INTERDEPARTMENTAL POSTGRADUATE PROGRAM
MASTER IN BUSINESS ADMINISTRATION

POSTGRADUATE THESIS

THE USE OF LABORATORY INFORMATION MANAGEMENT SYSTEMS (LIMS) AS A LEAN MANAGEMENT TOOL IN ANALYTICAL LABORATORIES

by

IOANNIS NISYRIOS

Supervised by
Prof. Katerina Gotzamani
Dept. of Business Administration
University of Macedonia

Submitted for the fulfilment of the requirements for acquiring the degree of
Master in Business Administration

Thessaloniki
September 2017

Στην Ελένη, που με στηρίζει σε κάθε μου βήμα
και δέχτηκε να μεταναστεύσει μαζί μου.

Abstract

The principles of Lean Management, once limited to the manufacturing sector, are being increasingly studied and applied in the services sector and more specifically in the field of commercial analytical laboratories. Large analytical laboratories benefit from the application of Lean Management, as this gives them a toolset for streamlining production and eliminating waste for the benefit of the client and their surrounding enterprise. Laboratory Information Management Systems (LIMS) are information systems aimed at minimising the administration load of the laboratory and automating the demanding and prone-to-error tasks of sample and data management within the laboratory.

This dissertation examines the use of LIMS as a tool for Lean Management in the analytical laboratory, by studying two cases of different size, commitment to Lean Management and stage of implementation of LIMS. It is indicated that LIMS is a very basic tool in applying Lean Management practices within the analytical laboratory and contributes invaluably to the workflow management of analytical production.

Περίληψη

Οι αρχές της Λιτής Παραγωγής, οι οποίες κάποτε περιορίζονταν στον κλάδο της παραγωγής αγαθών, μελετώνται και εφαρμόζονται με αυξανόμενο ρυθμό και στον κλάδο των υπηρεσιών και πιο συγκεκριμένα στο πεδίο των επιχειρήσεων παροχής αναλυτικών εργαστηριακών υπηρεσιών. Τα μεγάλα αναλυτικά εργαστήρια επωφελούνται από την εφαρμογή των αρχών της Λιτής Παραγωγής, καθώς έτσι τους παρέχεται μια εργαλειοθήκη για την εξομάλυνση της παραγωγής και την μείωση της σπατάλης προς ωφέλεια του πελάτη και της επιχείρησης. Τα Πληροφοριακά Συστήματα Διαχείρισης Εργαστηρίου (Laboratory Information Management Systems, LIMS) είναι πληροφοριακά συστήματα που στοχεύουν στην μείωση του διοικητικού φόρτου του εργαστηρίου και στην αυτοματοποίηση των απαιτητικών και επιρρεπών σε σφάλματα διαδικασιών της διαχείρισης δειγμάτων και δεδομένων μέσα στο εργαστήριο.

Η παρούσα εργασία εξετάζει την χρήση των LIMS ως ένα εργαλείο Λιτής Παραγωγής στο αναλυτικό εργαστήριο μέσα από την μελέτη δύο περιπτώσεων αναλυτικών εργαστηρίων με διαφορετικό μέγεθος, δέσμευση στις αρχές της Λιτής Παραγωγής και βαθμό εφαρμογής του LIMS. Διαφαίνεται ότι τα LIMS είναι ένα πολύ βασικό εργαλείο για την εφαρμογή πρακτικών Λιτής Παραγωγής στο αναλυτικό εργαστήριο και συνεισφέρει σε ανεκτίμητο βαθμό στην διαχείριση της εργασιακής ροής στον χώρο της παραγωγής αναλυτικών υπηρεσιών.

Contents

List of illustrations

1. Introduction

In academic institutions the focus lies in the experiment and its educational or scientific importance. On the other hand, commercial analytical laboratories, the application of science is a means of making profit and it is constrained by the needs of the modern enterprise – to provide services of good quality, at the agreed time, at a reasonable cost and with a profit. The profit margin in analytical laboratory enterprises is further limited by the high operational costs due to the high capital and maintenance costs of the scientific equipment and the high human resource costs of the scientific personnel. This study is concerned with environmental analysis laboratories, which are laboratories whose analytical matrix is typically soil or water. However, the findings of this research can readily be applied to other analytical laboratories, such as healthcare or forensics.

Commercial analytical laboratory operations have similarities to manufacturing work operations: There is a flow of incoming samples to which work has to be conducted on a variety of workstations which work in parallel; the final product is the analytical information which is required by the client – each workstation adding value to the final product by providing results on a specific set of analytes; the addition of value is conducted by the work of the analysts using instruments, techniques and reagents; finally, the results have to be delivered to the client at the agreed time and at the agreed quality.

Therefore, it is not strange that Lean Manufacturing practices are being applied in laboratory operations, especially in larger laboratories which handle a large number of samples, giving rise to the notion of Lean Laboratory Management. This term describes the set of Lean Management practices that are applied in laboratories and can benefit the laboratory and its surrounding enterprise by reducing waste, as it is defined in Lean Manufacturing, and optimising processes to the benefit of the client.

Furthermore, over the last 25 years, laboratory management software called Laboratory Integrated Management Systems (LIMS) is increasingly used in analytical laboratories to reduce the inevitable administration load of sample registration, data recording, result calculation and certificate of analysis issue. One of the prime reasons for the implementation of LIMS is allowing the laboratory to concentrate on producing value for the client and not consume valuable resources in administrative work.

As it can be seen, the implementation of Lean Laboratory Management and LIMS is aligned towards the satisfaction of the client. However, the scientific literature lacks in linking Lean with LIMS. In this dissertation, we will aim to study the extent to which LIMS benefits Lean Laboratory Management as a tool for its implementation, by examining its usage by two analytical services companies, one in Greece and one in the UK. These two companies process different numbers of samples and have also differences in their commitment to Lean Management and their extent of the implementation of LIMS. It would be interesting therefore to examine the differences in their approach to laboratory processes, their commitment to Lean Management and their reliance on LIMS.

2. Literature Review

2.1 Environmental analytical laboratories

Analytical chemistry is the study of the chemical composition of matter and provides the answer to two questions: *"What is it?"* (qualitative analysis) and *"How much is it?"* (quantitative analysis). Analytical chemistry is performed in analytical laboratories by specially trained personnel (analysts) using defined scientific methods. The analytical process generally follows the following scheme:

- Definition of the analytical problem in collaboration with the client
- Provision of a representative sample.
- Decision of the appropriate analytical method.
- Preparation of sample for analysis.
- Performance of measurement according to the recommended method.
- Calculation of results and reporting of data. (Christian, 1994)

For each analyte that needs to be determined, the laboratory has a choice of traditional and instrumental analytical methods of varying accuracy, ease of use and cost and the choice is made according to the laboratory's capability and capacity. Most analytical methods have been time-tested and established scientifically and can be found in the relevant scientific literature. For environmental laboratories (laboratories whose main analytical matrix is water and soil, as defined by EPA, 2017), popular sources are the Standard Methods for the Analysis of Water and Wastewater by the American Public Health Association (Rice *et al.*, 2012) and the US Environmental Protection Agency publications (EPA, 2017). Furthermore, scientific journals and even university-level reference books are used as well, as long as the methods have been scientifically proven to provide results which are fit for the purpose of the analysis.

There is an ever increased focus on the quality of the results of analytical laboratories, and this is especially the case with environmental analysis laboratories, as environmental and public health protection is a major issue worldwide. In the European Union, the relevant legislation includes the Council Directive 98/83/EC (1998) concerning the quality of water intended for human consumption, and the Council Directive 86/278/EEC (1986) concerning the use of sewage sludge in agricultural soil, which both set specific acceptance limits to a number of chemical parameters. Furthermore, soil analysis for agriculture provides an accurate image of the nutritional composition of the soil, which in turn is an invaluable guide for efficient crop resource management and effective fertilisation (Cottenie, A., 1980).

2.2 Laboratory operations

2.2.1 Quality and accreditation

Quality in analytical laboratories is an ongoing challenge which leads to scientific and operational development and it has become a factor of competition between laboratories, which is more pronounced in the modern globalised economy. Therefore, the development of a quality system in the laboratory is of upmost scientific and operational importance, both internally (for the scientific and operational continuous improvement of the laboratory) and externally (for maintaining the laboratory's competitive position in the market). (Benoliel, M.J., 1999)

The sole existence of a quality system in the laboratory is not indicative of the laboratory's capability to offer quality services to its clients. For this to happen, the laboratory has to be accredited by an authoritative body, which recognises the technical ability of the laboratory to perform specific analytical tests. This accreditation body acts as an intermediate, establishing confidence between the laboratory and its clients and thus removing barriers to international trade, as the relevant accreditation is globally recognised. (Cortez, L., 1999)

The current standard that collectively describes the requirements for the accreditation for an analytical lab is ISO 17025:2005 "General Requirements for the Competence of Testing and Calibration Laboratories". The accreditation certificate is awarded by the national accreditation body of each country, which in turn is has signed the Mutual Recognition Agreement of the International Laboratory Accreditation Cooperation and is peer-evaluated according to ISO 17011 (ILAC, 2017). For Greece, the national accreditation service is ESYD (ΕΣΥΔ, Hellenic Accreditation System) and for the UK it is UKAS (United Kingdom Accreditation Service).

By being ISO 17025 accredited a laboratory benefits from the following:

- Meeting regulatory requirements (e.g. EU directives state that export food testing laboratories should be accredited)
- Ability to meet governmental tender requirements
- Enhancement of the reliability and status of the laboratory in the industry
- Reduction of errors and, therefore, reduction of cost
- Legal standing of produced results. (Koupparis, 2016)

The ISO 9001 standard is incorporated into ISO 17025 (Chapters 1-4), hence a laboratory that is accredited by ISO 17025 is automatically also certified by ISO 9001 for its accredited operations. However, ISO 17025 further emphasises the requirements for the technical competency of the lab (Chapter 5) as regards to

- Personnel
- Accommodations and environmental conditions
- Test methods and method validation
- Equipment
- Sampling
- Test reports

2.2.2 ISO 17025 operational requirements and practical considerations

The ISO 17025 standard gives specific directions as regards to technical parameters of the accredited methods. Most important in the everyday operation of the lab are:

- Method validation: all validated methods should be experimentally proven in-house that they meet the requirements for their purpose
- Quality assurance of tests: quality control procedures should be in place in order to monitor the validity of tests undertaken.

The standard does not specify the practical aspects of these considerations. A number of technical guides are available, such as the CITAC/EURACHEM "Guide to Quality in Analytical Chemistry: An Aid to Accreditation" (2002), the JCGM GUM Guide (2008) and the NORDTEST "Internal Quality ConTroll: Handbook for Chemical Laboratories" (2011), which is frequently used by environmental laboratories.

In order to validate a method, the parameters of accuracy, trueness, precision, ruggedness, detectability, specificity, sensitivity, linearity and working range should be assessed experimentally in the lab for all matrices for which accreditation is awarded. In this way, the laboratory is able to demonstrate the knowledge of the uncertainty of measurement for the whole range of its application. The aforementioned parameters supersede the field of analytical chemistry and their importance has given rise to the science of chemometrics, which is "the application of mathematical methods to the solution of chemical problems of all types" and rely heavily on applied statistics and the use of computers in processing large amounts of laboratory-produced data (Miller and Miller, 2000).

The most important tool of the laboratory analytical control is the use of the control chart. As the true value of the analyte in the samples is unknown, a known control sample of similar composition and analyte concentration is tested together with the batch of unknown samples. The value of the measurement of the concentration of the analyte in the control sample is compared statistically to the historical measurements of the concentration of the analyte in the control samples in the laboratory and hence the performance of the measurement of the analyte in the unknown samples can be assessed by supposing that the measuring capability of the instrument or method is stable.

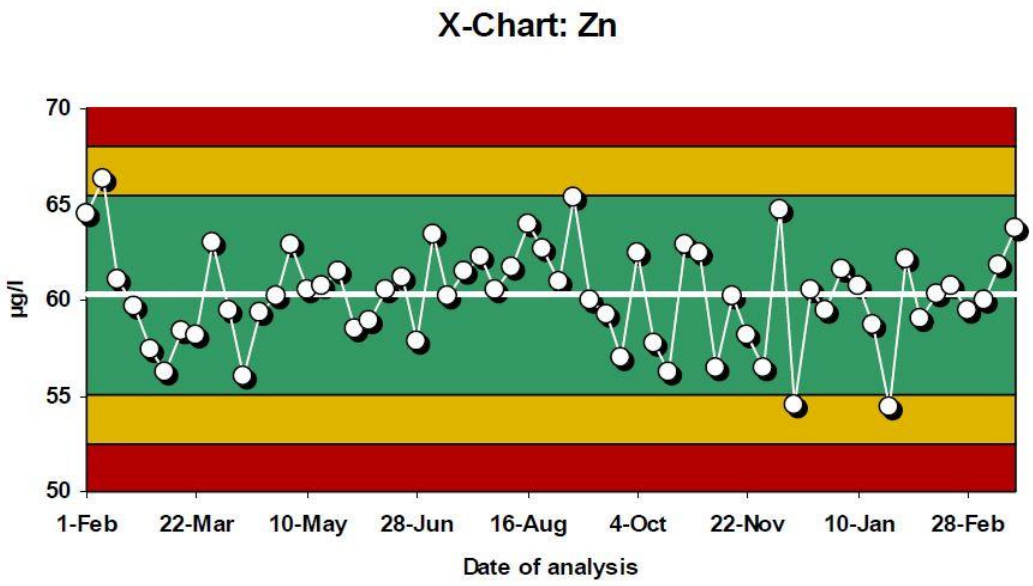


Image 1: A typical laboratory control chart for the determination of zinc (Zn). The control sample has a concentration of 60 µg/L. (NORDTEST, 2011)

As it can be seen in *Image 1* for an example control sample of zinc concentration of 60 µg/L, the obtained values from the method measurements vary over time, something which is expected. As long as this variation is random and is within the set limits, the analysis is performed within statistical control. The Shewhart limits of ±2σ and ±3σ are derived statistically from the laboratory operational data, under the supposition that the variation follows the normal curve. When the analytical process is under statistical control, the results are reported to the client with a 95% confidence and when the analytical process is outside statistical control (e.g. whenever a non-random trend is observed or control results are outside the set limits), testing stops and an investigation is undertaken in order to identify any systematic errors. Apart from control charts, other analytical control methods are also employed, such as the use of blanks, the definition of instrument system suitability checks and the participation in interlaboratory proficiency testing schemes. (NORDTEST, 2011)

In addition to the above, two more major practical considerations as per ISO 17025 are the requirement for the provision of a system for the unique identification of samples and the traceability of test results. Under this requirement, every sample in the laboratory should be uniquely identified, both physically and in all documentation, throughout its life in the laboratory and should not be able to be confused with any other sample in the laboratory, usually by the use of a unique serial number for each sample. Also all reported results should be traceable back to the original observations, hence printed or electronic forms for raw data are frequently used and archived in analytical laboratories. This provision is especially important when dealing with client complaints, for which the laboratory should have an established procedure.

2.3 Laboratory Integrated Management Systems

2.3.1 LIMS implementation

From the above it can be deduced that a modern commercial laboratory produces a vast quantity of test and control data that need to be stored, processed, checked, and presented to the client. Furthermore, as the laboratory procedures have elements of manufacturing production, elements of sample tracking, calculation of lead times, inventory etc. also have to be taken into account. The answer to the above problems has been provided by the development of laboratory computer technologies and the introduction of Laboratory Integrated Management Systems. In fact, the ISO 17025 standard makes a provision for the use of computer systems for "the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data" and it is required that the integrity, confidentiality and adequacy for use are validated.

