White Paper

Employing Flexible Data Management Solutions that Deliver Improved Productivity and Quality in the Water and Environmental Industry

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Key Words

- Clean Water Act
- Cost Containment
- EPA
- Instrument Integration
- ISO 17025
- Laboratory Automation
- Preparation and Analytical Batches
- Regulatory and NELAC Compliance
- Reporting
- Traceability

Introduction

This article will discuss the industry trends and challenges environmental monitoring organizations face today and will demonstrate how the use of a Laboratory Information Management System (LIMS) allows managers to make informed decisions to improve throughput, resolve environmental issues and risks faster, all while enabling organizations to comply with strict regulatory guidelines. An application example will illustrate how the flexibility and functionality of a LIMS can improve workflow efficiencies, productivity and sample integrity as well as ensure adherence to regulations governing environmental testing.

Environmental and wastewater testing laboratories face unique challenges when it comes to delivering accurate, consistent and traceable results. Furthermore, the current economic environment contributes additional pressure to standardize workflows and processes that facilitate regulatory compliance, ensure public safety and monitor quality throughout the entire sampling, testing and reporting process.

The History and Impact of Regulations

Environmental and water quality regulation in the United States began in 1889 with the Rivers and Harbors Act which gave authorities the power to regulate obstructions to navigation and effluent discharged into the rivers. Subsequent legislation put into action the requirement to monitor water sources, wastewater and effluent for contaminants that could be hazardous to health and the environment at large. Today, regulation places a significant emphasis on the monitoring of wastewater treated discharges and receiving waters. This covers bacteria, chemicals including nitrates and pesticides, metals (i.e., lead), as well as basic criteria such as turbidity. Compliance with accreditation requirements for environmental testing now mandates that the laboratories capture, store and track growing volumes of information to demonstrate that samples, results and records have been collected according to requirements.

Wastewater treatment organizations are responsible for collecting and treating wastewater, monitoring discharges and receiving waters, and regulating industrial discharges to ensure that harmful and toxic materials are kept out of the water and the wider environment. As a result, the laboratories that support them take many thousands of samples every year for testing in order to guarantee the water is safe and that quality standards are met. These samples can be taken from natural water sources, sewers and organizations as diverse as dental clinics, energy service providers and manufacturers.

The Crucial Role of LIMS

To demonstrate regulatory compliance, laboratories are equipped with the technologies and infrastructure that allow them to deliver consistent support to monitor and ensure the quality of the water. A LIMS can play a crucial role by enabling these laboratories to deliver a reliable service while demonstrating regulatory compliance. Perhaps, more importantly, a robust LIMS can also provide the flexibility necessary to cope with changing demands and practices as regulations and testing protocols are updated. A key benefit of the LIMS is improved operational efficiency as it provides the laboratory with a centralized tool for comprehensive sample recording, management and reporting. By automating and integrating the LIMS with laboratory instrumentation as well as external systems, time consuming manual processes and transcription errors are eliminated.

Sample Management Workflow in the Environmental Analysis Process

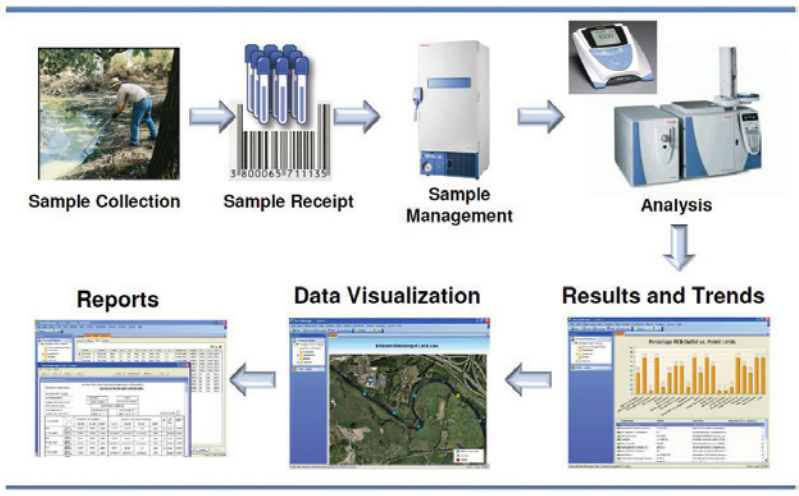

Figure 1. Thermo Scientific informatics solutions deliver end-to-end tracking for the environmental analysis process, from sample collection to analysis, results and data visualization to reporting.

