

Establishment of a SANAS accredited waste analytical laboratory (costs and implications)

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Under the auspices of the National Environmental Management Waste Act (no. 59 of 2008) (NEMWA) various Regulations and Norms & Standards¹ associated with waste management were promulgated on 23 August 2013. In terms of Regulation 8 of the Waste Classification and Management Regulations (WCMR), waste must be assessed in accordance with the Norms and Standards for

Assessment of Waste for Landfill Disposal prior to the disposal to landfill disposal facilities (GN R.635 promulgated on 23 August 2013). These Norms and Standards mandate that the potential level of risk associated with storage/disposal of materials/wastes must be determined by following the prescribed and appropriate test protocols. Accordingly, all analyses of the total concentration and leach concentration of risk elements and chemical substances in waste must be conducted by laboratories accredited by the South African National Accreditation System (SANAS) which certifies them as approved to conduct the particular techniques and analysis methods required.

SANAS accreditation is the official recognition that a testing laboratory is competent to perform specific tasks and has a documented Management System in place to ensure consistent implementation of its processes. An accredited testing laboratory will have demonstrated through formal assessment that it is competent to perform the specific tasks for which accreditation is sought. In addition, the testing laboratory needs to demonstrate that it satisfies both national and international criteria in this respect.

Enviroserv Waste Management Limited's Rietfontein laboratory is a SANAS accredited laboratory. Testing laboratory accreditation helps to minimize technical barriers and reduce the safety, health and environmental risks to both industry and regulatory authorities. Almost any evaluation of a waste testing laboratory is based on reports from accredited testing laboratories that are, in turn, supported by accredited calibration laboratories. SANAS accreditation provides assurance that the analytical services rendered by accredited laboratories are accurate, reliable and of good quality and have been evaluated and proven to be so.

This article will focus on the challenges faced by EnviroServ's accredited waste analytical laboratory and provide detail on the high start-up and maintenance costs, limitations on infrastructure, technical personnel training, technical competencies and staff retention, technical staff succession planning, equipment, timeframes for development and implementation of a quality management system, suppliers of calibration services and critical consumables, method validation and uncertainty of measurement and availability of relevant Proficiency Testing (PT) schemes relevant to the waste industry.

The article will also touch briefly on relevance of certification for analyses of waste versus certification for analyses of other matrices such as foodstuffs, pharmaceuticals, water, etc. and will challenge the perception that all accredited testing laboratories are suitable for waste analyses.

¹ Waste Classification and Management Regulations (GNR 634); National Norms and Standards for the Assessments of Waste for Landfill Disposal (GNR 635) and National Norms and Standards for Disposal of Waste to Landfill (GNR 636), National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008)

Keywords: Waste, analysis, accreditation, SANAS, ISO 17025, validation, Proficiency Testing, uncertainty of measurement, quality management system.

1. INTRODUCTION

In 1979, Wade Refuse was formed as a private door-to-door waste collection, disposal and management service and in 1984 became the first private waste management company to offer door-to-door domestic waste collection in townships surrounding Johannesburg, including Kwathema, Tsakane and Soweto. In 1987 the company began investigating various locations identified as suitable for the development of industrial waste disposal sites and as a result, Holfontein was commissioned as the Group's first permitted hazardous waste disposal facility in 1990. As the first commercial industrial waste management company, EnviroServ listed on the Johannesburg Stock Exchange in 1996. In 1997/98 EnviroServ acquired the remaining 50 % of Wade Refuse and then bought Waste-Tech, a leading industrial waste management company which provided EnviroServ with critical mass in all its operations and also ensured a national presence. EnviroServ thus became the largest privately owned waste management company in Southern Africa.

The core function of EnviroServ's Rietfontein laboratory is the analyses of waste under the landfill assessment regime². The assessment methodology for waste disposal is the identification of chemical substances present in the waste which entails sampling and analyses to determine the total and leachable concentrations of the elements and chemical substances specified in the Norms and Standards. All analyses of the total and leachable elements and chemical substances in waste must be conducted by a SANAS 17025 accredited laboratory.