ASTM International has developed a technical standard guide for LIMS (E 1578-06 "Standard Guide for Laboratory Information Management Systems", 2006), according to which a Laboratory Information Management System (LIMS) is a "computer software that is used in the laboratory for the management of samples, test results, laboratory users, instruments, standards and other laboratory functions" and "a class of application software which handles storing and managing of information generated by laboratory processes. These systems are used to manage laboratory processes including defining master data, sample management and chain of custody, work assignment, instrument and equipment management, standards and reagent management, scheduled sample collection and testing, result entry, result review, reporting, trending and business rule enforcement".

In practice, a modern laboratory with multiple workstations utilises computer terminals connected to LIMS at almost all areas and LIMS can partially or fully replace the tedious and prone-to-error procedures of data transposition, use of results forms or laboratory notebooks and the reliance on the human factor for quality control, material (samples and consumables) and data handling.

Gibbon (1996) provides a brief history of Laboratory Information Management Systems: The need for the use of computer systems in the lab had been addressed since 1973, in a symposium called "Guidelines for Defining and Implementing the Computerized Laboratory System", organised by the ASTM and with the participation of analytical instrument giants such as Perkin-Elmer, Varian, Digital Equipment Corporation, Hewlett-Packard and IBM Instruments, which exhibited various laboratory automation products. From 1976 onwards, the American Chemical Society had offered a short course named "Laboratory Automation: Micro-, Mini- or Midicomputer". Further symposia in the late 1970s and early 1980s provided sporadic build-it-yourself laboratory data handling solution. In 1982, the acronym LIMS entered the commercial world, as three companies (Perkin-Elmer, Purvis Systems and Spectrogram Corporation) provided the first integrated software solutions to laboratory needs. From 1987 onwards the yearly International LIMS Conferences have been the annual showcase of presentation of papers regarding LIMS.

LIMS is nowadays considered an essential element of any commercial laboratory operation and the choice of the LIMS to be implemented is one of the most important decisions for the enterprise, as it is a very important tool to improve the efficiency and proficiency of the laboratory.

The laboratory has a choice of either a "off-the-shelf" ready solution, or a tailor-made LIMS. Furthermore, there is a choice of numerous vendors (with big names such as Agilent Technologies, Analytical Information Systems, ChemWare, LabWare, LabVantage etc.). In any case, the LIMS chosen has to be customised according to the laboratory's mode of operation, needs and workflow; hence before installing and implementing a new LIMS a careful and thorough study of numerous parameters has to be taken into account. According to Edward *et al.* (2008), the key factors for a successful LIMS implementation are:

- **Thorough needs assessment**: A multidisciplinary team from within the lab (management, IT and end-users) has to clearly define, with the use of flow diagrams, the analytical processes (samples and data flow) that take place into the lab, to set clear requirements and goals and to communicate these clearly to the LIMS vendor.
- **Vendor selection**: The selection should take into account the budget of the enterprise, the hardware used in the laboratory, the adaptability of the system to future needs, training and user support by the vendor.
- **Organised implementation:** A project manager from both the company and the vendor should be assigned in order to ensure the problem-free installation of the system with extensive use of quality control checklists.
- **System validation:** As most laboratories operate within regulated environments, it is important that the installed LIMS satisfies predefined acceptance criteria for the way data is stored and all calculations are conducted.
- **Measurement of performance:** Finally, it is essential to check whether the goals that have been set in the initial needs assessment have been met; the vendor should be able to offer support for continuous improvement of the LIMS implementation.

2.3.2 LIMS functionality

All LIMS systems are, at least in some degree, customisable and adaptable to the needs of the laboratory. The LIMS encompasses elements of workflow management and warehouse management and it is also the means to process and store the production of the laboratory, which is analytical information. Of course, all data imported in LIMS can be used to produce information of operational and strategic importance to all levels of management.

According to Skobelev *et al.* (2011), the functions of a LIMS can be divided into five stages:

- Registration of samples
    - Assignment of a unique sample number (possibly by barcode)
    - Sample information database (client details, sampling point, description etc.)
    - Description of tests to be performed

    - Calculation of cost
    - Templates can also be created for specific clients and/or sample types.
- Assignment of work to analysts
    - Distribution of analytical work to the laboratory staff
    - Information about methods, required volume etc.
    - Monitoring of work progress and work performance
    - Alerts for specific holding times or overdue work
- Analysis
    - Sample preparation management
    - Sequencing and batching of analytical work
    - Inclusion of analyst observations, quality control samples
    - Management of reagent, equipment and staff use
- Input of results
    - Raw data can be entered manually or through interface with equipment
    - Recording of audit trail
    - Automatic results calculation and statistical processing
    - Data acceptance/rejection/flagging according to quality control criteria
    - Sample location tracking
- Inspection of test results and issue of reports
    - Ability to authorise staff to inspect final results for approval or rejection
    - Generation of certificates of analysis for the client in paper or electronic form
    - Generation of managerial reports with regard to KPIs, quality and production statistics, rate of reagent consumption, staff utilization etc.

The above list of features is non-exhaustive and the LIMS manufacturers offer a variety of solutions and can adapt their systems according to the needs of the laboratory. Further to the above, the LIMS should also have the capability to store for a specific amount of time sample information, raw data and final results and to do so with the required level of data integrity.

2.3.3 LIMS and its effect on laboratory and organisation operations

Schematically, the operations of a typical laboratory can be described with the work flow chart of *Image 2*:

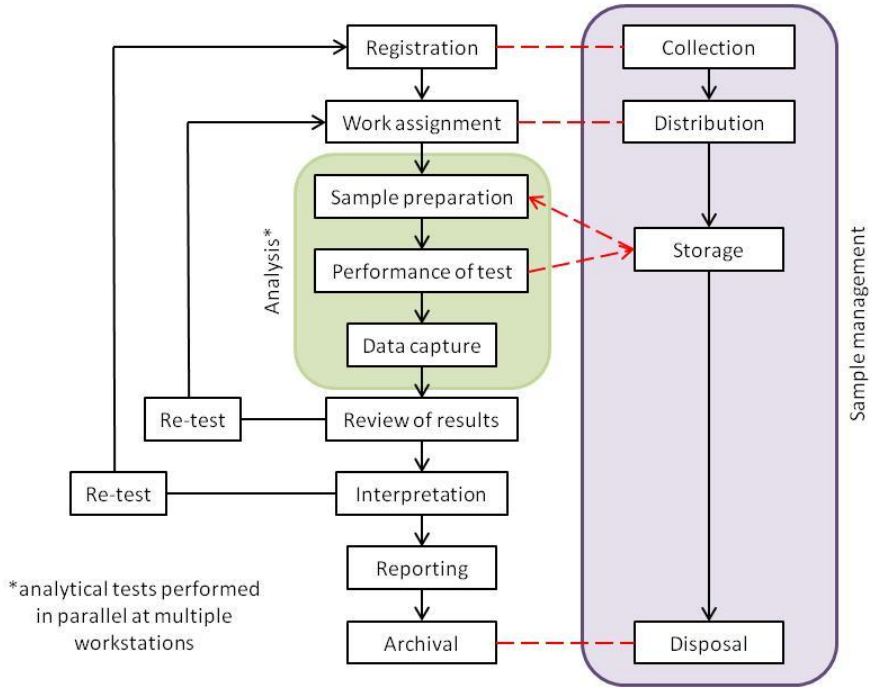


Image 2: A generic laboratory flowchart. The left process column shows the flow of information and the right column the actual movement of the samples in the laboratory (adapted from ASTM, 2006)

After the sample is received into the laboratory, it is registered into the laboratory's sample registration system and, according to ISO 17025, a unique identifier (a sample code or number) is assigned to the sample. From that point onward, this identifier is used for the whole life of the sample in the laboratory. Correspondence with the client or notes regarding the client's order can also be attached to the sample within the sample registration system.

A commercial laboratory which has established methods is usually comprised of multiple workstations, each of which performs one or more determinations onto the sample. The sample is thus registered for its required determinations and worklists are created per each workstation. The scientific part of laboratory work starts right afterwards. Usually, each method has a preparation phase (grinding, dilution, filtering, etc.) and the actual analysis phase. The laboratory can choose whether the preparation can be performed at a separate workstation or by the analyst before testing. After the successful analysis of the sample at all workstations, the raw data and/or calculations of final results and the relevant quality control checks are collected. A senior or a laboratory manager can then review the results and interpret them. This stage is essential to spot any errors that do not correspond to the nature of the sample and the requirements of the client. Any suspected error during the review phase can mean that the reviewer might check the initial raw data, order a partial or full retest of the sample, or additional tests to be conducted on the sample. (ASTM, 2006)

In laboratories where LIMS is not utilised, all operations regarding the information flow are performed manually with results being transcribed from notebooks or standardised printed forms and calculated in computer spreadsheets, while the issuing of certificates of analysis is a procedure requiring a secretariat fed with paperwork produced by the laboratory. It is clear

that the opportunities for delays, errors and rework are dramatically decreased by the use of LIMS, as these tedious procedures can be performed electronically.

The process of review and interpretation of results requires the skills and knowledge of a senior analyst or a laboratory manager can be aided by the use of LIMS by entering automatic rejection or flagging of results according to set criteria. Furthermore, the physical movement of the sample can be tracked and managed by LIMS by applying warehouse management principles, i.e. by logging the position of the sample every time it is moved within the lab.

LIMS can therefore be used as a tool for improving the laboratory operations. S.A. Broad of the successful LIMS manufacturer LabWare Inc. goes as far as to suggest that LIMS can be a *catalyst* of re-engineering of the laboratory's processes: For example LIMS capabilities can enable all stakeholders of the laboratory to gain access to laboratory-generated data (giving opportunities to gain from the laboratory data to clients, production development, the marketing department etc.), and can highlight internal inefficiencies of the laboratory (poor communication, standardisation, method protocols etc.). LabWare's clients often look for a LIMS to improve their production (by reducing data capture time and errors), communication of information to clients and the opportunity to standardise procedures in the laboratory. (Broad, 1997)

It should not be overlooked that LIMS is a tool that enables the laboratory to be integrated in its containing organisation operations. However, even ASTM (2006) approaches LIMS as a laboratory automation tool, without any mention to the needs of other departments of the organisation which support the laboratory operations. McDowall (1995) proposes that LIMS should have an operational (for the analysts), a logistic (for the laboratory managers) and a strategic (for the business) function, i.e. instead of being a "laboratory toy", LIMS should be providing information generated by the laboratory (the "information generator") to its surrounding organization (the "information users"), as seen in *Table 1*.

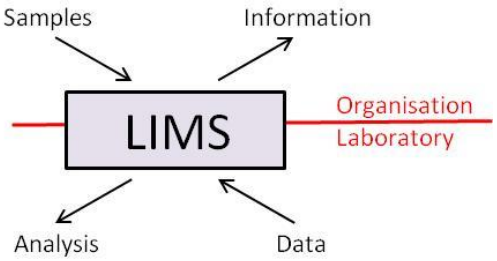
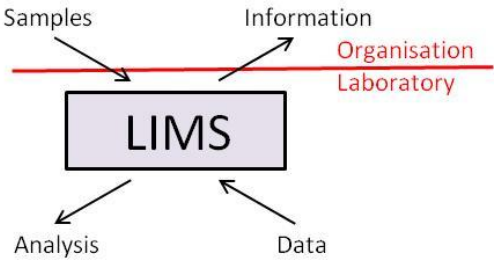
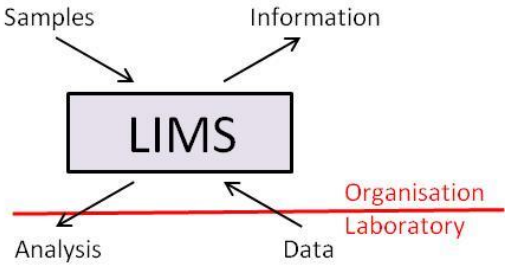
	This is the ideal setup of a successful implementation of LIMS. The LIMS benefits both the organisation (the information user) and the laboratory (the information generator).
	A bottom-up implementation of LIMS. The laboratory is the sole user of the LIMS and the organisation does not benefit from its implementation.
	A top-down implementation of LIMS. Emphasis has been given on the organisation needs and the laboratory is let to develop its own solutions independently.

Table 1: Implementation of LIMS with regard to the relationship between the laboratory and its surrounding organisation. Adapted from McDowall (1995).

One of the most important functions of a successfully implemented LIMS for the organization is its capacity to accurately measure the performance of various aspects of the laboratory operations, thus enabling managers to have a real image of the effect of implemented commercial or operational strategies in the laboratory (Stafford, 1998) and his is an invaluable input in the DMAIC (Define-Measure-Analyse-Improve-Control) cycle of continuous improvement of the organization's processes. Undoubtedly, using LIMS solely as a laboratory automation tool is an underutilisation of its capabilities. According to Murphy (1996), when designing the implementation of a new LIMS the first concern should be the needs of the client and not the needs of the laboratory or the organisation and LIMS should be a business tool to achieve and measure a high degree of client satisfaction.

It should be noted that further scientific bibliography on the matter of improvement of laboratory operations is rather limited and dated, although at least one scientific journal is concerned with laboratory information (*Laboratory Automation and Information Management*, later incorporated into *Chemometrics and Intelligent Laboratory Systems*). Contemporary bibliography is concerned with the technical design and improvement of specialised applications of LIMS. This can be attributed either to the obvious improvement of laboratory operations of the implementation of LIMS as they have been proven over time or the lack of academic interest to laboratory process optimisation.

2.4 Lean laboratory management

2.4.1 Lean management

Lean Management is a concept to which the manufacturing industry was familiarised through the works of Taiichi Ohno ("Toyota Production System", 1988) and Womack, James and Roos ("The Machine that Changed the World", 1990), both cited in Holweg's (2007) historical account of Lean production management and almost in all literature detailing the theoretical and practical aspects of Lean. Lean has attracted enormous interest since then and has given rise to a new set of (mostly Japanese) terminology which is now commonplace in the manufacturing and the services sector, as a toolbox to increase productivity and quality with an emphasis in the satisfaction of the client.

Lean is a philosophy in Operations Management whose main objective is to "eliminate waste by concurrently reducing or minimising supplier, customer and internal variability" (Shah and Ward, 2007). The concept of waste (*muda*) is key in the understanding of Lean management and can be defined as "any activity that does not add value in the eyes of the customer" (Heizer and Render, 2014). The key sources of waste are known as "Ohno's seven wastes" and are:

- **Transport:** unnecessary movement of material and products
- **Inventory:** unnecessary components, work in progress and finished product stock.
- **Motion:** unnecessary movement of people or equipment
- **Waiting:** idle time and storage, including production bottlenecks
- **Overproduction:** inventory of raw material, work in progress, and production ahead of demand
- **Overprocessing:** work that adds no value
- **Defects:** Rework, client complaints and claims.

In addition to the above seven wastes, the untapped human potential of the company has also been proposed as an "eighth waste". In order to minimise or eliminate the above wastes, the operations design should focus in the removal of variability (in processes, demand and supply) and the improvement of the throughput, i.e. the lead time for each order. (Bicheno and Holweg, 2016)

The concept of Lean management has been developed in the manufacturing industry and more specifically, it started its life at the Toyota factories in Japan. However, a lot of its tools and concepts can be applied to the services industry, where the same benefits in increased customer satisfaction can be observed.

According to Hicks (2007), the same principles of identifying value, understanding the flow of the processes and the identification of waste apply to the services industry (and more specifically, in information management), although the product and waste is not as clearly understood, due to its intangibility. Nevertheless, the concepts of Lean management can be applied to any information processing activity, as long as the definition of value and waste is possible.

