utilizes Thermo Scientific SampleManager LIMS™ for Largest Russian LNG Project Ever



Sakhalin Energy is bringing onstream one of the largest integrated oil and gas projects in the world in Russia's Far East. The Sakhalin II Project combines partnership incorporating the recovery, production and transportation of oil and Liquefied Natural Gas (LNG). Sakhalin Energy standardized on Thermo Scientific SampleManager LIMS (Laboratory Information Management System) for use in its main laboratory located at its LNG plant/Oil Export Terminal (OET), as well as in upstream satellite laboratories throughout Sakhalin Energy.

Profile

Headquartered in Yuzhno-Sakhalinsk in Russia, Sakhalin Energy was founded in 1994 to develop the Piltun Astokhskoye (PA-A) oil field and the Lunskeye gas field east of Russia. The fields are located off the north-east coast of Sakhalin in waters frozen for six months of the year.

The Sakhalin II project refers to the world's biggest integrated oil and gas project. It is being built from scratch in the harsh sub-arctic environment of Sakhalin Island located in the Sea of Oshotsk. Sakhalin II is the largest single foreign investment project in Russia at \$10 billion, and is the first offshore development project in Russia, as well as Russia's first Liquefied Natural Gas (LNG) project.

The two fields contain reserves of approximately 140 million tons (1 billion barrels) of oil and 550 billion cubic meters (20 trillion cubic feet) of natural gas. The oil reserves equate to more than one year of crude oil exports from Russia and the gas reserves represent nearly five years of Russian gas exports to Europe or enough to supply current global LNG demand for four years. To export the gas, the company is building Russia's first-ever LNG plant, which converts the gas to a liquid by cooling it to a temperature of minus 161 degrees Celsius (minus 258 Fahrenheit) so that it can be transported by ship.

The Sakhalin LNG plant will be the world's second in a cold climate. The gas will be transported from the gas field platform by pipelines to an Onshore Production Facility (OPF) and then via an 800 km onshore pipeline to Prigorodnoye in the south of Sakhalin Island, the site of the LNG plant and oil and LNG export terminals. The OPF's main purpose is to process gas and condensate produced at the Lunskeye gas field before pumping them into the pipeline system for transportation to the oil export terminal and LNG plant.

Prigorodnoye's ice-free sea makes it a perfect location to enable full year round export of oil and LNG. Divided over two liquefaction trains, the LNG plant has a capacity to produce a total of 9.6 million tons of liquefied natural gas. Shell's Double Mixed Refrigerant (DMR) process was selected for the Sakhalin plant. This DMR technology was specifically developed for cold climates like Sakhalin has, and for locations with large seasonal temperature variations. Under these circumstances, DMR achieves much higher power utilization than the conventional C3/MR process would of the 88 MW GE Frame-7 gas turbines that drive the refrigeration process.

Sakhalin is located close to emerging economies in Asia and will guarantee uninterrupted supply of LNG to Asian markets year-round. Customers in Japan, South Korea and the U.S. have already bought all the gas to be produced at Sakhalin for the next 20 years.





Requirements

The Sakhalin II Project is the largest integrated oil and gas development project in the world and as such, has a major undertaking for sampling and testing. Environmental and Health and Safety compliance have been important drivers in the development of Sakhalin II both to monitor the field operations and plant processes and to measure product specification and quality test the products. The function of the laboratories on Sakhalin Island include quality testing of oil and gas, process monitoring at LNG plants, testing at upstream facilities and environmental monitoring across the island.

In order to provide a real-time round-the-clock analytical regime, an ultra-modern laboratory was commissioned to be located at the LNG plant/OET. This new central laboratory is also supported by upstream satellite laboratories. In 2007, the state-of-the-art LNG/OET laboratory successfully passed certification tests to the requirements of Gosstandart and the international ISO 17025 standard.

Laboratory specialists are now analyzing samples of oil, gas, chemicals and wastewater from the LNG/OET site. In addition, the laboratory will be used to analyze, as required, samples brought from the Onshore Processing Facility (OPF) as well as managing non-routine samples.

The decision to invest in a new LIMS to manage the sampling process from upstream to sample report was imperative for Sakhalin Energy's new laboratory. Sunil Pandya, the Head of Laboratory for Sakhalin Energy, explains, "Our laboratory has well-defined procedures for essential quality control work, for scheduling samples, to

managing resources and reporting on samples. To manage the workload and integrate with the instrumentation, we selected Thermo Scientific SampleManager LIMS for the laboratory. SampleManager is a widely used LIMS for the oil and gas industry and it is implemented in our main laboratory, in the upstream satellite laboratories as well as for data management of environmental monitoring throughout Sakhalin Energy operations."