The need to establish a quality system within EnviroServ's Rietfontein laboratory was realised when customers began challenging analytical data. Even though our laboratory employed skilled personnel to conduct analyses customers were not entirely satisfied. Customers wanted to see demonstration of quality and without a formal ISO 17025 system in place it was difficult to provide evidence of implementation.

ISO 17025 was established with the aim of bringing global standardisation to testing laboratories. Through the requirements set for management systems, processes and staff, ISO 17025 forms the basic requirements under which a laboratory is accredited. Laboratory accreditation is not a new idea. Neither is compliance to ISO 17025, the governing standard for calibration and testing laboratories. Although ISO 17025 can be a formidable and complex standard that requires a collection of interwoven documents, it is one that EnviroServ has come to depend upon as a critical tool for quality results. EnviroServ's Rietfontein laboratory is a SANAS 17025 accredited laboratory. EnviroServ's Rietfontein laboratory had their first external SANAS assessment in November 2011 and received their original certificate and schedule of accreditation on 13 February 2012.

The implementation has proven to be challenging, as it requires not only embracing and managing change, but it also requires a total paradigm shift in operating and managing the laboratory.

Given the requirements for SANAS accreditation in the Waste Regulations, EnviroServ's Rietfontein laboratory realised the importance of developing and implementing the ISO 17025 system as early as 2010. The implementation of ISO 17025 is not only to satisfy the requirements in the Waste Regulations, but also to provide proof that the analytical data that is generated by the laboratory can be accepted as a valid and true reflection of the samples analysed, which at the end provides waste generators', authorities and the community assurance that the waste can be treated and disposed in an environmentally safe and responsible manner.

² Mandated by the National Norms and Standards for the Assessment of Waste for Landfill Disposal, National Environmental Management: Waste Act, 2008 (ACT No. 59 of 2008).

The road to implement ISO 17025 started in mid-2010, when the position of a Quality Manager was created, approved and filled. Despite the challenges that the laboratory faced, it managed to successfully implement aspects of ISO 17025 to get where it is today.

2. CHALLENGES

The process and cost of ISO 17025 accreditation with SANAS has been highlighted as a stumbling block for many laboratories. The development and implementation of an ISO 17025 system was not Enviroserv's facility's first attempt at establishing a quality system. Since 2004 Enviroserv employed the services of a quality consultant to assist with development and implementation of the system. Full implementation of ISO 17025 never took place as the system was too cumbersome, costly, required too many documents to work smoothly in a laboratory where a quality manager was not present on a full time basis and personnel didn't fully commit to implementation of the system. However, the lack of implementation helped Enviroserv to establish the role of management and the quality manager in quality systems and provided the impetus for the present system. It also illustrates the important lesson that a laboratory needs to have a suitable size quality system relevant to the size of the organization.

A survey of water testing laboratories carried out by the Water Research Commission in April 2011 identified approximately 200 laboratories, of which 103 completed and returned the survey. Fifty-eight laboratories with SANAS 17025 accreditation regularly undertake water quality testing. This is approximately 30% of the total number of laboratories identified. The remainder of the laboratories listed various reasons for non-accreditation such as financial constraints; personnel limitations; equipment requirements; infrastructure upgrades, procedure too difficult; in the process of obtaining accreditation; and "other".

2.1. Start-up and maintenance costs

The Water Research Commission survey results showed that 25% of respondents cited financial reasons for non-accreditation. The initial financial implications of attaining ISO 17025 accreditation are severe, as a management system needs to be put in place. In most instances, as was with Enviroserv's Rietfontein laboratory, the appointment of a quality manager especially during the start-up stage is vital for the development and implementation of an ISO 17025 system. The purchase and maintenance of equipment, procurement of laboratory consumables and reference materials, method validation, laboratory analyst technical competency per method, and record keeping are vital in achieving ISO 17025 accreditation. These stipulations are specific to ISO 17025 standards which indicate the value of being accredited to this standard. Another implication of accreditation is the stock of chemicals that need to be retained. In order to be accredited one extra sample from each chemical is needed to be kept in stock for quality control purposes. The financial implications of this may be a significant factor for laboratories when deciding to become accredited. However, the cost of not being accredited or not having consistently good reliable results could be much higher.