2.4.2 The Lean Laboratory

Until recently, literature about analytical laboratories has been focusing mainly in the scientific and quality attributes of laboratory work. However, analytical laboratory operations are part of wider companies or organisations and the business mindset is affecting their philosophy of work. It is therefore not strange that the concepts of Lean management are quite attractive in this rather complex working environment.

Most papers regarding lean laboratory management focus on the management of healthcare laboratories, something that it is to be expected given the high throughput, costs and the high client demands of this sector – nevertheless the same principles can be applied to all kinds of laboratories, as the demand for meeting the expectations of the client (be it a government agency, a hospital patient or a feedstock factory) has to be satisfied. However, the academic interest in the matter of Lean laboratory management is not pronounced and the available academic literature is limited to an introductory presentation of Lean principles for the laboratory. More specialised literature on the matter is in the forms of white papers and Lean application guides by manufacturers of analytical instruments and laboratory furniture, which are sometimes reprinted in the relevant industrial press.

Herasuta (2007) applied the Womack and Jones' (1996) steps in implementing Lean management in the laboratory:

- **Identification of value:** How the service meets the client's needs, at a specific price and at a specific time. In laboratories, time is quite often a very important aspect to the client.
- **Identification of the value stream:** All the activities that contribute to value from the time of sampling until the time of return of the results.
- **Improvement of flow:** The uninterrupted movement of the service throughout the system. Often, batch processing in analytical laboratories is a contributor of the slowing down of the process.
- **Allow customer pull:** Provide service to the client only when he needs it. This also includes identifying the true needs of the client in order to avoid extra tests being performed on the client's samples.
- **Work towards perfection:** The laboratory should repeat this process in order to constantly improve its work procedures.

It should be noted here, that the concept of working towards perfection, or continuous improvement (*kaizen*, in Lean terminology) is inherent in the ISO 17025 standard as a never-ending process to improve the laboratory's effectiveness of the management system through the procedures described therein, which should be a part of the laboratory's quality system. (ISO/IEC, 2005, 4.10-4.12).

As regards to the factors that affect laboratory performance, Reynolds (2009) claims that the main problem in managing the workflow in analytical laboratories is the volatility and variation in the type and volume of work that has to be performed and not the waste in time and motion within the laboratory. More specifically, he identifies the following factors to streamline analytical production by applying Lean techniques:

- **Volatility in the incoming workload:** This is a common problem in laboratories, with the main impact being the increased lead time during peaks in demand. Of course, in periods of low demand, the low productivity of the laboratory is a waste of resources.
- **Too much work in progress (WIP):** Poor flow resulting from inadequate cross-training and instrument conflicts.
- **Long and variable lead times:** Large batches are often preferred for methods with long setup times. This practice should be applied with care.
- **Ineffective practices for urgent samples:** Most samples have separate procedures for urgent samples, which are prioritised over the normal workflow. Unavoidably, at times, the number of urgent samples becomes unmanageable. In an ideal Lean environment, there should be no urgent samples, as all sample lead times are reduced.
- **Lack of cross-training:** Laboratories tend either to operate in a factory-like mode (each analyst being trained on a specific task) or at the other end of the spectrum, by having the analyst perform the full testing schedule for each sample. Both extremes are counter-productive. The analyst should be performing defined tests, but should be able to carry all tests in order to meet increased needs of the laboratory, due to increased demand or staff shortages.

3. Methodology

3.1 The case study as a research method

The case study method has been used in our investigation, as a semi-quantitative approach to illustrate our proposed theory. This section presents some of the concepts that underlie our research.

Case study can be defined as *"the intensive study of a single unit for the purpose of understanding a larger class of (similar) units"* (Gerring, 2004). Yin (1994) describes case studies as being the preferred strategy to answer "how" or "why" research questions. The case study approach uses a limited number of observations as a means to generalise a theoretical preposition, while the experimental approach replicates the studied phenomenon under different conditions and uses statistics to extract its generalisations. From this description, it is clear that the case study approach is particularly useful to social sciences, as it can be used to examine phenomena whose environment is difficult (if not impossible) to control and it also emphasises the complex, real-world context in which the studied phenomena occur (Eisenhardt and Graebner, 2007).

In order to use the case or cases presented as a means of investigating a phenomenon, a specific *research design* has to be implemented. The research design is the action plan that leads from the questions to the conclusions, the way to ensure that there is a clear view of what is to be achieved by examining a case study. The basic components of the research design are:

1. The study's questions
2. The study's propositions
3. The study's units of analysis
4. The logic linking the data to the propositions
5. The criteria for interpreting findings. (Rowley, 2002)

Due to the subjective approach used in case study research, it is also important to ensure the integrity of the method employed. It is therefore essential to gather supportive evidence from a variety of sources. McGrath (1982, as cited in Scandura and Williams, 2000) borrows the term *triangulation* from the navigation and military strategy as the use of multiple reference points to locate the exact position of an object. In simple terms, a variety of method is used in order to examine a phenomenon, in order to produce more reproducible and reliable findings.

As described by Ketokivi and Choi (2014), case study research can be used to generate, test or elaborate a theory – and in order to induce coherent results, research can be qualitative or quantitative and should satisfy the duality criterion. The terms *qualitative* and *quantitative* are used in a way similar to the natural sciences, but with the differentiation that quantitative data for this type of research does not necessarily need numbers in order to quantify a phenomenon: Cross-case analysis can use comparison to highlight the emergence of a pattern and the choice of polar types of cases can be used to study the covariance of multiple variables – i.e. to show that there is a cause-and-effect relationship between them (Gerring,

2004). The term *duality criterion* refers to the demand of the data to be both situationally grounded and in the same time seeking a sense of generality.

3.2 Research question and research design

The research questions that will be investigated in this study are:

- *Is LIMS used as a tool of Lean Management in analytical laboratories?*
- *Is there a direct relationship between a laboratory's commitment to Lean Management and the extent to which it uses LIMS?*

Commercial analytical laboratories have many similarities to manufacturing production in spite of their offering services to clients. In a way of thinking, the product is actually the client-requested information that is being built up in multiple workstations working in parallel, with more-or-less defined lead times and consumable demands. Hence, Lean Management principles could be beneficial to the workflow in the analytical laboratory and LIMS can be used as the control centre in order to eliminate most sources of waste.

The hypothesis of this study is that not only are Lean Management principles applied in analytical laboratories, but there is a direct relationship between the extent of LIMS application and the commitment to Lean. The logic behind this hypothesis is that LIMS greatly reduces the waste in the analytical procedure, especially as regards to the physical flow of information within the laboratory and the need of repeat work due to transcription errors – this is the main reason for LIMS being implemented in laboratories anyway. It would be interesting, however, to examine whether the implementation of LIMS can be used as a tool for systematically applying Lean in the laboratory.

In order to answer these questions, the cases of two companies offering analytical services have been examined, Agrolab SA in Greece and ALControl Ltd. in the UK. Both are leading providers of analytical services in their respective markets and accredited to ISO 17025 in a wide scope of analytical techniques and matrices. In order to facilitate our study by having comparable data provided, we have focused on the procedures applied in each company's environmental department, i.e. the department that analyses waters (potable water, surface water, ground water, treated and untreated sewage, leachates and sea water) and soils for their chemical composition.

These two cases are used as polar examples to study the relationship between the use of LIMS and the application of Lean Management. As it will be further discussed in the next section, there are differences in how each company deals with the efficiency of its production and how this is perceived by its clients. Furthermore, Agrolab SA has implemented the use of LIMS quite recently and, at the time of the interviews, the system was being used as a supplementary system to the main paper-based records; while on the other hand ALControl has almost completely switched to a paperless computer-based system for about a decade.

The information needed to answer the questions of our research were mainly provided by interviewing key people of both companies, conducting site visits and using any available information that each company provides to the prospective clients through their corporate website.

The interviews were held at each company's premises and lasted for about an hour. At ALControl a site tour was conducted after the interview, while at Agrolab SA the author's experience as a member of the analytical staff of the company provided the necessary on-site perspective. Extra material was provided by the laboratories' online promotional material.

- At Agrolab the interviewees were Dr. Alexandros Giannousios, General Manager, and Mr. Giorgos Stratakis, Marketing, Tenders and International Business Manager. The interview was held on 23rd December 2015 at the head laboratory of the company in Sindos, Thessaloniki, Greece.
- At ALControl the main interviewee was Mr. Ian Blackburne, Quality Manager, with the aid of Mrs. Anna Kiourtsidi, analyst, giving insights from the analysts' point of view. The inverview was held on the 15th February 2016 at the head laboratory of the company at Hawarden, Flintshire, United Kingdom.

For the benefit of the flow of the interview, a questionnaire with open questions was used in both cases, with the questions being followed loosely. The purpose of the questions was to let the interviewees describe in their own words the following:

- Elements of the workflow procedures inside the laboratory.
- How Lean Management principles are applied in everyday work.
- How LIMS is used in the laboratory and how it is planned to be used in the future.

Especially as regards to Lean Management, the axis that was chosen to facilitate the interview was how Ohno's seven wastes have been dealt with in the laboratory. The main questions of the questionnaire are can be found in the appendix.

4. Results and Discussion

4.1 Presentation of cases

4.1.1 Agrolab SA

Agrolab SA (trading as Agrolab RDS) is a member of the Redestos-Efthymiadis Agrotechnology Group, a group of companies providing integrated services to the agriculture sector – plant protection and nutrition, propagation material, laboratory and consultancy services, production and trade of agricultural products (Redestos-Efthymiadis Agrotechnology Group, 2008). Agrolab covers the laboratory and consultancy services wing of the group, it is currently the largest private integrated laboratory and consultancy provider in Greece and one of the major such companies in Southeast Europe. The services provided by the company mainly cover the agricultural sector, food and feedstuff industry, and the environmental sector – with clients being local authorities, agricultural cooperatives, food manufacturers and individuals. The CEO of Agrolab SA is Mr. Efthymios Efthymiadis and the General Manager is Dr. Alexandros Giannousios. (Agrolab SA, 2016a)

Image 3: Agrolab SA corporate logo (Agrolab SA)

Agrolab describes that its mission is to provide laboratory and consultancy through quality excellence, reliability and continuous development and the key elements in achieving it are "quality as a competitive advantage, innovation as a driving force for growth, the customer service as a priority and clear superiority and maintenance of the high reputation of the company". (Agrolab SA, 2016b)

The company laboratory operations are situated in two autonomous laboratories, one in Sindos, Thessaloniki (headquarters) and one in Markopoulo, Attica. In 2015, Agrolab SA acquired the Volos-based Envirolab IKE, an environmental laboratory specialising in water analysis (Agrolab SA, 2015b), which will keep its name and staff and will be a subsidiary of Agrolab SA . One business unit in Sofia, Bulgaria supports the company's presence in the Balkans.

Image 4: Agrolab SA facilities in Sindos (above) and Markopoulo (below). (Agrolab SA)

The company analytical operations are divided into the following laboratories:

- Sindos facility
    - Food Contaminant Laboratory
    - Feedstuff Nutritional Labelling Laboratory
    - Environmental Laboratory
    - Sensory Testing Laboratory
    - Quality Control Laboratory for Plant Protection Products
- Markopoulo facility
    - Pesticide Residue Laboratory
    - Microbiology Laboratory
    - Genetic Modification Control and Molecular Analysis Laboratory
    - Oil Analysis Laboratory

(Agrolab SA, 2015a)

As regards to the Environmental Laboratory, according to the company's ISO 17025 certificate of accreditation (Hellenic National Accreditation System, 2016), the laboratory's scope of accreditation covers potable, irrigation, drilling, surface and underground water, sewage and soil for a multitude of inorganic tests. The tests provided by the laboratory are used to cover legal requirements and to provide consultancy for fertilisation and cultivation, thus supporting the operations of the other companies of Redestos-Efthymiadis Agrotechnology Group.

For 2014, Agrolab SA reported an annual turnover of €4.6 million (+8.2% from 2013) and operating profit of €315,595 (+16.7% from 2013) (Agrolab SA, 2015c). Both facilities process about 50,000 samples per year, of which about 10,000 are for the Environmental Laboratory.

The company employs about 80 people in both facilities, of which 8 people comprise the Environmental Laboratory analytical staff.

4.1.2 ALcontrol UK Ltd.

ALControl Group (trading as ALcontrol Laboratories) is the largest provider in Europe for analytical services for the environment, construction and the associated sectors, providing mainly to national and regional governments, to manufacturing and retailing organisations, to the private sector for consulting purposes, and to consumers in conjuction with local government partners. The group caters for its clients' needs throughout Europe, which often comprise of provision of consistent and uniform analytical services throughout the continent by employing a global marketplace approach (Pan-European Lab). This is achieved by a Europe-wide network of offices and analytical laboratories and sophisticated international logistics suppliers.

Image 5: ALcontrol UK Ltd. corporate logo (ALcontrol UK Ltd.)

The client-contact offices are spread out in 11 countries throughout Europe (Belgium, Denmark, Finland, France, Germany, Netherlands, Norway, Spain, Sweden and UK), providing sample drop-off points and consultancy services in line with local regulations. The analytical laboratories are situated in Rotterdam (Netherlands), Linköping (Sweden) and various sites in the UK. (ALcontrol UK Ltd., 2016a)

The group focuses in the following analytical matrices:

- Food and waters
- Environmental samples (soil and ground water)
- Oil and fuel

ALcontrol UK Ltd. was the UK-based branch of ALcontrol Group and one of the main providers of laboratory services of the group. ALControl UK has been acquired in November 2016 by ALS Group, a global analytical services organisation based in Australia with operations in 350 locations in 55 countries and a throughput of 20 million samples per year (ALS Environmental Ltd., 2017a). However, as the operational restructuring process is still ongoing in July 2017 (ALS Environmental Ltd., 2017b), it would be more useful for the purposes of this project to provide information for ALcontrol UK as it was before the acquisition.

The CEO of ALcontrol UK was Mr. Simon Gibbs and the Managing Director was Mr. Richard Hepburn. The company had 8 facilities in the UK, with each facility focusing in one of the three analytical matrix categories:

- Hawarden, Flintshire, Wales (headquarters, environmental testing)
- Aberdeen, Scotland (environmental testing)
- Bellshill, North Lanarkshire, Scotland (food and waters)
- Conwy, Wales (oil and fuel)
- Dunstable, Bedfordshire, England(food and waters)
- Newton Abbot, Devon, England (food and waters)
- Rotherham, South Yorkshire, England (food and waters)
- Shrewsbury, Shropshire, England (food and waters)

(ALcontrol UK Ltd., 2016b)

Image 6: ALcontrol UK Ltd. facilities in Hawarden as they were before the acquisition by ALS Group. (ALcontrol UK Ltd.)

ALcontrol's operations were based on applying lean management techniques to laboratory processes, investing in skilled staff and advanced laboratory and automation technologies and providing expert knowledge to its clients, caring for their increased productivity and profitability. The clients of ALcontrol valued the provision of services according to their needs and accurate scheduling in sampling and reporting of result was achieved by the clients' direct ordering and tracking of services through the company's information management system, called @mis. (ALcontrol UK Ltd., 2009)

According to the ISO 17025 schedule of accreditation for ALcontrol (United Kingdom Accreditation Service, 2016), the Hawarden site covered chemical tests for landfill gas, natural gas, ambient air, sewage sludge, soil, potable water (non-regulatory), ground water,

saline water, treated and untreated sewage, trade effluent, surface water and landfill leachates, for inorganic, organic and microbiological tests.

