

实验室信息管理系统

很多时候，企业会视政府法规、标准和监督累赘、麻烦，有些人甚至会说是乱来。如果企业反过来能将如ISO 17025等标准看成可靠、高品质运营的实验室清单，可能会受益无穷。本文探讨了一个集成的数据管理解决方案，如实验室信息管理系统（LIMS），如何可以帮助石油和天然气公司遵守ISO 17025标准以及其实际上可以作为一种催化剂获得更好的整体表现

Laboratory information management systems

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

根据ARC咨询集团最近的“ARC View”，“烃加工实验室正成为几乎像第三方服务的实验室。”该软件的作者Paula Hollywood继续说，“这意味着，拥有如ISO 17025等标准认证不仅仅好，对于确保一致性和客户满意度也是必要的。”在一个真正的第三方实验室的情况下，这里的关键是客户的满意度，无论客户是内部的还是外部的。合规性，换句话说，不是LIMS的最终目标；提供更高质量的产品和客户满意度才是。

那么，LIMS和ISO 17025等法规如保持一致或相互配合呢？从根本上讲，ISO 17025和LIMS在12个重点领域重叠，该标准下面的章节中将会列出：

- 4.4. 要求和合同的审查
- 4.6. 采购服务和耗材
- 4.8. 投诉

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

- 4.9. 不符合要求测试的控制
- 4.10. 纠正措施
- 4.11. 预防性行动
- 4.12. 记录
- 5.2.5 人员培训和授权
- 5.4.5. 方法验证
- 5.5. 设备
- 5.9. 测试结果的质量保证
- 5.10. 报告结果

快速浏览一下，你会看到，每一个领域都注重应该已经有全体员工遵守最佳实践的实验室业务的一个方面。但坚持最佳实践哲学有很大的不同 - 相比采集要简单得多，管理和报告方法、时间、人员和与下面标准相关的方面。

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

一个行之有效的综合数据管理系统，如Thermo Scientific SampleManager LIMS，目的是为了减轻与这些软件自动连接的复杂性，让符合石油和天然气实验室规定更容易，而最重要的是，揭露先前未确认的增进表现的机会。让我们来探讨LIMS如何可以帮助将合规转化为机遇。

在同一页上

ISO 17025第4.4和4.6节同一页上阐述了任何企业以及内部或外部客户的基本最佳实践。对于不同的客户在不同的情况下，正在执行哪些测试、必须怎样处理样本、必须使用哪些耗材等差异很大，放松遵守可能要付出高昂代价，特别是在涉及解决任何争议时。审

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 how's, when's, who's and what's 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 & 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

Section 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

边栏：库页岛II

库页岛II是世界上最大的综合性石油和天然气开发项目，该项目证明对于LIMS来说，没有什么要求 – 环境条件 – 是过于苛刻的。该项目还揭示ISO 17025合规以及追求产品质量如何一并实现。

在库页岛II超现代的实验室现场提供二十四小时的陆上和海上餐饮、环境和安全监测及水质质量控制和分析测试。虽然ISO 17025规定需要验证分析方法、仪器校准和安全控制措施等，但有了LIMS，实验室可以做得更多。

库页岛II实验室管理严格的LIMS系统每日范例时间表，包括氮、甲烷、乙烷、丙烷、丁烷气体的分析，以及二氧化碳、硫化氢、硫醇、硫化羰（COS）和总硫含量的定量分析。可以确保实时合规同样的系统还可促进从每批货物计算密度和总热值到签发合格证的质量控制。

在这种复杂的操作的情况下，LIMS不仅仅是合规工具。在库页岛II实验室等设施中，LIMS可以取代效率低下、基于风险高纸张的流程，转而采用度集成的自动数据采集和传输，消除手动流程所造成的错误。不仅监管机构，影响产品质量和整体盈利能力的驱动商业决策的决策者也可以及时获得数据。

计过程中跟踪此信息并作出证明似乎是苛刻的，但在现实中，这只是良好的业务。因此，事实上，LIMS中删除“太费时”的异议，其余的全是商业利益。

根除低效

在一个复杂的行业中，如石油和天然气行业，我们要学会预料意外之事。第4.8至4.10节阐述了管理事件的正式程序，不是简单地推卸责任，而是要迅速解决问题，避免同类事件再次发生。在LIMS的“事件管理”的功能包括针对不同的事件类型的模板，定义所需的行动并对通过成功封堵响应进行归档。通过LIMS，实验室不仅可以加快事件响应以及由此产生的投诉，而且还会有一个永远学习的数据库，不断根除低效和风险。

预防无小事

第4.11节规定实验室要确定不合规的潜在来源。这可以公开

进行何种测试、如何处理样品、使用什么产品、哪些供应商是合格的，这些问题的答案对于不同的客户及不同的情况是具有很大差异的，放松坚持可能会付出很大的代价，特别是在解决分歧时