Solution

The laboratory provides analytical services to the LNG/OET facilities. It generates analytical reference data for product quality and custody transfer invoicing, calibration of on-line process analyzers, plant performance, equipment condition and environmental monitoring. It also provides expert advice on LNG and crude oil Sales Purchase Agreements (SPAs) and plant troubleshooting. It also provides ad-hoc laboratory services to other Sakhalin Energy assets (OPF, pipelines, offshore platforms).

The majority of samples are taken by operations staff and delivered to the laboratory. Laboratory staff train the senior operators and maintenance technicians to collect samples. Laboratory staff collect special samples that require complex sampling techniques, such as 2-phase samples, flue gas, etc. The sampling and testing requirements are agreed and scheduled with operations, engineering, environmental and technology departments.

Various internal customers use the analytical reference data;

- Operations for plant performance monitoring and product export
- Engineering for equipment condition monitoring

- Technology for efficiency checks and troubleshooting
- Environmental services for environmental monitoring and compliance
- Marketing for customer liaison support
- Finance for invoicing

Objectives

- To provide unbiased laboratory services and advice to LNG/OET and third parties in a timely, accurate and reliable manner
- To achieve and maintain a high standard in health, safety and environmental performance

The new LNG/OET laboratory handles the samples coming from upstream operations, through the LNG plant and the final products. The analyses of final products are performed when the LNG storage tanks are prepared and isolated or during the ship's loading. When sufficient reproducible results are obtained, the mean and weight average composition are both calculated. The mean composition of each cargo is used to calculate density and gross heating value and all values are included on the Certificate of Quality.

Any data required by the business is automatically available from the LIMS with sophisticated automatic data transfer. The LIMS is used to interface seamlessly with critical IT systems including Sakhalin Energy's corporate Energy Components (ER) package and Process Information (PI) system for efficient reporting and documentation support.

Thermo Scientific SampleManager LIMS was selected by Sakhalin Energy because of its pedigree in this industry.



A proven system that works in the rugged demanding environs of the oil and gas industries, SampleManager LIMS is used in many organizations needing to demonstrate regulatory compliance while ensuring optimum product quality. The company required a LIMS that could provide documentation of compliance with ISO 17025, which is the international standard for analytical laboratories developing their data management systems for quality, administrative and technical operations.

Benefits

The Sakhalin Energy facility handles the entire process from extraction to issuing SOPs and Certificates of Quality with all samples tracking managed from within the SampleManager system. The laboratory has to

operate according to GLP/OECD guidelines and uses SampleManager to demonstrate its procedural conformity.

Sakhalin Energy staff use SampleManager LIMS 24/7 to help manage the data from the thousands of samples that are required throughout the sampling stages on Sakhalin Island. Some instruments of the laboratory are planned to be connected into the LIMS so that reports can be accessed centrally and instruments can be scheduled for calibration, etc. from within the LIMS. The data from the facility's state-of-the-art equipment, including GCs, is all directly transferred into the LIMS and SampleManager is tasked with storing and tracking data processed in the laboratory. The LIMS is also used for data trending and analysis, or to identify when product is moving out of specification.

Since the implementation of SampleManager LIMS at the LNG/OET laboratory, major benefits realized include improved sample turnaround times, centralized access to data and improved operational efficiencies. The system also meets the laboratory's need for GLP and ISO 17025 compliance. The solution has been capable of handling standard and non-routine sampling requirements, providing audit trails to track deviations and amendments to each study. Sunil Pandya explains "SampleManager was selected due to its proven performance within the Shell group of companies and in this industry. Our laboratories have been designed from the ground up to support this site – this project represents the new frontier in oil and gas development and our laboratory needed a LIMS that was proven to be reliable in this environment and dependable for the future of the project."

Conclusion

Sakhalin Energy is Russia's largest project in the oil and gas industry and its ultra-modern laboratory has been designed to provide the scientific background to ensure LNG production is maintained year-round. With both a commercial and a scientific driving rationale, Sakhalin Energy has equipped its laboratories with the technologies and infrastructure that allow it to deliver consistent support to the production and shipping cycle of finished product. To deliver this reliability of service while demonstrating regulatory compliance, Sakhalin Energy has standardized on SampleManager LIMS in its new state-of-the-art LNG/OET Laboratory. Since its implementation, the system has allowed Sakhalin to develop and manage a sophisticated sampling program with the objective that all the LNG supplies for the emerging Asia markets will be delivered from Sakhalin Island for the coming decades.