For 2014, ALcontrol UK reported an annual turnover of £31.1 million (+0.9% from 2013) and a loss of £1.5 million (+56.7% from 2013) (ALcontrol UK Ltd, 2015). The Hawarden facility processed about 300,000 samples per year, produced about £10 million in revenue and had about 200 employees, of which 150 were analytical staff.

4.2 Processes and implementation of Lean

4.2.1 Laboratory operations

The clients of Agrolab's Environmental Laboratory are mostly farmers, agricultural cooperatives, water utility companies and industries. The usual samples received are samples of arable land and waters for drinking, irrigation and effluent regulatory testing. Sampling is done on-site either by the client or by Agrolab's sales department and is brought to the company by courier, post, intercity bus delivery or in person by the client or the salesperson. Clients are given clear guidelines on the sampling procedure and the quantity needed, but there is no standard container supplied to the clients and sometimes the clients provide a sample which in much greater or much less quantity than needed.

ALcontrol's clients are building and waste management companies (e.g. landfill sites), land remediation agencies and utility companies which analyse water and soil to meet environmental agency regulations with regard to drinking water, wastewater and soil contamination. Sampling is done by the client in standard sample containers supplied by the company, which are sent to the client and then brought to the laboratory by the courier who works on behalf of the company. It should be noted that sample containers are sent out with barcodes on them in order for the samples to be identified when they arrive back to the laboratory.

From the time that the samples are accepted in the company, they are registered, analysed at the different workstations, the data is collected, processed and presented to the client, and then stored for an agreed period of time, which is one month for both laboratories. The process follows the flowchart in *Image 2*.

Although the general operational principles are the same between the two companies, the key difference in the processes between the two companies is that, while in Agrolab the sample container is physically transferred into the laboratory and any sample preparation is done on the laboratory bench by the analyst at each workstation, ALcontrol has an exclusive preparation area, which is exactly next to the registration and storage area. There, soil samples are dried, ground and extracted and water samples are filtered as required. Each laboratory workstation receives racks of subsampled vials, ready to be tested without any further preparation. However, the much larger sample volumes processed by ALcontrol (ca. 250,000 per year) justify a much greater specialisation in each workstation, i.e. each analyst operates one instrument or analytical method for a large number of daily samples, while at

Agrolab each analyst performs a multitude of tests daily in a much smaller number of samples (ca. 10,000 per year).

Another important difference is that at ALcontrol the client has the ability to log his sample through @mis, a web-based tool through which the client can schedule the tests needed and, so, when the sample arrives at ALcontrol testing can start without delay.

4.2.2 Implementation of Lean practices

4.2.2.1 Client-perceived definition of value

Both interviews have underlined that the most important quality aspect for the service delivered by the laboratory is the timeframe of the analysis. The level of the analytical testing is implied by the ISO 17025 accreditation of both companies and it can be found anywhere in the industry, so as quality is perceived as a commodity, time is the field of competition in the industry.

For both companies, a secondary level of service is provided beyond the basic analytical testing, which is the technical support and consultancy. Alcontrol says that, apart from providing a quick and efficient analytical service, relationships are built up on the technical support offered by the company. For Agrolab's clients in the agricultural industry, the fertilisation consultancy report which is offered with the testing of soils is the most valued product – most soil clients do not even value the level of analytical accuracy provided by the laboratory.

It is quite interesting to note that ALcontrol promotes its Lean practices through its corporate marketing communication: most prominently in their corporate video on YouTube, where it is clearly mentioned that the company implements Lean laboratory practices and the principles of Kaizen and Six Sigma. Mr. Blackburne noted that, for the company's clients, the fact that the laboratory implements Lean Management is an indication that cheaper and quicker service is offered for the same level of analytical quality and that the fact that Lean Management practices are followed differentiates the company from the competition. Agrolab's managers claimed that such communication would have no point for their clients, as "what they [only] care about is their analysis time to be reduced".

External failures (i.e. found after the client has received his certificate of analysis) are also an important commercial factor for both companies. Agrolab's clients consider such errors as critical and are a reason for their ceasing the collaboration with the company. ALcontrol's clients understand that errors can happen and will appreciate the honesty on behalf of the company. In both cases, avoiding exposing a failure to the client would be damaging to the reputation of the company, so any erroneous results are recalled and rectified without delay.

It is interesting to note how the voice of the client is communicated throughout the two companies. In both cases, the analytical staff is not concerned with the individual clients and their needs (these are dealt with in the client services and registration department), but have to regulate a constant flow of samples coming in the laboratory. In ALcontrol's case, each sample comes with a specific turnaround time and a specific delivery date which is agreed

with the client. Thus, the analyst can easily prioritise samples by arranging them by due date. Furthermore, a whiteboard in every room is used to communicate to the analysts the KPIs that are relevant to the demands of the clients (most importantly, satisfaction of agreed delivery and errors). In Agrolab, a specific pace of work with which the laboratory is comfortable dealing with has been developed over the years and samples are organized by the laboratory manager in batches to fit this pace of work. A vague turnaround time (usually 5-15 working days) is agreed with the clients, which suits most of the cases. Any special arrangements or urgent samples are communicated to the laboratory manager verbally or through the "comments" section of the job order and she has complete freedom to prioritise work in any way she sees fit.

4.2.2.2 Improvement of flow

Agrolab is part of the Redestos Group, a group of companies providing integrated services mainly to the agricultural industry. Due to this fact, a large proportion of the samples arriving at the Environmental Laboratory follow an annual seasonal circle which can roughly be forecast, but in order to normalise the annual workflow the company offers better prices and other incentives for clients who which to bring their samples in low demand periods. In any case, Agrolab forecasts the demand for each client bimonthly, but due to the changes in the industry in Greece due to the ongoing financial crisis, the demand cannot be accurately forecast. Also, the Environmental Laboratory relies heavily on tender contracts with local governments, agricultural cooperatives and universities, which vary in seasonality and can pose a strain in the laboratory workflow. Any such peaks of demand are met *ad hoc*, by one of the following methods:

- Analysing larger lots of samples
- Drawing staff from other departments (a number of analysts are cross-trained)
- Using placement students as extra staff for support work
- Applying a shift pattern employing temporary analysts. A pool of readily available previous members of staff exists, which can agree to cover extra temporary needs.

Most tests in the laboratory are offered as standardised analysis suites, which helps organising the workflow. However, if a client wishes a non-routine test to be done, the laboratory will accommodate his needs even if this is not to the benefit of the workflow. An example is tobacco merchants, each of which has his own analysis suite. Generally speaking, however, the organisation of the workflow lies entirely on the shoulders of the laboratory manager.

On the other hand, ALControl has very limited seasonality which is mostly dependent on the weather and the day of the week (work is less at the beginning of the week because sampling is not usually done over the weekends). The pace of work is set by the preparation workstations and the analysts at the analytical workstations should practically analyse everything that comes to their workstations at the pace that it is received. Practically, some degree of prioritisation does take place (by due date), but it is discouraged.

Giving client incentives to provide samples in periods of low demand (i.e. in the beginning of the week) is considered, but otherwise variations in demand within the week are met by encouraging the analysts to take their day off on Mondays and work on Saturdays or even close the laboratory for a day if the demand is not sufficient.

Analysis is offered to the client in the form of ready-made analysis packages but any non-routine work will be met by the relevant technical team if it is possible to be done. Offering analysis packages does not make too much of a difference to the workflow, but it is seen as a marketing opportunity.

In case a peak of demand arises, extra people can be moved to the sample preparation or analytical workstations from departments that are not busy at that particular period. Furthermore, there is an arrangement with an agency to provide agency workers at 2-3 days' notice if needed. These workers, although they need to be trained in a very short period of time, they are treated the same with the permanent staff because they can affect the quality in the same degree.

With regard to standardisation of work in the workstation level, in both laboratories the work is highly standardised as specific analytical methods are used. For the bulk of the analytical work, ISO 17025 certified methods are employed, which ensures that they are documented and verified, the analysts are adequately trained and that daily checks are being employed using statistical process control. All the relevant documents are controlled and can be traced back if needed for an audit. In case that a non-validated method needs to be employed, it is treated with professionalism and an endeavour to provide as accurate results as possible.

The bulk of the reagent supplies are provided by a local chemical supplier, with whom both companies have a time-tested relationship. Agrolab reagent stores are replenished every week, while ALControl's every month. However, any urgent needs can be met by the supplier and any specialist reagents can be sourced from other companies. None of the two companies keeps large quantities of reagents in stock but they also do not employ just-in-time practices, as these would be too risky.

4.2.2.3 Continuous improvement

Analytical continuous improvement is an inherent demand in ISO 17025 and is employed by both laboratories both for accredited and non-accredited methods. ISO 17025 provisions dictate that the performance of all accredited tests is controlled statistically and that internal and external audits are performed regularly to continuously improve the methods and their quality characteristics. Both laboratories adhere to these provisions and promote the improvement of their methods on a scientific basis. Furthermore, operational continuous improvement is important to both companies as part of their business sustainability programme and this is communicated to a greater or lesser degree to the members of staff.

Agrolab acknowledges the fact that improvement is a continuous process and believes that it relies on building a sturdy foundation and developing from thence upward. Improvements are continuously being made (e.g. by increasingly using controlled reference materials even with non-accredited methods) but work has still to be made with the training of the staff. However, it is considered that working more economically and reducing waste is a matter of a general stance of the staff which cannot be policed and it is difficult to enforce. It is regarded that with regards to standard methodologies, no economy can be made. Generally speaking, the business performance of the laboratory is seldom and only broadly communicated to the analytical staff. Personal appraisals are done on an *ad hoc* or annual basis.

ALControl encourages the analytical staff to provide ideas with regard to improving the processes in the laboratory in the morning meeting which is held within each work area. The financial and operational performance of each work area is communicated to the analysts every month via a notice board which gives information of the trend of the laboratory performance over time, its produced revenue, cost of analysis and performance characteristics with respect to KPIs. An area on the notice board is kept free for the analysts to write down brainstorming ideas on the improvement of the laboratory which are discussed at team meetings. The individual performance of each analyst is appraised annually but it is also monitored daily through LIMS. Each analyst can access their daily performance at will and has specific personal KPIs that need to be met.

4.2.3 Reduction of waste and integration of LIMS in the laboratory workflow

Waste reduction for both Agrolab and ALControl is an important and continuous challenge for the enterprise, mainly due to the high cost of repeats due to errors and the increased administration needs within the laboratory (sample and result filing, calculation of results etc.). Both companies use LIMS for their operations as a tool to optimise production and minimise waste, but they differ on the degree of its integration in the laboratory workflow.

Agrolab has implemented a custom-made LIMS since 2013, however its implementation had been decided back in 2006. The decision to choose a custom-made LIMS was made on grounds of cost and functionality. As fertilisation consultancy is the main reason for conducting soil nutrient analysis for most of the laboratory's clients, it was a requirement that the new LIMS would have the ability to automatically produce certificates of analysis providing fertilisation consultancy in text. *Image 7* features a typical section of a certificate of analysis for a soil sample, which is produced automatically by LIMS after the approval of the analysis results.

Σελ. (page) 2/3 Αριθμός Πιστοποιητικού/ Certificate No : 01-2135/03.03.2016

Αποτελέσματα Αναλύσεων / Results

Κωδικός δείγματος *Sample Code* **2016-6537**
Περίοδος Ανάλυσης *Period of Analysis* **25/02/2016 - 02/03/2016**
Χαρακτηρισμός Πελάτη *Client's Declaration* **150216-04 ΕΛΙΕΣ ΣΕ ΠΑΡΑΓΩΓΗΣ**
Τοποθεσία *Location*
Χειρισμός Δείγματος *Sample manipulation*
Κατάσταση δείγματος κατά την παραλαβή *Sample condition upon receipt* **Κανονική / Acceptable**

A. Βασικές Αναλύσεις Εδάφους / Basic Soil Analyses

A1. Φυσικοχημικές Ιδιότητες

Παράμετρος Parameter	Μονάδα Unit	Αποτέλεσμα Result	Μέθοδος Method	Χαμηλό Low	Οριακό Medium	Επαρκές Normal	Υψηλό High
Άμμος	%	**59,3**	Ο.Β. 1.2.313 Βουγιούκος				
Ιλύς	%	**28**	Ο.Β. 1.2.313				
Άργιλος	%	**12,7**	Ο.Β. 1.2.313 Βουγιούκος				
pH	μονάδες pH	**7,4**	Ο.Β. 01.302 1:2 νερό				
Ολικό CaCO3	%	**0,1**	Ο.Β.01.303 Pressure Calcimeter Method Modified based on Method of Soil Analysis 1996 Part 3				
Οργανική Ουσία	%	**3,0**	Ο.Β.01.304 Modified Walkley-Black based on Method of Soil Analysis 1996 Part 3				
Ειδ. Ηλ. Αγωγιμότητα	mS/cm	**0,87**	Ο.Β. 1.2.311 τροπ. πάστα κορεσμού				

Ο χρόνος τήρησης του αντιδείγματος ορίζεται στον 1 μήνα από την ημερομηνία έκδοσης του παρόντος πιστοποιητικού (στις κατάλληλες συνθήκες διατήρησης), εκτός και αν ο πελάτης εγγράφως έχει ορίσει διαφορετικά. Εξαιρούνται ευαλλοίωτα δείγματα, τα οποία δεν μπορούν να συντηρηθούν για το προαναφερθέν χρονικό διάστημα.

Προϊστ. Εργ. Περιβαλλοντικών Αναλύσεων
Head of Environmental Analysis Laboratory

Μ. Σταμπουλίδου/Αναλυτική Χημικός
M. Stampoulidou/Analytical Chemist

Σελ. (page) 3/3 Αριθμός Πιστοποιητικού/ Certificate No : 01-2135/03.03.2016

Καλλιέργεια / Crop : **Ελιά σε παραγωγή**

Σχόλια και οδηγίες για τη μεταχείριση του εδάφους / Comments and instructions for soil manipulation

pH: Το pH πιθανόν να δημιουργήσει προβλήματα τροφοπενιών μικροθρεπτικών και φωσφόρου.Το άζωτο είναι σκόπιμο να εφαρμόζεται σε όξινη μορφή και προτιμότερο στην βασική λίπανση σε αμμωνιακή ενώ στην επιφανειακή λίπανση,σε νιτρική μορφή (βλέπε και ανθρακικό ασβέστιο).Προληπτικά χρήσιμοι θα είναι και διαφυλλικοί ψεκασμοί που να περιέχουν και ιχνοστοιχεία όπως επίσης και φώσφορο
Ειδ. Ηλ. Αγωγιμότητα: Η αλατότητα σε επίπεδο μη ανησυχητικό.
Ολικό CaCO3: Επιθυμητό ποσοστό.Το άζωτο είναι σκόπιμο να εφαρμόζεται σε όξινη μορφή και προτιμότερο στη βασική λίπανση σε αμμωνιακή,ενώ στην επιφανειακή λίπανση σε νιτρική μορφή.Ένα μέρος του μπορεί να εφαρμοσθεί αμέσως μετά την καρπόδεση σε νιτρικό ασβέστιο.Προληπτικά,πιθανόν χρήσιμοι θα είναι και διαφυλλικοί ψεκασμοί με σκεύασμα ασβεστίου.Κρισιμα στάδια στο μικρο καρπίδιο κατά τη διάρκεια μεγαλώματος των καρπών και 15 μέρες πρίν τη συγκομιδή.
Οργανική Ουσία: Η οργανική ουσία σε ικανοποιητικό επίπεδο.Να μειωθεί η δόση του Ν κατα 2-4μον/στρ. Χρήσιμο θα είναι, να ενσωματώνονται ελαφρά κάθε 3 χρόνια το φθινόπωρο,1-2 tn/στρ.χωνεμένης κοπριάς ή 2-3kg ανα δέντρο σε δέντρα μικρά ή πυκνής φύτευσης και 8-10kg/δέντρο σε δέντρα μέτριας ανάπτυξης εως και 15-20kg/δέντρο σε δέντρα μεγάλα ή πολύ μεγάλα αραιοφυτεμένα άν υπάρχει δυνατότητα.Η εφαρμογή μπορεί να γίνεται κάθε 3 χρόνια.Να ελαττώνεται η δόση του αζώτου κατά 1,5-2 μονάδες για κάθε 1tn προστιθέμενης χωνεμένης κοπριάς στο στρέμμα.
Μηχανική Σύσταση: Έδαφος μέσης σύστασης, ευνοΙκό για την καλλιέργεια.Να γίνει προσπάθεια διατήρησης της οργανικής ουσίας σε ικανοποιητικό επίπεδο(Βλέπε οργανική ουσία).Για να διατηρηθεί η κατάσταση αυτή,να αποφεύγεται η κατεργασία του εδάφους.Προτιμότερο να χρησιμοποιούνται καταστροφείς, χορτοκοπτικά ή ζιζανιοκτόνα

Συμβουλευτική Λίπανση / Consulting soil

Image 7: Section of a typical certificate of analysis produced by Agrolab's LIMS for a soil sample.