A LIMS can help to determine the quality of wastewater and environmental waters, demonstrate compliance with industry regulations and track and manage laboratory operating costs and processes more efficiently. LIMS are invaluable tools in helping environmental monitoring laboratories assist treatment operations to achieve compliance with Federal and State clean water standards, as well as facilitate the automation of its processes to create an extremely cost and time efficient laboratory.

Such use of a LIMS in the environment and wastewater testing industry is increasingly widespread due to the advantages it brings with regards to sample tracking and data management capabilities. Moreover, a LIMS helps ensure that an operation is compliant with regulations during its treatment and analysis of wastewater. While a LIMS has built in functionality specifically designed for the water and environmental industry, it can also be configured to meet a company's evolving business model practices. With the right high-end LIMS, a laboratory can be confident that the data system does not dictate how operations are run. Rather, its flexibility can allow the system to reflect how a company wishes to operate.

An Application Example

A typical mid-western wastewater treatment agency (the Agency) employs a LIMS not only for its sample tracking and data management capabilities but, more importantly, for its flexibility to be quickly customized to meet rapidly changing requirements in the environmental monitoring arena. The LIMS has the ability to constantly evolve in little and big ways to stay in tune with the company's business models. This ease in extendibility has allowed the Agency to configure the LIMS to meet its ever changing needs and practices.

In addition, the Agency works with over 1,000 industrial clients to substantially reduce the amount of pollution entering the wastewater collection system. This Agency issues a license to each client and performs regular monitoring under the terms of the license. Each client must test its discharge through properly constructed test and analysis regimes and report their findings regularly – the Agency then uses its LIMS to conduct spot checks to ensure that legitimate data are being reported.

Tracking Costs and Improving Lab Productivity

Our example laboratory found that its LIMS can also be configured to act as a cost tracking system, recording where and what areas it is spending its time and then allocate budget accordingly. In past decades, this was completed by using a paper based recording system. With the flexibility of the LIMS, these processes were automated so employees log into the database on specified intervals and indicate where their time has been spent. The system calculates hours spent per analysis in real-time, enabling more timely, efficient and accurate records. Managers can use this information to determine how efficient their operations are running and implement continuous improvement measures to increase lab productivity. With this kind of real-time monitoring, changes in analytical time productivity can be spotted and issues can be identified and addressed. This productivity tool also provides more credible data that demonstrates the positive results of implementing productivity enhancement strategies.

Permit Reporting Module and Regulatory Compliance

As required by the Clean Water Act, the National Pollution Discharge Elimination System (NPDES) permit program controls water pollution by regulating point sources that discharge pollutants into waters of the United States. Every discharger must have a permit and file monthly reporting of data, including complex calculations such as rolling average limits. Prior to implementing the LIMS, all permits at the Agency were done by hand. In the late 1970s, a primitive Fortran system was used to collect all necessary data and produced an output report which was manually transcribed to create the official reports issued by the state. Every time a new permit was issued, new rules and how data needed to be reported would be introduced. As a result, the Fortran program had to be rewritten and the old code did not always get saved; at that point, rerunning the NPDES permit report for a prior period would not produce the same result. As the Agency is responsible for being able to verify the correctness of calculations used to generate reports, the loss of code documentation was a real concern.

One of the most important customized reporting tools that the Agency implemented is the NPDES Permit Reporting Module so all of the appropriate data would be stored and then reported within the LIMS. Now when a permit change occurs it can easily be incorporated and the previous code that was applicable in the past is retained. The LIMS now keeps a complete history and when old reports are rerun, the LIMS implements the code that was in place at that time. The Permit

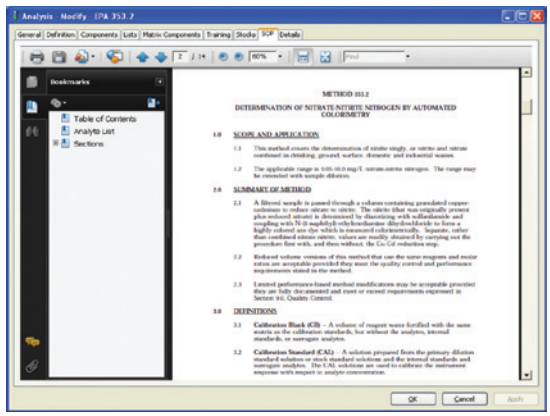

Figure 2. The ability to link external documents such as Standard Operating Procedures (SOPs) to analytical methods further demonstrates the ability of SampleManager LIMS to integrate critical laboratory information through one central source. Integration to instrument software and other enterprise systems ensures SampleManager is flexible and expandable to fit your business operations.