SampleManager LIMS Helps Sakhalin Energy Meet ISO 17025 Requirements

The 2005 release of ISO 17025, General Requirements for the Competence of Testing and Calibration Laboratories, covers laboratories using standard, non-standard and laboratory-developed methods. This international standard is the accepted standard for analytical laboratories developing their data management system for quality, administrative and technical operations.

There are several critical areas of compliance for any oil and gas operation, including security, instrumentation calibration, maintenance of electronic records, traceability of procedures and personnel and environmental and



equipment monitoring. The ability of laboratory managers at Sakhalin Energy to have control of this vital information is an important aspect of the oil and gas operation and ensures that production can continue uninterrupted by changes related to environment, personnel, instrumentation or equipment that falls out of calibration or becomes damaged in the production process.

SampleManager LIMS offers a centralized system to access data and extract information, enabling effective management of laboratory operations. SampleManager LIMS provides evidence and documentation to support laboratory compliance with ISO 17025.

SampleManager addresses the security required for laboratories conducting testing in their “permanent facilities, at sites away from permanent facilities, or in associated temporary or mobile facilities,” by providing full security controls, including “group security,” which can be used to segregate work from different clients or in different laboratory areas. SampleManager’s enhanced functionality covers a broad range of requirements, including validation of methods, instrument calibration, sampling, control of non-conformance testing and reporting of results.

To meet ISO 17025 requirements regarding the “control of non-conforming testing and/or calibration work”, SampleManager has built-in functionality for incident management and statistical analysis of both calibration standards and sample results. SampleManager also automatically maintains all electronic records and makes them available for either reviewing or reporting, and has built-in archiving, which allows for the removal of older records once their retention period has expired. Full audit trail facilities are standard for SampleManager, allowing full traceability of the personnel and the procedures that were entered. These built-in capabilities allow laboratories to more easily review their quality system by having ready access to all incidents, corrective actions, non-conforming results and other events.

To address the Technical Requirements of the standard, SampleManager has built-in functionality to handle environmental monitoring, a critical component of laboratory compliance with ISO 17025. Within SampleManager, environmental monitoring of key areas of the laboratory



can be scheduled on a routine basis. Certain instrumentation can be connected via SampleManager’s Instrument Manager function, and data can be collected and logged at periodic intervals. Validation of methods is a critical ISO 17025 requirement, for which SampleManager has built-in functionality to allow lab managers to be in continuous compliance. SampleManager’s Batch Management functionality provides analytical QA/QC support, including automatic and interactive sample assignment according to pre-defined templates.

Equipment and instrument calibration, also an important part of ISO 17025, is managed by SampleManager through Instrument Calibration Scheduling, allowing the LIMS to prevent the use of any instrument that is past its calibration due date. SampleManager provides reporting that indicates which instruments are out of compliance or need calibration. Finally, to comply with ISO 17025 reporting requirements, SampleManager’s existing functionality includes powerful and flexible report writing, making it possible to create any report format required by the laboratory, and including any data stored within the SampleManager database.

Additional **Case Studies**



If your lab is challenged by increasingly complex data management, let us show you the power of Integrated Informatics Solutions.





Thermo Fisher Scientific has been providing state-of-the-art and enterprise level Informatics solutions for more than 30 years. We are proud to count amongst our portfolio some of the largest global organizations across every industry, including the broadest range of complex customer requirements related to integrated, enterprise-level informatics solutions. Our comprehensive Informatics solutions are designed to deliver full laboratory functionality for method execution, laboratory and data management on one proven platform – LIMS, LES, SDMS, in addition to full integration with CDS and other laboratory instrumentation.

As an organization, Thermo Fisher Scientific is committed to providing comprehensive enterprise-level informatics solutions that encompass ISO 9001-certified quality software, implementation, training, and ongoing technical support. Our Quality Management System (QMS) is registered and certified by ISO 9001 requirements, and includes all of our software development locations around the world. This ISO registration covers our Quality Management System for the design, development, sales, implementation and support of all our computer based laboratory information automation systems.

The global scale and comprehensiveness of the continuous ISO certification of our Quality Management System is unique in the industry. Across the full range of life sciences, from bioanalytical labs, to R&D, pharmaceutical manufacturing and QA/QC labs, Thermo Scientific Integrated Laboratory Informatics are helping our customers meet their laboratory and business goals.

For more information about Thermo Scientific Integrated Informatics solutions for the oil and gas industry, visit www.thermoscientific.com/SM11 or contact us at marketing.informatics@thermofisher.com