Up to the full implementation of LIMS, all support activities in the laboratory were made manually, including registering samples, batching, preparing worksheets by test, recording data, calculating and checking results, and typing the certificates of analysis. This high degree of reliance to manual work was often causing errors that needed repeating due to erroneous registration of tests and, furthermore, cost greatly with respect to the analysts' and managers' time that would otherwise be spent for analysing samples.

Agrolab has implemented LIMS to all of its laboratories, but it is still using LIMS as a supplementary system to many of its functions. Hence, while it is fully utilised for registering samples, preparing worksheets by workstation and issuing certificates of analysis, many aspects of analytical work are not utilising LIMS to its full:

- Most data are being recorded manually onto the printed worksheets and afterwards typed by the analysts into LIMS. Computer terminals have been acquired for most work areas, but it is not always practical to record data into LIMS whilst performing the analytical tests.
- No statistical process control is done through LIMS for the control samples. The relevant control data are recorded manually and the control charts are created using Microsoft Excel.
- There is no connection between the instruments and LIMS. Data are either exported from the instrument to Microsoft Excel and then copied into LIMS, or they are typed.
- Electronic filing has not been ISO 17025 accredited with regard to data integrity, auditing etc. Hence all archives are kept on paper and all LIMS-derived results have to be printed and signed off manually, which causes a lot of physical movement of paper and requires a large archiving space.
- Small-volume routine tests and all non-routine tests are handled completely outside LIMS.

On the other hand, ALControl is implementing LIMS in a much more general scale. LIMS has been in place for more than a decade and has solved many of the problems that were being caused by manual handling of samples, data and results. A customised ready-made solution was chosen, which is supported by an on-site IT team. LIMS is the primary system for sample results recording and registration, while the paper system is being used as a backup system and as a means for recording comments and observations. Paper is seldom used – electronic data handling and archiving has been integrated into the company's ISO 17025 system and it is being audited as the accreditation requires.

All of ALControl's analytical equipment is connected to LIMS and data are transferred automatically without them needed to being manipulated in any way. LIMS is also used for the statistical process control of the analytical quality control samples – any results from a batch of samples that fails to meet the AQC criteria is automatically not accepted into LIMS and repeat tests have to be performed.

LIMS at ALControl is also used as an HR tool to monitor the performance of the analysts. Each analyst logs in LIMS with his own credentials and allocates his time to analytical, maintenance or administration work. Thus, the laboratory manager has an overview of the

production capacity of the laboratory, any untapped human potential and the amount of work performed by each analyst – which is measured as output per hour per analyst and any deviations from set limits are flagged within LIMS. The performance of each analyst can also be monitored by his quality control results and possible sample repeats. LIMS has also warehouse management functionality, by having recorded the exact position of the original sample in the refrigerated stores – samples are scanned in and out at their storage positions. Finally, the client has the ability to book tests and see his results as they are being approved through the online @mis system by using his own credentials.

Agrolab does not use these LIMS functionalities. Sample warehouse management would require first of all an organised storage space and the ability for the client to book tests on their own would require a redesign of the laboratory's processes. A process re-engineering would also be required if each analysts' performance was to be appraised through LIMS; at the moment some tests are conducted by more than one analysts and the exact arrangement of work is a matter of the internal agreement among the analysts on the day according to the workload. A high degree of workload automation is also not desired, because a certain degree of flexibility is required in prioritising and allocating work to analysts. However, automated data transfer from the instruments to LIMS is a change which is within the plans of the company's management.

5. Conclusions

It is clear from the above that we are dealing with two different models of laboratory workflow management, although both laboratories are leaders in their respective markets and process large numbers of samples.

Agrolab is a company which is does not appear to be committed to Lean Laboratory Management, although it wishes to optimise its procedures, especially being in the environment of the Greek financial crisis which puts enormous pressure onto enterprises to reduce unnecessary costs. However, this financial crisis has limited the cash flow required for costly ventures such as process re-engineering and implementation of LIMS.

ALControl is committed to Lean Laboratory Management, it applies workflow optimisation practices and it is proud to communicate it both inside and outside the company. The UK analytical services market does not suffer from the problems of the Greek analytical services market but process optimisation and usage of Lean Management is a field of competition among the analytical services laboratories, as the clients seek for the best value for the cost of their tests.

The economies of scale that are possible for the size of ALControl are, of course, a matter that allows the company to implement best Lean practices which are borrowed from the manufacturing industry: ALControl analyses 300,000 samples per year utilizing about 150 analysts at their Hawarden environmental laboratory (2000 samples per analyst per year), while Agrolab analyses 10,000 samples per year utilizing 8 analysts at the Sindos environmental laboratory (1250 samples per analyst per year). In fact, the ALControl laboratory facilities have a factory-like feel, with workstations manned mostly by chemistry graduates. On the other hand, Agrolab's analysts are experienced, have many years of experience in the laboratory and exhibit a high degree of commitment, although their skills are sometimes underutilised.

Is treating laboratory work with the same principles as manufacturing work the key to optimising laboratory operations? Perhaps the issues of retaining highly skilled scientific staff and lack of engagement in an environment which favours standardisation and repetition of processes is a matter which could be investigated in a future HR study, but otherwise laboratory work has the characteristics of a manufacturing process and lean principles could and should be applied. The environmental analysis studied here is just an example; many other analytical services sectors, especially in healthcare, could benefit from this approach.

How committed are analytical laboratories to Lean Management? It appears that there is a varying degree of commitment to Lean Management in analytical laboratories. The relevant laboratory management journals still host articles which provide introductory approaches to Lean Laboratory Management; this could mean that for many laboratories the systematic approach to operations optimisation provided by lean management tools is not utilised. In the cases that we have studied, Agrolab seeks optimisation of its processes but does not mention Lean Management at all, while ALControl systematically applies Lean Management to all of its analytical operations.

Is LIMS used as a tool of Lean Management in analytical laboratories? Undoubtedly, LIMS is one of the most important components of the Lean transformation of a laboratory. It is impossible to imagine that processes are automated or effort is being put in minimising transport and inventory while relying on paper worksheets and manual calculations to produce reliable and error-free results. LIMS is perhaps the most important component in the effort to minimise the waste of unnecessarily reworking samples due to simple transcription or calculation errors and through its functionalities it can prove to be a catalyst of change in the laboratory.

Is there a direct relationship between a laboratory's commitment to Lean Management and the extent to which it uses LIMS? We have studied two cases, of two large analytical environmental laboratories which can be considered in varying degrees of Lean and LIMS implementation. Through the study of the cases it has been shown that commitment to Lean was more profound in the case of ALControl comparing to the case of Agrolab and in all areas where Lean Management was applied, the extent of the use of LIMS was proportionately greater. This observation can be easily generalised if we consider how pointless implementing a Lean Management strategy in the analytical laboratory would be if no LIMS is present.

Can Lean Management and reliance on LIMS be a bad thing for the analytical laboratory? Beyond the obvious need for a backup data system in case of LIMS failure, both companies claim that not all laboratory work should go through a strict Lean workflow regime, as there is always the need for flexibility and project work. Mr. Blackburne of ALControl has also indicated that overreliance to LIMS and the factory-like work procedures can alienate the analyst from the nature of the sample, i.e. it removes the "sanity check" from the results, which at the end become a lot of numbers for the analyst without him being able to judge whether the results that he has produced make sense to how the sample looks, smells and feels. In this case, the analyst becomes an operator rather than a scientist.

In both cases however, the laboratories would not go back to the previous manual system. Agrolab, where the management and the staff have an experience of just a few years with LIMS, reckons that LIMS made possible the increase of 50% in laboratory work with the same number of staff and with practically zero transposition or sample registration errors. For ALControl, LIMS is a given reality for the last ten years. The number of samples processed through their laboratory would definitely require more staff dealing with administration work and any cost associated with LIMS acquisition and maintenance can be easily offset by the cost of the extra staff, administration and errors implied by the manual system.

6. References

- Agrolab SA (2015a), *Agrolab RDS – Εξαγορά των Εργαστηρίων Envirolab IKE (Χημικά Εργαστήρια Γούναρης) στον Βόλο – 16/11/2015*. [press release] Available: http://www.agrolab-rds.gr/default.aspx?lang=el-GR&page=310&newsid=220 [retrieved 13/11/2016]
- Agrolab SA (2015b), *Integrated Laboratory & Consultancy Solutions* [brochure].
- Agrolab SA (2015c), *Ισολογισμός 31ης Δεκεμβρίου 2014 - 19η εταιρική χρήση (1 Ιανουαρίου - 31 Δεκεμβρίου 2014)*. Available: http://www.agrolab-rds.gr/Default.aspx?lang=el-GR&page=272 [retrieved 30/11/2016].
- Agrolab SA (2016a), *Management and Organization Chart*. Available: http://www.agrolab-rds.gr/Default.aspx?lang=en-US&page=271 [retrieved 13/11/2016]
- Agrolab SA (2016b), *Mission Statement*. Available: http://www.agrolab-rds.gr/Default.aspx?lang=en-US&page=270. [retrieved 13/11/2016]
- ALcontrol UK Ltd. (2009), *ALcontrol promo*. [corporate video presentation] Available: https://www.youtube.com/watch?v=x2N3U2elsQU [retrieved 13/11/2016]
- ALcontrol UK Ltd. (2015), *Report and Financial Statements: 31 March 2015*, Cardiff: HM Companies House. Available: https://beta.companieshouse.gov.uk/company/07066581. [Retrieved: 30/11/2016]
- ALcontrol UK Ltd. (2016a), *Pan-European Lab*. Available: http://uk.alcontrol.com/en/pan-european-lab-united-kingdom. [Retrieved 13/11/2016]
- ALcontrol UK Ltd. (2016b), *Contact Details*. Available: http://uk.alcontrol.com/en/contact-details-united-kingdom. [Retrieved: 13/11/2016]
- ALS Environmental Ltd (2017b), ALControl Integration Update – March 2017, Available: https://www.alsenvironmental.co.uk/about-us/news/ALcontrol-Integration-Update---March-2017_853. [Retrieved: 24/06/2017]
- ALS Environmental Ltd. (2017a), *ALS Acquires ALControl's UK Businesses*, Available: https://www.alsenvironmental.co.uk/about-us/news/ALS-Acquires-ALcontrols-UK-Businesses_801. [Retrieved: 24/06/2017]
- ASTM International (2006), *ASTM E1578-06: Standard Guide of Laboratory Information Management Systems (LIMS)*, West Conchohocken.
- Benoliel, M.J. (1999), "Step-by-step Implementation of a Quality System in the Laboratory", *Trends in Analytical Chemistry*, 18 (9-10): 632-638.
- Bicheno, J.R. and Holweg, M. (2016), *The Lean Toolbox: A Handbook for Lean Transformation*, 5th ed., Picsie: London.
- Broad, S.A. (1997), "LIMS – A Catalyst for Re-engineering", *Laboratory Automation and Information Management,* 33, 9-12.
- Christian, G. (1994), *Analytical Chemistry (International Edition)*, 5th ed., New York: John Wiley & Sons.
- CITAC/EURACHEM (2002), *Guide to Quality in Analytical Chemistry: An Aid to Accreditation*.

- Cortez, L. (1999), "The Implementation of Accreditation in a Chemical Laboratory", *Trends in Analytical Chemistry,* 18 (9-10): 638-643.
- Cottenie, A. (1980), *Soil and Plant Testing as a Basis of Fertilizer Recommendations* (FAO Soils Bulletin 38/2), Rome: Food and Agriculture Organization of the United Nations. Available: http://www.fao.org/docrep/018/ar118e/ar118e.pdf [retrieved: 22/04/2017]
- Edward, M., Muntean, N., Mihăiescu, T., Mihăiescu, R. (2008), "LIMS use in Laboratory Data Management", *ProEnvironment*, 2, 19-23.
- Eisenhardt, K.M. and Graebner, M.E. (2007), "Theory Building from Cases: Opportunities and Challenges", *Academy of Management Journal*, Vol. 50, No. 1, 25-32.
- European Council Directive (1986) 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture, OJ L181/6.
- European Council Directive (1998) 98/83/EC on the quality of water intended for human consumption, OJ 330/32.
- Gerring, J. (2004), "What Is a Case Study and What Is It Good for?", *American Political Science Review*, Vol. 98, No. 2, 341-354.
- Griffiths, R., Trew, L., Foxon, S and Rose, J. (2013), *UK Environmental Laboratories Market Assessment 2013*, Shrewsbury: Environment Analyst.
- Heizer, J. and Render, B. (2014), *Principles of Operations Management: Sustainability and Supply Chain Management*, Pearson: Boston, pp. 660-679.
- Hellenic National Accreditation System (2016), *Annex F1/A16 of the Certificate 44-4: Scope of Accreditation of the Analytical Laboratory Agrolab SA (Laboratory in Thessaloniki)*. Available: http://esyd.gr/portal/p/esyd/el/showOrgInfo.jsp?id=17662 [retrieved 13/11/2016]
- Herasuta, M. (2007), "A "Lean" Laboratory", *Lab Medicine*, 38(3), 143-144.
- Holweg, M. (2007), "The Genealogy of Lean Production", *Journal of Operations Management*, 25, 420-437.
- ILAC (2017), "ILAC's Role". Available: http://ilac.org/about-ilac/role [retrieved: 22/04/2017]
- ISO/IEC (2005), *ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories*, Geneva: ISO/IEC.
- JCGM (2008), *Evaluation of Measurement Data – Guide to the Expression of Uncertainty in Measurement* (GUM Guide).
- Ketokivi, M. And Choi, T. (2014), "Renaissance of Case Research as a Scientific Method", *Journal of Operations Management*, Vol. 32, 232-240.
- Koupparis, M. (2016), "Introduction to Quality", presented at the "Laboratory Accreditation According to ISO 17025" seminar by the Greek Chemists' Association, Thessaloniki, 9-10 April.
- McDowall, R.D. (1995), "A Matrix for a LIMS with a Strategic Focus", *Laboratory Automation and Information Management*, 31, 57-64.
- McGrath, J. (1982), "Dilemmatics: The Study of Research Choices and Dilemmas" in J.E. McGrath, J. Martin & R.A. Kulka (Eds.), *Judgment Calls in Research*, Newbury Park, CA: Sage.