Reporting Module is extremely granular and allows the company to effectively manage NPDES permits, discharge points, parameters and samples. This is vital for how laboratories do their work and document the accuracy of historical processes.

Due to its flexibility, the same reporting module is also used to electronically report a complete set of process control data every hour to all of the treatment plant operators to help facilitate efficient and compliant running of plants. In the past each section of the report had to be distributed via paper using an in-house designed report format.

Tracking Warehouse Orders and Costs

The LIMS also provides an automated system to track warehouse orders and costs. The Agency built a module that mimicked its warehouse ordering system so lab employees can easily track and manage warehouse orders using simple drop-down lists. This eliminates errors associated with filing and paperwork and provides management the ability to track warehouse costs in a very efficient manner. In addition to labor hours, expendable costs and equipment amortization are components of the larger picture of productivity – the total cost of units of analytical work. The tracking of all material purchasing costs (and trends) in the LIMS allows this information to be seamlessly merged with labor and other costs into real-time measures of the total cost of doing business.

Automating Lab Operations with Instrument Integration

Automating sample handling by integrating the LIMS with instruments has dramatically improved data quality and lab efficiency. By integrating the LIMS with inorganic auto analyzers, the Agency utilizes and automatically populates worksheets with results and approved methods to eliminate manual, error prone processes. Worksheets can be created to set up batches (analytical runs) and create a 'run list' to organize samples, ensuring sample accuracy and improving process efficiencies. With this automated bidirectional exchange of data, between the LIMS and instrumentation, all information is stored in the LIMS, making certain that reliable methods are always used and data quality is preserved. Again, the flexibility of the LIMS allows for easier configuration to accommodate the large variety of instrument data formats.

Ensuring Regulatory Compliance and Traceability

The use of a LIMS provides the Agency with a corporate standard for sample tracking and data management, enabling efficient testing of all samples that pass through the laboratory for process testing and quality assurance purposes. Furthermore, the LIMS facilitates the efficient electronic collection, movement, storage and tracking of data and results. This enables the lab, plant operations and its clients to improve productivity and efficiency all while ensuring regulatory compliance.

Our example utility agency must ensure that their laboratories are able to constantly evolve in order to keep up with scientific advances and regulatory changes. Their LIMS can be easily adapted to help them meet these needs. It is easy to search and find specific times in the database and formulate reports. By centralizing projects and standardizing processes, managers can quickly and easily search data i.e. for gathering and presenting reports to inspectors, demonstrating full compliance and ensuring that regulatory requirements have been met.

A key feature of the flexible LIMS is the ability to have a "one stop shopping" environment for all Lab operations. All data is centralized and accessed through the standard LIMS interface. For example, all analytical Standard Operating Procedures are stored in the LIMS and are immediately reviewable at any point in the analysis. Even the Lab Quality Assurance Manual is one click away from the LIMS opening screen. This centralization of storage and access assures greater consistency and standardization across all laboratory processes.

Figure 3. These **twelve essential quality control (QC) checks must** be clearly documented in the written SOP (or method) along with a performance specification or description for each of the twelve checks.

1. Demonstration of Capability (DOC)
2. Method Detection Limit (MDL)
3. Laboratory reagent blank (LRB), also referred to as method blank
4. Laboratory fortified blank (LFB), also referred to as a spiked blank, or laboratory control sample (LCS)
5. Matrix spike, matrix spike duplicate, or laboratory fortified blank duplicate (LFBD) for suspected difficult matrices
6. Internal standards, surrogate standards (for organic analysis) or tracers (for radiochemistry)
7. Calibration (initial and continuing), initial and continuing performance (ICP) solution also referred to as initial calibration verification (ICV) and continuing calibration verification (CCV)
8. Control charts (or other trend analyses of quality control results)
9. Corrective action (root cause analyses)
10. QC acceptance criteria
11. Definitions of a batch (preparation and analytical)
12. Specify a minimum frequency for conducting these QC checks