一个集成的数据管理解决方案（LIMS），如可以帮助石油和天然气公司遵守ISO 17025标准的实验室信息管理系统

An integrated data management solution, such as a laboratory information management system (LIMS) can help oil and gas companies adhere to ISO 17025 standards



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



分析“面临失控”，甚至那些在技术上还“规范”的进程。如果没有一个系统来识别，如LIMS统计质量控制（SQC）和分析质量控制（AQC）工作表和图表，实验室工作人员几乎不可能发现可能存在的问题。

SQC / AQC图表也是验证方法（参见5.4.5节），并确保测试结果质量的有价值的工具。许多人认为，第5.4.5节实际上是ISO 17025最重要的章节。有机会获得一个一目了然的图表作为早期预警系统并视觉性能监视器使用提供的好处远远超出合规。

积极主动的石油和天然气实验室可以对与氮、甲烷或丙烷含量

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 authorised, 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

有关的数据趋势作出标记，例如，使用的LIMS作为一种工具来监视质量和可能的环境或安全的影响。AQC工作表包括初始化检查、校准检查、干涉检查、矩阵轴辐、副本和其他信息等可以公开的模式，包括实验室需要警告的特定模式。

报告好消息

报告最繁重的一部分是编制数据。然而，随着LIMS访问控制可以确保每个步骤、每一次访问被授权、记录和存储。相应的文件、注释和外部链接伴随访问每次访问的实例，创建容易访问和审查的审计跟踪。再次，ISO 17025合规可能表示访问控制制度和相应的文档，但不可否认捕获该表现评估信息是需要智慧的。如果没有LIMS，这将肯定是一个负担，而借助LIMS，这是一项最佳实践。

合规性流程可以是提高整体设施和表现及盈利能力综合方案的一部分

装备精良

一个复杂的石油和天然气实验室维护的技术清单包括仪器仪表、备品备件、消耗品和互补的实验室设备。ISO 17025要求实验室必须保持每件设备和适当的校准的全面记录。这可能是特别沉重的负担，特别是在大型实验室和/或与卫星或伙伴实验室上游和下游有合作关系的实验室。但将LIMS作为记录系统使用，负担变成利益且企业中的利益相关者可以开始获取通知企业范围内的实验室效率、表现和资本设备决定的信息。

行业寻求部署新的勘探、开采和加工技术时，石油和天然气的实验室必须解决所面临的各种分析方面挑战的困难。ISO 17025解决了使用新的或非标准的方法，并提供了一个框架，用于捕获所有相关信息。这意味着，结果的用户可以肯定，生成该信息使用了最佳实践，实验室可以相信，新的方法可以成功地开发和再造。

结论

石油和天然气公司可能将一些法规，如ISO 17025看成负担或催化剂。在LIMS之前 - 以前无法运作无纸化实验室 - 合规确实是费时且昂贵。然而，现在，合规性流程可以使提高整体设施和多表现及盈利能力的综合方案的一部分。ARC View认为，“符合ISO 17025表明对质量的承诺，并为客户提供实验室的管理和技术要求符合全球公认的最佳实践的保证。由SampleManager LIMS编制的文件证实客户和监管当局的测试实践和数据质量可信。”因此，开始实施该法规作为动力或只是希望提高质量的石油和天然气行业的实验室，采用LIMS最终的结果是相同的：一个综合系统，让两个世界最好。

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 sulfur 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 as 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.

practices were used in generating that information and the lab can be confident that new methods can be developed and reproduced successfully.

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. ■

赛默飞世尔科技公司SampleManager实验室信息管理系统

为您带来Connected Productivity™：最具安全性能的产品，最具可持续性的流程，为所有利益相关方创造卓越的价值

无论您的企业从事哪一行业，生命科学或是食品饮料行业，石油与天然气或是石油化工，环境保护或是饮用水和废水处理，金属与采矿或是水泥生产，电力与公用事业或是化工制造业，我们面对的都是相同的基本业务问题。

- ▶ 我们如何在全球范围内提供最安全的产品——使用标准化流程、满足规范要求、确保员工安全并监测整个供应链的质量？
- ▶ 我们如何在业务中应用最具可持续性的流程——减少能源使用、减少浪费、采用更多的自动化技术？
- ▶ 我们如何在实现这些的同时仍保持盈利——更好地利用我们所有的资源，制定更具协调性的流程，降低风险，同时不断寻求流程的改进？



我们向您推荐SampleManager 10——目前全球应用最为广泛的实验室信息管理系统，提供更加全面的企业级应用程序，该应用程序可满足企业基础建设中三个各不相同但相互关联的部分——实验室人员、IT和系统管理员以及管理人员切实的业务及运营需求。

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适用于管理人员

最先进的数据可视化工具，依据主要指标进行性能监控与测量。

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