- Miller, J.N. and Miller J.C. (2000), *Statistics and Chemometrics for Analytical Chemistry*, 4th ed., Harlow: Pearson Education Ltd., p. 15.
- Murphy, M. (1996), "The Lab, the LIMS and the Enterprise", *Laboratory Automation and Information Management,* 32, 63-69.
- NORDTEST (2011), *Internal Quality ConTroll: Handbook for Chemical Laboratories* (NORDTEST Report TR 569), Oslo: Nordic Innovation Center.
- Ohno, T., 1988. The Toyota Production System: Beyond Large-Scale Production. Productivity Press: Portland.
- Redestos-Efthymiadis Agrotechnology Group (2008)*, Company Profile*. Available: http://www.redestos.gr/default.aspx?lang=en-US&page=86 [retrieved 13/11/2016]
- Reynolds (2009), "Thinking Lean: An Introduction to Lean in the Laboratory", *Lab Manager*, September, pp. 30-32.
- Rice, E.W., Baird, R.B., Eaton, A.D. and Clesceri, L.S. (Eds) (2012), *Standard Methods for the Analysis of Water and Wastewater*, Washington, D.C.: APHA.
- Rowley, J.R. (2002), "Using Case Studies in Research", *Management Research News*, Vol. 25, Iss: 1, 16-27.
- Scandura, T.A. and Williams, E.A. (2000), "Research Methodology in Management: Current Practices, Trends and Implications for Future Research", *The Academy of Management Journal*, Vol. 43, No. 6, 1248-1264.
- Shah, R. and Ward, P.T. (2007), "Defining and Developing Measures of Lean Production", *Journal of Operations Management*, 25, 785-705.
- Skobelev, D.O., Zaytseva, T.M., Kozlov, A.D., Perepelitsa, V.L. and Makarova, A.S. (2011), "Laboratory Information Management Systems in the Work of the Analytic Laboratory", *Measurement Techniques*, Vol. 53, No. 10.
- Stafford, J.E.H (1998), "LIMS: An Automating or Informating Technology?", *Laboratory Automation and Information Management,* 33, 163-168.
- United Kingdom Accreditation Service (2016), *Schedule of Accreditation: ALcontrol Limited Trading as ALcontrol Laboratories*. Available: http://www.ukas.org/testing/schedules/Actual/1291TestingSingle.pdf [retrieved: 13/11/2016]
- United States Environment Protection Agency (2017), *Environmental Chemistry Methods (ECM)*. Available: https://www.epa.gov/pesticide-analytical-methods/environmental-chemistry-methods-ecm [retrieved: 22/04/2017].
- Womack, J.P. and Jones, D.T. (1996), *Lean Thinking: Banish Waste and Create Wealth in your Corporation*, Simon & Schuster: New York.
- Womack, J.P., Jones, D.T., Roos, D. (1990), *The Machine That Changed the World,* Rawson Associates: New York.
- Yin, R.K. (1994), *Case Study Research: Design and Methods*, 2nd ed., Thousand Oaks: Sage.

7. Appendix

7.1 Questionnaire used in the interviews

Lean Management

- Why would a client choose your company over the competition?
- Which is the competitive advantage of your company?
- Which procedure is followed as regards to the movement of the sample through the laboratory?
    - Coding
    - Handling of samples by the laboratory staff
    - Repetition of analyses in case of error
    - Storing of samples after completion of analyses
    - How is information (the product) being moved through the laboratory?
    - Is the workload distributed in a team or a position basis?
- What are the strategic goals of the laboratory?
- Does the current system of workload distribution adequate to achieve these goals or should a more rigorous system be employed?
- Do you employ a lean management system?

Waste sources according to lean production

- Do you employ the following in the environmental laboratory?
- Is there intention of optimising their usage?
- Where does LIMS help?

- Movement of information and samples
    - Is there a common database for all laboratory, client and management information?
    - How is sample movement controlled between work posts?
    - Is there an archiving and retrieval system for completed samples in case additional analyses or analysis repeats are required?
    - How much is paper used in the laboratory?
    - How is completed analysis data stored and retrieved?

- Bottlenecks
    - Can demand be forecast? Are there any seasonal trends?
    - How does the laboratory respond to demand fluctuations?
    - Is there a provision for extra staff in demand peaks? Multi-skilled analysts?
    - Does the company give incentives to customers to choose slow periods?

- Work standarisation (do it right the first time)
    - Are standard methodologies in place?
    - How is the staff being trained and re-trained?
    - How is the quality of the analyses controlled statistically?
    - Which are the main errors found in results? How are they dealt with?
    - How important are errors for the customers?
    - What happens when the customer is dubious about the results?

- Inventoring:
    - How often are usual reagents and consumables replenished?
    - Do you prefer small or large orders?
    - Are reagents stocked just in case or are they ordered in time from the suppliers?
    - Do you prefer a small or large number of suppliers? How do you choose them?

- Production flow (variability impedes efficiency)
    - How do you standardise the product for the customer? Analysis packs according to legislation?
    - Is the customer given incentives to choose standardised analysis packs in order to facilitate production flow?
    - How are customers with extraordinary needs dealt with (samples needing analyses not done often or extra-urgent samples)
    - How is the workload assigned to individual analysts?
    - Do you prefer small analysis lots in order to avoid delays?
    - Is the workload organised in specific workstations (each analyst performing specific tasks) or in work cells?
    - How do you avoid work-related accidents? (Training in H&S issues, personal protective equipment etc.)
    - How do you regulate instrumentation failures? Is there a preventive maintenance schedule in place?

- Continuous improvement (kaizen)
    - Is there a clear mission from the management as regards to continuous improvement? Is this known to the staff?
    - Are the analysts encouraged to employ more economic or more efficient work methods? How?
    - When an analyst discovers a systematic error, how is it dealt with and how is is made sure that it will not be repeated? Is the analysis stopped in this case?

Using LIMS

- Since when is LIMS used in the laboratory? When was this decided? How widely are these systems used by other laboratories?
- Which are the principal problems that using LIMS solves?
- Have you chosen a ready-made platform or have you ordered a custom-made one? By which supplier?
- Have you mapped the laboratory processes prior to implementing LIMS in order to decide which processes could be facilitated by LIMS?
- How have you decided on the level of LIMS process automation?
- Could overusing LIMS to traditional manual paper practices pose problems? (e.g. paperless work, digital quality control charts, automated batching etc.)
- Do you consider the transfer from paper to LIMS to be a successful one?
- Do you use LIMS as the primary record system or as supplementary to paper?
- Has workflow changed after transfering to LIMS?
- Is there a measurable profit gained from implementing LIMS? (speed, errors, paper economy etc.)
- How could LIMS be used to limit time waste and errors?
- How is LIMS integrated in ISO17025 or GLP?

- Supposing that LIMS is used for coding, data entry, results calculation and issue of certificates, are any of the following integrated into LIMS (or do you intend to integrate them?)
    - Single database for ERP and LIMS
    - Information on sample characteristics (quantity, container, description)
    - Sample tracking functionality
    - Automated pack creation for each customer
    - Automated batching
    - Automated data entry from instrumentation
    - Notification for periodic maintenance of equipment
    - Automated inventory check

- Sample and analysis tracking (where is the sample and when will the analyses be finished)
- Access to customers in order to track their samples (I know you do this. How useful is it? Do customers use it?)
- Measuring each analyst's performance for appraisal purposes.
- Deadline control
- Automatic scheduling per analyst according to set priorities
- Electronic QC charts.
- Automated error control (by setting acceptable values or calculating ion balance)

7.2 Transcript of the interview at Agrolab SA (translated from Greek)

The interview was held at the headquarters of Agrolab SA, at Sindos, Greece on the 23rd December 2015. The interviewees were Dr. Alexandros Giannousios, General Manager, and Mr. Giorgos Stratakis, Marketing Manager of Agrolab SA.

Which parameters are important for the customers of the environment lab?

Giorgos Stratakis (GS): We're concerned both on quality and speed.
Alexandros Giannousios (AG): The customer doesn't probably even know the tests they need. We tell them. Especially as regards to soils, they don't care about the accuracy of the analysis. What they care about is the fertilization consultancy, and they want it to be delivered quickly. They don't care about all the other parameters.

Does Agrolab employ a lean production system?

AG: For years now. That's why we have LIMS now, for the analysis certificates to be printed out straight from the lab.

Would it be beneficial for Agrolab to communicate their lean production system to their customers?

AG: That would have absolutely no point at all for the customer. What they care about is their analysis time to be reduced.

Would a maximised workflow benefit Agrolab's strategic goals?

AG: Improvement is continuous and it is performed step by step every day. As sample numbers increase, the company has to react with an increased speed of production and with more quality.
GS: I don't think that it is a matter of maximising production, but rather a matter of optimising production. Reducing dead time, extra costs…
AG: That's what you are looking for, I think. Optimisation. Even with 10 samples, you want to reduce time and improve accuracy. That's why it is a continuous process. ISO 17025 says the same thing: you set up a sturdy foundation and on that you build continuously, you continuously improve yourself. When we started, we had no CRMs for every test, and now we have CRMs. We started without the ability to write results directly on LIMS, now we do. The next step will be to take results from the instruments directly to LIMS. It is a continuous process.

Is there an intention to integrate LIMS with the company's SAP?

GS: We can't do this. They function differently. They are linked, however. SAP is a clearly financial system, an ERP, which does many things of financial and accounting nature, plus it can partially deal with some customers. On the other hand, LIMS is a system for sample management, issuing of results, office raw data management etc. What we have achieved is to link the initial ordering function between SAP and LIMS. You can't open a new order in LIMS if this order isn't opened in SAP and linked with LIMS first.
AG: There are LIMS that do not need SAP. However, our group of companies uses SAP, hence we have to use both systems. This is a waste of time, but we can't do anything about it. If we were an autonomous company, we would only have LIMS and no SAP.

The lab has its own self-organised system of sample archiving. Could this be done in a more organised fashion, perhaps through LIMS?

AG: We haven't ever thought of that. It seems to be a clever thing that could be done.
GS: Especially if the volume of samples increases.
AG: This needs an organised storage space, though.

The lab uses a lot of paper, causing waste of money and time. What are the company's goals on this?

AG: Going paperless is our goal. However, we have technical problems with ISO 17025 and GLP systems as regards to implementing this. It is a procedure that has been introduced in the company, as a way of thinking.

How does ISO 17025 support the use of LIMS?

AG: The archive security has to be accredited. It is a procedure with many steps. You have to accredit the archive security, you have to validate your procedure, the Hellenic Accreditation System has to do their audit… there is a procedure for which we are not ready yet, but it's within our goals.

How does Agrolab keep their archives?

AG: Analysis certificates are already paperless. We only keep raw data on paper. The lab keeps their raw data on file.

There is a seasonal variability in the sample volume the lab has to cope with. Does the company forecast the demand?

GS: Of course. We forecast bimonthly and for each customer. We forecast for each customer and for each category of analysis for the largest customers of the company.

And how does the laboratory adjust its work to the change in demand? Are some members of staff multi-skilled, changing roles according to the demand?

AG: This is done, but it is done *ad hoc*. How else could it be done? We haven't got that much staff to be able to do it according to some kind of schedule. We are doing it *ad hoc*, because we may be doing our forecasting, but the forecast isn't always true. Last November, I was seeing the numbers yesterday, we had 20,000 samples – this year we have 10,000. And the forecast was the same. Last year we were 10,000 samples over the forecast, and we should have had the same numbers this year.
GS: The conditions of the market change.

Does the company give incentives to the customers to choose periods of lower demand?

AG: Yes we do.
GS: Better prices, and other things.

All methodologies are standardised and written down. How is the staff trained and re-trained?

AG: Yes, we check the staff's competency through the interlaboratory tests. This is our testing and our training part. Apart from that, there are training programmes. There aren't at the best possible level, but they aren't bad either. There are also comparative tests between the analysts.
GS: Errors that have to be dealt with, when spotted.
AG: There is a mechanism through ISO 17025 for errors; if there is an error there should be a re-training if needed, whatever the ISO 17025 demands.

Apart from interlaboratory testing, ion balancing, quality control charts and the approval of the results through a second pair of eyes by the lab manager or the agronomist, are there other quality control methods employed by the lab?

AG: There are internal audits by the QA Manager, or by someone else. For example, I could myself be auditing some of the Environmental Lab's methodologies in random. The manager of the Thessaloniki Pesticide Residues Lab could be auditing the Athens lab, and vice versa. At the Molecular Lab they bring in an external auditor. There are procedures like these. As regards to LIMS, we have introduced ion balancing for waters and at the Food Composition Labelling Lab, LIMS records both their CRMs and their repeat samples. Because we haven't got a team that can build LIMS the way we want it exactly, I and George continuously make corrections according to the information we receive from the others. There are LIMS that have all these features integrated. Our LIMS is custom-made for us. It would cost much more if we bought a ready one and we had to adjust it to our work, because we aren't a lab that does one single thing. We do a thousand different things. For example, I don't know of any LIMS in the market that has the ability to do soil fertilization consultancy. There isn't any LIMS that can do hydroponic water consultancy. There isn't any LIMS that automatically refreshes the MRLs. All these are our features and it would cost us a fortune to incorporate these features in a ready-made LIMS.
GS: We're talking about hundreds of thousands of euros here.

Apart from analytical errors, what are the types of errors that can be found in our results?

AG: Now with LIMS we have almost zero transposition errors. There are non-existent, almost. We also have very seldom coding errors. At this time, our errors are only analytical and regarding pricing of the tests.

How important are errors to the customers?

GS: They are critical.
AG: You lose the customer, that's it. He never excuses your error.

When the customer has doubts about the results, what is the mechanism?

AG: There is a procedure for retesting the sample, first as regards to transposing raw data, checking the method and, if there is a problem, the customer is informed and a problem report is filed. If there isn't a problem and the customer still has doubts, we file a problem report, the sample is retested at the

customer's expense. Now, if we really charge him or not, that's a matter of the customer services department, but that's how the procedure goes.

As regards to inventorying, would it be better for the company to buy in large quantities if it were economically sounder?

AG: The company doesn't have an inventory space. We can't have it, neither practically nor in accounting terms. Plus we don't need it; the Tax Office doesn't give us the right to have one. As regards to large quantities, we do it, if possible.

Generally, the company prefers having many or a few suppliers?

AG: Many, in order to have options.
GS: This could be a LIMS feature: keeping data on critical materials and be informed for imminent shortages.
AG: You can't have that, because you can't have inputs.

As regards to workflow, is it beneficial to provide standardised test packs?

GS: The majority of our testing is through standardised packs.
AG: The packs are made through legislative requirements and scientific knowledge.

What happens when a customer demands some exotic analysis that is seldom done?

AG: We do whatever the customer wants. We don't have the power to impose to the customer what's better for our workflow. It's the rules of the market. We aren't like Coca-Cola: this is our product, take it or leave it. Sheer lack of power. We do whatever we can, but each customer has his own needs. For example, in tobacco analysis, every tobacco merchant has his own analysis pack.

Does the lab make an effort to have small lots in order to avoid delays?

GS: That a concern of the lab manager. Customer services doesn't interfere with this.
AG: We do it, though. For waters, for example, we have separate lots with the large analysis pack and lots with the small analysis pack. And lots with whatever extra the customer wants.

Is there a commitment by the management as regards to continuous improvement?

GS: Of course.
AG: It's mandatory, under the ISO 17025, the quality policy.

Is the staff encouraged to employ more economical and more efficient methods of work?

GS: This is not a matter of work, this is a matter of the general stance of the staff. The analyst has to follow the methodology. All the others are a matter of perception
AG: And a matter of training. You can't be economical on the standard methodology. Now, if you are to shut off the lights or the water before leaving the room, it is a matter of each one of us to employ. There is a vertical demand for economy; I had sent an email some years ago but I don't think anyone practices what I said there. Generally, shutting off computer screens, lights, having airconditioning at a normal temperature etc. is a matter of saving energy.