Reporting: Regulatory Reports, DMR

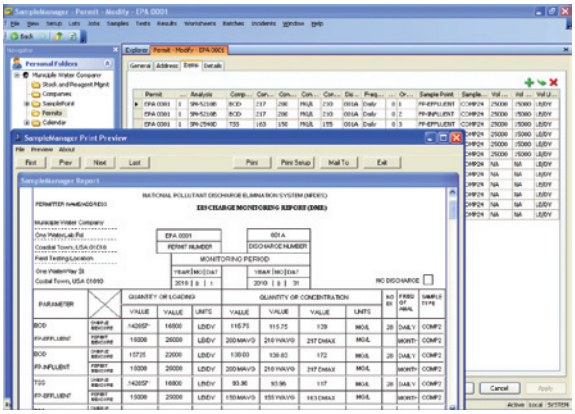

Figure 4. Pre-defined report templates allow customers to automatically generate regulatory required reports at a fraction of the time.

Data Visualization: Dashboards

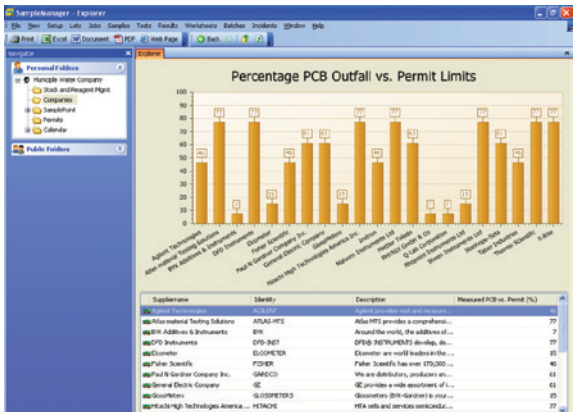

Figure 5. Dashboards provide graphical representations of information to allow laboratory management and analysts to visualize critical information in various forms.

Today's Challenges and Future Requirements

Within the environmental monitoring industry, there are always new requirements and growing needs that need to be addressed. One such example can be seen in the ever increasing need to standardize QA/QC processes, specifically in automating the QC aspect of the laboratory. Recently, organizations and ideas are converging and a fixed set of requirements are being identified. There is an increasing understanding between the various regulatory groups which means laboratories are much more clear about what needs to be done and how to automate all QC work done by laboratories.

With the evolution of analytical and regulatory communities over the last 15 years, environmental monitoring companies need to implement next generation tools that allow them to adapt and stay relevant. For example, all water resources have to be managed in compliance with regulatory requirements, including those outlined by the National Environmental Laboratory Accreditation Conference (NELAC). This has been driven by the US Environmental Protection Agency (EPA), as well as State programs that certify laboratories to ensure that quality protocols are in place. The EPA has developed a list of 12 QC elements (Figure 3) that need to be part of all approved methods – one being that every analytical method has to be defined as a batch and then assessed and tracked against quality indicators. Companies in the wastewater treatment industry must be able to demonstrate that batches are being tracked from the initial stages through to completion, with detailed information including reagent expiration dates, how much reagent is being used, when the reagent was purchased and what chemicals have been added. Environmental laboratories require a LIMS that has efficient, effective QA/QC and data tracking capabilities that are built around batches. Their core capabilities have to be able to meet EPA/NELAC batch requirements and automate the tracking and reporting of all data, components and history.

Conclusion

The environmental monitoring and wastewater industry is constantly evolving, with regulations frequently impacting organization's day-to-day operations and business strategy. A flexible LIMS will enable environmental monitoring companies to meet these changing business processes and developments. LIMS vendors, such as Thermo Fisher Scientific have developed purpose-built LIMS for the water and environmental market by incorporating industry specific functionality such as automated sample scheduling, operator training records, SOP storage, data visualization dashboards and flexible reporting tools that enable effective project management, tracking of samples and general status reporting of samples as they progress through testing, all while ensuring records or sample history are easily accessible by regulatory management authorities. A flexible LIMS is an invaluable tool that can be configured and integrated within an organization, allowing processes, both inside and outside the laboratory environment, to be automated for greater efficiency.

Collaborators

We thank, John Hubbling, Laboratory Services Manager, Metropolitan Council Environmental Services for his expertise, scientific advice and input.

For More Information

For more information on Thermo Scientific Water and Environmental LIMS, please visit **www.thermoscientific.com/waterandwastewater.**

You may also contact us for immediate assistance at +1 866-463-6522 (US), +44 161 942 3000 (EU) or e-mail marketing.informatics@thermofisher.com

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