When a systematic error is discovered, what is the procedure followed?

AG: Testing stops, investigation of the problem, revalidation of the method.

When was LIMS decided to be installed in the lab?

AG: In 2006 or 2007.

Do other labs use LIMS in Greece?

AG: Nowadays, yes. Ready-made, not custom-made. But they are smaller than Agrolab, there isn't any other lab comparable to Agrolab's size.

What principal problem does LIMS solve?

AG: Lab management and errors.
GS: Lab management, errors, co-ordination, speed, knowing what is where, many things…

Why did Agrolab choose a custom-made platform?

GS: There wasn't a platform that could cover our needs. When we were looking for a LIMS, all platforms were module-based and they cost hundreds of thousands of euros. We hired a computer data processing specialist, Dimitris Mylonas, knowing a special programming language, who was building our project for 3-4 years, even after leaving the country, and then we did some alterations with a computing company, Altanet. Under his supervision, all the time, providing technical assistance.

Was a process mapping done before designing LIMS?

GS: Many years have passed, but yes, it was done. In a very primitive stage, when we only wanted to use only data handling into LIMS. From then on, we have integrated many more modules.

How were the processes to be integrated into LIMS chosen?

AG: The first thing we did was data handling, sample coding, analysis orders and it was first tested on soil samples, because they have the largest volume of data entry.

Would there be a problem if a fully automated LIMS was introduced in the lab?

AG: We haven't lived that, but it would have caused problems. But first of all, we didn't have the money. A LIMS back then cost 100-150 thousand euros, an amount that we didn't have.
GS: We would have had to change our processes.

Is the transition from manual to LIMS considered successful? Is this quantified?

AG: Yes, it was successful: Increase in productivity, that's our quantification. For the last years we are same number of people and the samples have increased over 50%. The methodologies haven't changed, only the way results are handled, because we adapted LIMS to our methodologies.

There are some tests, such as pool water testing or sludge testing, that are still handled outside LIMS. Are they considered to be integrated into LIMS?

AG: We haven't integrated them yet, because the sample volume is small. They will be integrated over time.

Would over-automation cause problems?

GS: A certain flexibility is always needed, but more automation could be implemented if the management wishes so.
AG: There could be problems, but one has to adapt.

Apart from all the things we described, which of the following LIMS features do you use or you might use in the future?

- **Information on sample characteristics (quantity, container, description)**

GS: We have them, as open fields. LIMS supports them, if they are typed in.

- **Sample storage information.**

AG: If we ever get a sample storage space, we could use it.

- **Automatic order creation by customer.**

GS: We do it, but not automatically. We create a pack for the specific customer and create his entry manually. We can't do it with our customers, because our customers order a variety of tests. We don't have a customer that always asks for a specific test pack.
AG: There is no need for this. Either way, we would have to make an offer, the offer should be accepted, it's not, say, internet-based.

- **Automatic batching.**

GS: We need the lab manager to do this, to prioritise. It's not a first in – first out procedure here. We wouldn't want such a thing, even if there were different priority attributes set up by the customer services.
AG: It would be nice to have, if we had specific demands from our customers. All our customers want their results yesterday, so everything would be extra-urgent.

- **Automatic data entry into LIMS by the instruments.**

AG: This is the right thing, to be a link between the instrument and LIMS. This costs.

- **Sample tracking functionality.**

AG: We have this already. And it will be available to customers, too.
GS: This is the next step. It will be done before the end of 2016.

- **Measuring each analyst's performance for appraisal purposes.**

AG: No, we don't want to do this. It would cause many problems with ISO and traceability, because the analyst who starts work on a sample would have to finish it as well. If the analyst takes a leave of absence in the meantime, what would we do? So, we just assign tasks to "analyst1", "analyst2" etc. and

at the end, whoever finalizes the analysis writes his name. We do this for ISO. We have adapted LIMS to our procedures and not our procedures to LIMS.

- **Deadline alarms.**

GS: This will be done afterwards. The due samples alerts will be visible to the lab managers.
AG: The analyst has received the samples and he has to finish them. The lab manager, who sets up the lots, will have to see the alarms. The lab manager has a list with the due dates, and if they need to change, he sees the new dates.

- **Automatic work scheduling.**

GS: To do this, each analyst would have to do only one thing. For example, if we had 200,000 samples and we had 200 people, you might only be measuring pH for 5 years. We don't want this.

7.3 Transcript of the interview at ALControl UK Ltd.

The interview was held at the head office of ALControl UK Ltd., at Howarden, Flintshire, United Kingdom on the 15th February 2016. The interviewee was Mr. Ian Blackburne, Quality Manager and Mrs. Anna Kiourtsidi, analyst at ALControl, gave some insights from the analysts' point of view.

I saw in your promo video on the internet, that you actually advertise your lean management techniques, which is bizzare; because I didn't know that your customers might be interested in your techniques. I thought that the customers care only about the results and when they are going to get them.

Well, they do, but what they like innovation also. So, the benefits of us having a lean system is that we are potentially faster in responding, we've cut out waste, and ultimately it means that you can deliver cheaper service for the same level of quality. So, the quality is always implied, the quality is always to the required level, and that's one of the key things with quality: you have to ascertain what the customer wants, to be able to meet their quality level, it's not a standard of quality as such, it depends on what they want. We have different levels of testing to be accredited. The fact we have the lean system means that we should be cheaper, really.

This means that your clients are big customers who are liaising with people who understand the concept of lean management, right?

It's only one aspect of it. Essentially, we are a lab that generates results. So do all the other labs. So, what differentiates us from all the labs? Things like innovation, the LIMS systems, or lean working all help differentiate us – it's part of the added value we can add to the customers. If they just want standard testing and results they can get that anywhere.

What kind of customers do you have? Environmental agencies, for example?

In the UK, environmental agencies don't do any testing. They set the regulations and the users have to demonstrate that they meet the requiremets. It could be a factory, there's Airbus across the road – it could be Airbus, because they're a factory and any output from the factory is considered an effluent, because they discharge it to streams and rivers and they have to monitor the quality of the water they are discharging. So, we would test that water.

So, suppose I'm Airbus and I have a waste treatment plant, where I produce wastewater and sludge, and I have to do my analyses somewhere. There are many labs in the UK. Why would I

choose your lab and not anyone else? What differentiates you from the competition, apart from your quality management?

Well, most labs have that. In many ways, that isn't the differentiator. The quality is the same between most of the labs. What differentiates us is that we think we provide a good service and we have good relationships with our customers. If they just want a basic test and straightforward results then perhaps we can't offer them anything different. We offer a lot of technical support, we have technical knowledge, we're able to manage big jobs and we're able to manage them quicky. So, quite often we specialise in 10% of their work and they can get the other 90% done somewhere else, but they value the service they get from ALControl and the relationships they build up, so they put all their work in ALControl because it's that 10% they can't get elsewhere, and it's that important 10% that makes them change their decision.

Some basic information now: How large is ALControl?

It's split, really. We have our European divisions; we have three different divisions in the UK: We have the food and water division, we have the environmental division (which is this site), part of this lab is a lab in Aberdeen for wastewater and we have a site in Conwy, North Wales, for oil and fuels. This environmental site is about 200 people. Analytical staff is probably 150.

Your samples are sludges, effluents?

Soil as well. It's mostly contaminated land, but if one of our nitrogen tests or phosphorus we do on contaminated land it could also mean that it's safe to spread on the land.

How many samples do you process in this site?

We process about 5,000 tests a day, it's about 800 samples a day.

Do you have a figure of the revenue last year?

For this site, it's about €12 million.

Which is the process a customer follows in order to bring a sample to the lab?

They phone up, get through to our customer services, we then transfer them to our couriers. So, we have a courier company that works on our behalf, they have a separate warehouse that has all our containers and bottles in. They make an arrangement with the customer to deliver the containers, so we ship out cool boxes with containers they go to their site and drop them off. We don't do sampling, they sample their own and then our couriers pick them up and bring them to the lab. All our containers are sent out with barcodes on them and so they're sent to us with the chain of custody identifying each container with what testing the customer wants.

And then, having your barcode and some contact with the customer through the customer services you know that analyses need to be done.

That would be the chain of custody that accompanies the sample. But we also have an web-based button, called @mis, and the clients can schedule their own work, so when we receive the container, we just scan the barcode and the all the testing comes up.

The scheduling of jobs is done through the LIMS?

Yeah. If the customer does it though the web, it feeds directly to the LIMS. If it's done though the chain of custody, it's manually scheduled.

Each analyst performs some specific tasks, right?

The samples have to be prepped first, and this is partly when lean comes from. So, the way it used to work is that the samples would go to the analytical area, extracted and analysed. That isn't done now, we have a prep area and we prep all samples from all areas except from samples for volatiles, where Anna works. They come in their own containers, because it's obviously a volatile test and it's easy to lose the products, so that's prepped in the analytical area. Generally it's just extracted and if it's water it's tested straight. In fact, waters you just do them straight off, isn't it? Volatiles: headspace is taken off, soils: it's extracted. In all areas, samples are prepped in the prep area and then they are split. Soils, for example, need to be dried, crushed, weighed, we need to make out the moisture content and then we set off.

So, each analyst, at the start of the day, has a list of specific things to be done, or is it an ad hoc procedure?

I'll let the analyst explain that one.

Anna Kiourtsidi: It depends on the priorities that have to go that day. We have a meeting each morning.

Ian Blackburne: Well, yes and no. What they decide is about the work in the lab, what needs testing, if it's something of higher priority than others. What really is their job is to test all samples that are there, because the prep should come through at the same speed as the analytical. So, they should just run what comes through. Any work we accept, we give a turnaround time. There's two things, also: Every sample has an expiry date, which depends on the stability. So, we need to analyse it before it expires, i.e. it's still stable and we need to run it within the agreed turnaround we give to the customer. We may receive two samples next to each other on the same day and one customer has a 10-day turnaround time and the other has 5 days. They may even be prepped at the same time, and what Anna is trying to say, is that they wouldn't perhaps be analysed at the same time because they are not due at the same dates. We try to move away from that and just test what comes through, because it's inefficient to stop and pick samples out, it should be done at the prep stage, they should prioritise and prep the samples that need testing first, first and when they come to the lab they don't have to worry about that, they just test what comes into the lab.

Do you do it? Do you have this kind of procedure?

Yeah, it's always evolving because it's always trying to meet the turnaround time. So, they try to process each day what has been generated each day.

So, I suppose that whichever bottleneck or error that appears can be avoided if the correct job is done at the prep department.

Yeah. And we have multiple prep stations and we can put people in if we have a bottleneck. One of the challenges of the business that we said earlier is about the 800 samples a day – well, they vary, as that's an average. Everyday is not the same. Beginning of the week should be quieter – Monday would be really quiet because no-one's taking samples on a Sunday and it builds as you get towards the week, it gets busier. And you never really know what's coming in the following day.

Do you have some kind of seasonality in the year as well?

There is seasonality, but it's more linked to the temperature outside. So, for sure you have seasonality for Christmas, nobody is out on any site on the first week of January digging samples or taking water samples. January is really quiet. That is seasonal. The other thing, of course, is when it snows, the ground is frozen and then again it gets very difficult to take sample. As regards to waters, we don't get a lot of that, but even so it will be slightly offset by round of something somewhere else, so we won't see more samples I suppose.

If the customer thinks that something should be retested, what do you do?

We have a process for that. It first goes to our data check process and the customer queries the result. We generally do a repeat on the first aliquot and then we go back to the original sample, less possibly with volatiles, but quite often we get to the original sample and retest that. So, first by retesting the first aliquot you confirm whether your method is OK or not. If you get the same result, great, but that doesn't tell you too much. That just means that you know what's in that aliquot, but it still could mean that something's got wrong with the aliquot, or it could be the wrong aliquot that's got prepped, or it has got mixed and then you really have to go back to the original sample. We then compare the two, three or four sets of results and then say which one is correct.

And, say, it's proved that it's your mistake. What do you do then?

We should test the result and start and investigation to try to see what went wrong, and if we can put some measures in place to stop that happening again. You get the ISO 17025 procedure of complaints and corrective action.

Let's now see some practical aspects of the workflow and how LIMS helps in these aspects. Do you have a common database for your customer side and your laboratory side? Can you see in a single page the customer's data and where the sample is at the moment, for example?

It's essentially the same database. Internally, if I were to put information into our LIMS system I would be able to see the customer's information. We have a slightly different system for billing, so for invoicing it's like an ERP, it's linked in LIMS but it's not part of it. If you use @mis, you could use in that function that you said. When you log in, you see all your jobs and you can type in a sample number and you can see the history of that sample and when it's expected to be due.

Do you have an archiving system for all your samples' results?

We keep all data for 7 years and the sample for a minimum of 30 days. We've got a stores, it's 4 storeys high, enough for 40,000 samples.

Generally, how much paper do you use in the laboratory?

Not so much. We do use paper and it does follow samples through, but it's a backup in some respects. One of the requirements of ISO 17025 is that any original observations are recorded and kept. So, they act like a comment page that follows the sample through and you guys know that you can write on it, the run log is like the batch information, isn't it? It has the QC sample and all of the run and they write on that, and that gets filed. Our primary filing system is the LIMS, and all of the instruments are attached to the LIMS, and the balances are attached to the LIMS and the LIMS tells the guys how to prep the sample. For example, when they scan the bottle, it tells them how much to split into another container and which container to use.

Do you have a provision for extra staff when there's a peak in demand?

Yeah, so se use agency workers. We have an arrangement with the agency, as I said earlier we don't get a lot of visibility for our samples. So, we may have someone for a few days, but we treat our agency staff the same as our permanent staff, there's no differential in terms of quality, they can affect the quality as much as the permanent staff, so they have to be adequately trained. That's a challenge for agency staff, because the need 2-3 days of training before they even start analysing.

The structure within the laboratory is that each sub-analytical area is run as it's own area, it's called a cell. So, we have the volatiles cell, this is where Anna works, as there's an organic soils cell. Each of these cells is managed like a mini-laboratory and if, for example, in volatiles they're not very busy then they have to give out their staff to other areas. Each cell would have a laboratory manager. Each manager could manage more than one cell, but all cells have a leader, who is like a laboratory supervisor.

Do you give your customers incentives to send in more samples in slow periods?

It is something we try, it's something we consider and try, yes. What we do is on Mondays we try to have less staff, while Saturday is quite a busy day, so we split our shifts. And what we try to do this year, when we are quieter, rather than getting in more work, we close the lab for an extra day and we encourage people to take time off.

As regards to work standardisation, since you have the ISO 17025, you have specific methodologies. Do you train your staff as needed?

Most of our methods are laboratory-developed or based on a standard method and we do some developing. There are methods to doing that: if we have a totally standard method, and we do have some, then everytime that method changes, and it could be changed by whoever writes it, we have to respond to it. So, it's not always visible when changes are being made and you have to respond even if that change is of no benefit to you. So, there's always a benefit to developing your own methods, because you've already demonstrated your method works.

Do you validate all your methods?

Yes. We do run unaccredited methods, though, which don't meet the requirements of ISO 17025, but they would be validated. They would be validated to a lesser degree. One of the things we offer is this professionalism and this pride in our technical results, even on unaccredited methods we still endeavour to make them as accurate as possible. We run AQC samples on unaccredited methods.

The main errors on analytical results, they could be credited to what you said previously and can be attributed to human error.

I don't like human error as a cause, but the only thing that's guaranteed is that people make mistakes, and I make this clear to everybody. The question is why did that person make the error. People do make mistakes, but you should have systems and processes designed that have checks in. A good example is in areas you write a lot, such as with burettes. All those results are countersigned and checked when they type them in, to make sure there's no transposition error.

How important are errors to your customers?

Quite often, the samples we get can be complex, and they can be quite horrible I suppose at times, they're not easy samples. So, matrix effect can come in, so even within soil you can have clay, or you

could have a loamy soil, and they react differently. And, of course, in waters, you could have saline water, a river, effluents. They're chemically totally different. You can never rule out an error coming from the sample itself.

Commercially, how important are errors?

Well, it's double-edged, if you like. There's a balance here. The customers would prefer us to get the results right the first time. Without question. But they're also realistic: they know errors can happen. I think they appreciate more the honesty when you do phone them and tell them you've made a mistake. If that's going to happen, you need to make sure you're responding as fast as possible, because we would never not notify the customer. If we find that we've issued the wrong result, we would correct it.

Is there a possibility you might lose a customer due to an error?

Yes, but they're going to go somewhere else and everybody has these sorts of errors. I think, I'd rather lose a customer by being honest and tell them we've made a mistake than covering it up and actually damaging your reputation.

Let's go to inventorying. How often are your reagents and consumables replenished?

Anna Kiourtsidi: Every month, I would say. We keep them in stores.

Ian Blackburne: We have a stores and we keep some inventory, but not everything. What do you get from Steve?

Anna Kiourtsidi: We get our standards, but for other compounds we may keep them for three years, we don't order them every month.

Ian Blackburne: Some of the things you buy are frozen, so they keep for a long time. We don't live and breate "just-in-time", it's a bit too risky sometimes. And I don't think it's clever enough, if you like. The BMW Mini factory they do JIT to the point that they don't keep more than 50-60 minutes' worth of bumpers, for example. Which means that you've got to keep an eye on the motorways to see trucks delivering parts you'll be using later in that day. Do you imagine doing that here? It's just incredible, the logistics. They even load the truck in the right order you are going to use them. You've really got to have great commitment from your suppliers. We do trust our suppliers, but you've got to weigh in the benefits of working in JIT system. When it comes to a car factory, where they potentially have to double their amount of storage and tear the building apart, you can see it making a big difference. For us, to hold a few days' worth of extra standards is worth it, because the consequences of running out are massive. Not just to what it means with customers, there might be penalties occurred, and then you create a backlog in that lab that affects the other customers potentially. While we don't hold a lot of stuff we don't need, we can't run out.

Do you liaise with many suppliers or do you have a few that you trust?

We do have to have fully traceable standards, and then really, to some extent, it doesn't matter where you buy them from. We have an arrangement with a local chemical supplier and they can get anything, really.

As regards to production flow, do you provide analysis packs, ready for the customer?

Yes, we do. For example we have a WAC-suite (waste acceptance criteria). To some extent it does help standardise the workflow, but it doesn't make too much of a difference. It's more of a marketing

opportunity. It's more of how we can offer a nice little package to the customer, something we can sell. You put 2-3 tests in a pack and you sell them for a bit more.

Do you give incentives to your customers to prefer these packs?

We sell them, yes, probably not always with financial incentive. What you sell is the ease of doing it, the fact that all information is presented in a package. In fact, for a lot of customers, we can put their limits into our system. So we know, for their samples, that it's above an agreed value. So, they know that they don't need to do anything unless we tell them a sample is above a certain level.

Do you have any customers with extraordinary needs, some exotic analysis that you do only once every six months?

Yes, we've got a technical team and they will look at that non-routine work and we'll try to do that. It could be anything. It would be unaccredited probably, but yes, if we can do it we could look at that.

As regards to extra-urgent analyses?

We have the ability to offer high priority turnaround.

When you organise work in your work cells, do you prefer large lots or small lots?

The batch size is defined, it's fixed. It's 20 samples. It's not in ISO 17025, but we also run MCERTS, which is performance criteria for an environment agency in the UK, and that specifies a batch of no more than 20 samples. What it rather says, is that you have to run an AQC every 20 samples.

How do you deal with work-related accidents? Do you do H&S, have a first-aid team etc.?

Yes, and we monitor our daily operations for near-misses. We operate the safety triangle, a really posh near-miss reporting, and, hopefully, if you eliminate the near-misses, you eliminate the accidents.

As regards to the equipment, do you have a maintenance schedule that you follow?

We have maintenance contracts for most of our equipment with external companies or the manufacturers of the equipment.

Is there a commitment from the management as regards to continuous improvement and has this been communicated to the staff?

Well, you perhaps need to ask the staff, but this is something I believe in, continuous improvement. It is a requirement of ISO 17025 also, so our regulations dictate that you have to follow continuous improvement, but this doesn't mean anything. If you don't believe it, you're not going to do it.

Anna Kiourtsidi: We are encouraged to give ideas, usually in the morning meeting.

Are you also encouraged to apply more economic, more efficient work practices?

Anna Kiourtsidi: Obviously.

Ian Blackburne: What we've started doing this year is that each cell has a morning meeting and they've got a big notice board up and so we are really trying to push visual management. On this notice board there would be a lot of quality things, like any non-conformance reports that are open, PVC (prime variable cost) that affects their consumable cost. So, they monitor what they're spending each month. The supervisor passes the information to the analysts and so, as a group, they can all think about. First of all, it's made aware where we're spending 10,000 pounds this month, what does that mean. In the first month it doesn't mean anything because you don't have anything to relate it to, but over time you see: Is that consistently spent? Does is go up, down? Does it feel right? And then, as a laboratory, we're always looking to spend less.

Now, as it gets to LIMS, because it's a very integral part of your management system, since when do you use it? What were you doing before LIMS?

Anna Kiourtsidi: They've told me it 10 years now.

Ian Blackburne: Well, I wasn't here then. I've worked in labs all that time and, yes, it would all be paper-driven. And, in fact, the end test reports were typed. So, a lot more administration and many errors. And you wouldn't even know about the errors, because they would be so many steps where it could go wrong.

How widely are LIMS used in other laboratories?

As far as I'm aware, everybody.

What are the principal problems LIMS solves, apart from errors and paperwork?

You've got the reporting, your LODs, accreditation status, you can make changes for dilutions, workflow. So many variables that can be controlled, and also the batching of the work.

Anna Kiourtsidi: Checking the QCs…

Ian Blackburne: We've got electronic control charts. If the QC fails, then that batch will be rejected and it will be redone.

Have you chosen a ready-made platform?

It is a ready-made platform, but we have a development team on-site. So, our version is totally customised to our needs.

Before LIMS, had you done any process mapping to see where LIMS could help?

Yes, they did that the last time they did a major change from one system to another.

To what degree do you use the LIMS? Are some things done manually, such as scheduling?

No, it's all through the LIMS. I'd say 99% of what we do is LIMS.

Do you think that overusing LIMS may cause problems?

Yes. What it does, is that it potentially removes the sanity check that the analyst or the supervisor should do. People get so used to it: it can't go wrong, these are the numbers because that's what it tells me. If you write numbers down, you see that's 50, 50, 50, 20000. Where did that come from? And your mind starts this sanity check that we're doing. Whole lot of numbers from the instrument, you just click the button. And that's what can happen: people get removed from the samples. Even looking at the sample and saying "would that work?" is what I would call a sanity check. The analysts would become operators.

Don't the results pass through a second pair of eyes?

They do have to be authorised, they do. The supervisor would do that. That will be done in isolation, you will be looking at a set of results. I want somebody to look at the sample as well, and say "why do we have something that looks like a cup of coffee but it's not?". And it's just applying the "Does this apply to what we normally get? Does this look like out of the normal order?" and that could be the problem. If you have a totally automated laboratory, it would work for most of the samples but you'd never detect these odd, funny samples.

If you see something strange with the results, what can you do?

Anna Kiourtsidi: I go back to see the sample.

Is there a measurable profit gained from using LIMS over paper?

I would say so, I wasn't here when we made that change. But if we go back and use paper, would you be able to do the same outputs?

Anna Kiourtsidi: No, no way, that volume of samples.

Ian Blackburne: We would need more staff, which is more cost, so unquestionably. That should be offset against the cost of maintaining the LIMS system, I think it's still cheaper, and the cost of buying it.

How do you integrate LIMS in your ISO 17025 system?

Very easily, ISO 17025 doesn't talk too much about this. But, you have to have relevant change control and you've got to test it. As regards to the archive, we say what we need to do. We specify a procedure, we specify what we do with our archives, but of course, just like paper archives, you have to be able to retrieve readily the information. One of the audits is on IT and on archiving, so we would ask to retrieve information from the past.

Apart from all the things we described, which of the following LIMS features do you use or you might use in the future?

- **Single database for ERP and LIMS**

They are going to stay separate, because we are the headquarters here, so our ERP system is for the group, but the group doesn't all use the same LIMS system.

- **Information on sample characteristics (quantity, container, description)**

All that's in there. We can add photos, but we tend not to. We can do that, because I know we can send chromatograms as part of our test report.

- **Sample tracking functionality**

What I know about the @mis, is that as soon as the analyst authorises the results, it gets loaded into @mis. Whereas if they're not on @mis, the test report is sent out by the customer services representative once all the work is in. So, they would be certainly be able to see the level of completeness of the work, yes. Every job is given a turnaround time, and so, in some respect, it's whether it's going to meet the turnaround or not. It would show in the lab areas, if a sample is overdue. We have two operations meetings: one in the morning, and in that morning meeting they look at what samples are due that day. We should always work one day ahead, so there should be nothing due for today. So, the list is not huge, it's just a few samples, they're the ones that have to go out today. If you're working on the day, then you're a day late, really, because if something goes wrong you won't be able to get the result. We then have another meeting at 4 o'clock and that is for any sample that was due that day and wasn't reported. There's always a reason, there could be a good reason or a bad reason. This is my point, which I try to get across: It doesn't matter what the reason is, the problem is that if you were a day ahead, you wouldn't be late. Of course, if you're running on the day, the risk is that you'll be running late. And if, say, an instrument broke, that's no excuse. I know it's not always as easy as that, because we try to keep things tight. So, if we can deliver in 4 days instead of 5, when we tell the customer we can do it in 4. We can charge them more if we can do it quicker, as well.

- **Automated pack creation for each customer**

If they use @mis, they are able to see exactly what they ordered previously, but we have a customer service team, and certainly for our bigger clients, we have dedicated customer service representatives that deal with these clients. We're talking about big companies here, that could have thousands of consultants, so it could be one person asking "what did we do in the Manchester office?". Unless they give us information, or a job number, we can see what they did.

- **Automated inventory check**

No, our ERP doesn't have the stock levels. That's why we have to do a manual stock every month. You can go to that level, but then we have our standards, they get diluted, it's perhaps a next level of admin that I'm not sure it benefits us. If we had a proper JIT, we would have to know what we're using.

- **Measuring each analyst's performance for appraisal purposes.**

We are obliged to test each analyst's competency, which is different to their appraisal. When we do appraisal is about the personal development, or the professional development and about forward planning. But we do have to do a competency check. Each analyst, once a year, has to show and prove that they're competent in the methods they're trained in. They would run some samples and compare them to another trained analyst's, they should get the same results. The sample output of each analyst it is starting to be looked at. First, they are assessed on the lab's output. It's an average and it's assessed per day.

Anna Kiourtsidi: We have targets, 6 samples per day. But somebody could be doing calibration, or prepping the QCs, so these count out.

Ian Blackburne: If you are doing calibration, that should be booked in as calibration time, or testing time. So, the OPH, is the hours put in conveyoring. And that's the key point: if they didn't need Anna today, Anna would go to another area and they would take Anna's hours out of the OPH (output per hour) figures, because she's not in there doing the analysis. So, it's two things we look, really: The total output of this area and the OPH figure. Because, if they have 15 analysts and they only have enough work for one, they should do the others do other things. The OPH for that analyst would be great, but the total output of the department would be rubbish. We have a red, green and gold measurement for their OPH figures, and those in departments that are understaffed would get a gold measurement. It's

kind of an incentive – when the OPH is red, you're instantly drawn to it, "why is the OPH red?", and they can be good reasons for it. Say, you've got more soils, and soils can get longer to test in fact, so that can impact. So, it's evolving. It has to be taken as an average because of these slight little variables. But in the absence of anything else, it's actually a good way of monitoring. The information I see every morning are taken from the LIMS system. If you get red outputs, even if they've got no lates, if every cell has half a person too many, you can't lend out half of those. So, you don't lend that person out and you keep it yourself, because if you lend that person out, then you're half a person not enough. But if you multiply that through 10 areas in the laboratory, that's 5 extra people, which is too much for the laboratory. So, the cells have to get the idea of sharing staff. If you've got so many, it's in your benefit to send somebody out, because your OPH figures will look bad. It's standardised procedure, I don't know if it's written as a procedure, but it's something we do every day, something we monitor. You have to balance against the quality, of course. Essentially, the cells themselves, they can decide whether they need the staff or not, in conjunction to their managers, but if they say "no, you can't have my staff" and they get red outputs, then they'll have to answer that.

7.4 Transcript of ALControl UK Ltd. promotional video

This is the transcript of the promotional video for AlControl Laboratories' promotional video, which can be found at https://www.youtube.com/watch?v=x2N3U2elsQU (accessed 25/09/2016). The video features images of the company's site at Hawarden, scientific equipment, sampling procedures and images from the company's information management system, @mis.

At ALControl Laboratories we are Europe's largest provider of laboratory test services for customers in environment, construction and associated sectors. Every year we carry out millions of tests in soil and water samples providing the critical information to help you manage your business effectively while complying with the latest international and national legislation standards. In Europe we employ over 2,000 people in our network of 30 specialised laboratories and customer service centres.

In the UK and Ireland we provide industry-leading environmental testing facilities backed by full on-site sample collection, expert knowledge and dedicated technical and application support. So, with ALControl as your business partner you can be sure that we have the skills, experience and resources to meet the needs of your organisation today, tomorrow and into the future.

Yet, ALControl is not alone in supplying laboratory services – so, what is it that makes us different? In fact, it's many things. For example, it's our innovative philosophy of lean laboratory processes based on globally-recognised Kaizen and Six Sigma management techniques, it's our commitment to continuous improvement, our industry-leading quality control based on ISO and MCERTS standards, our investment in the most skilled staff and advanced laboratory and automation technologies, plus our determination to give you the best service at all times. Just as importantly, it's our ability to understand your business, to nurture long-term relationships with you and your colleagues and to deliver the services that give you real and lasting value. Services that include expert knowledge, specialised training and technical seminars, led by our internationally-recognised team of scientists. Services that are backed by technology, such as @mis, bringing you fast and accurate scheduling, reporting and access to data for increased productivity and profitability.

At ALControl, our commitment starts from the day you make your first inquiry. Our goal is to ensure speed and efficiency. For example, we supply sample containers and cool boxes, provide on-site courier collections, offer dedicated technical support and give you access to 24/7 scheduling and reporting facilities via our unique @mis system. @mis is your connection to our laboratory services. It's an easy-to-use online tool that enables to setup and schedule your own tests, check on the progress of each test procedure and access, analyse and archive all your test reports. @mis gives you the power to manage your test procedures; it's available any time of the day and night from anywhere with an internet connection and it's designed to help you reduce the time required from initial sampling to final reporting. Ultimately, @mis will save you time, eliminate the potential for errors and make real cost savings for your business.

At ALControl Laboratories our aim is to offer you the best possible combination of soil and water testing services with fast and accurate soil and water analyses, easy access to data and competitive, transparent pricing. So, everything we do is designed to support your business, giving you the data, knowledge and security of information that enables you to make decisions quickly, accurately and confidently. Ultimately, with ALControl Laboratories as your business partner, you will have the confidence to act.