2.2. Limitations on Infrastructure

The need for reliable and accurate measurements of elements or compounds at trace concentrations is well established. Less well known might be the fact that the reliable analysis of samples is often found to be hampered by insufficient control of analytical blanks and sample matrices. The total and leachable concentration limits of the chemical substances in a waste stream must be compared to the threshold limits of specific elements and chemical substances specified in the Norms & Standards of the Waste Regulations. The specific type of waste³ measured against the standards for disposal is based on the determination of the total and leachable concentration limits of the elements and chemical substances in a waste exceeding the corresponding total and leachable concentration threshold limits respectively. As the threshold concentration limits in the Norms and are sensitive for specific elements and chemical substances, a laboratory is required to achieve these threshold limits

on analyses. Because of the need for stringent control to limit contamination during sample handling, preparation, segregation, separation and either concentration or dilution of samples during the determination process, establishment of a clean laboratory environment is critical. In the case of chemical analysis, the cross contamination between samples and possible environmental contamination of samples are likely to be the overriding considerations. Another concern is that chemical testing requires standards or certified reference materials often comprised of concentrated solutions of materials which are being tested for at trace levels. It is common to monitor the temperature of chemical laboratories. Some laboratory building designs fail to meet the minimum requirements for ISO 17025 accreditation on temperature control which tends to discourage management from spending money on building renovations. Enviroserv had to renovate parts of the existing laboratory building to accommodate some of the more temperature sensitive equipment such as the GC/MS⁴ and ICP-OES⁵. The need for a clean environment, especially for the GC/MS, is absolutely essential for the equipment to operate optimally for stability and produce reliable results consistently. A clean dust free environment ensures minimal downtime due to environmental influences.

2.3. Laboratory Personnel

From the Water Research Commission survey it was found that ~73%, of the laboratories surveyed, have less than ten laboratory personnel employed, this includes permanent and contract or in-service trainee personnel. Enviroserv's Rietfontein accredited laboratory has less than ten laboratory personnel who are directly involved with analytical work. The rest of the laboratory personnel are made up of management, administration and cleaning personnel.

2.3.1. Laboratory personnel commitment to the implementation and maintenance of Quality

Under the previous waste management regime⁶ applicable in SA it was merely a recommendation that samples requiring waste classification and assessment for landfill be analysed by accredited laboratories whereas the Waste Regulations mandate waste samples to be analysed by an ISO 17025 Sanas accredited laboratory.

Since the laboratory began implementing ISO 17025 the perception and opinion of laboratory personnel was that this was the sole responsibility of the quality manager. Laboratory personnel, viewed as important stakeholders in implementation, were reluctant to be part of the implementation phase. Laboratory personnel who were employed in their positions as analysts for many years, some as long as ten years, were reluctant to be part of the implementation. The lack of understanding and not realising the benefit of the having an ISO 17025 system were some of the reasons that personnel did not want to assist with implementation. Laboratory personnel were unsure of their roles and responsibilities in the implementation and maintenance of an ISO 17025 system. These were some of the reasons identified by management and regular meetings were held with personnel to show them the benefits of an ISO 17025 system. Once personnel understood the importance and realised the benefits, behaviour and attitude changed which made implementation easier. Since the laboratory began implementing ISO 17025 the perception and opinion of laboratory personnel was that this was the sole responsibility of the quality manager. Laboratory personnel, important stakeholders in implementation, were reluctant to be part of the implementation phase.

³ Type Profiling based on consideration of total and leachate concentrations of substances published in Paragraph 6 of GN 635 and the appropriate landfill class determined with reference to the Waste Acceptance Criteria in Paragraph 4 of GN 636.

⁴ Gas Chromatograph Mass Spectrometre

⁵ Inductively coupled plasma optical emission spectrometer

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Data from the Water Research Commission survey shows that approximately 30% of respondents believed that it is the quality manager's role to implement maintain and manage a quality management system within a laboratory.

The introduction of ISO 17025 also introduced a significant increase in the amount of work, especially in terms of administration and record keeping. This was seen in a negative light, as it meant that the routine activities were taking much longer to complete than before. Before implementation, there were very few traceable records. Part of maintaining a system requires personnel to verify the chemical balances, record the weight, check the pH, positive and negative controls, determine expiry date and label the reagents and certified reference materials. It can take a full 24 hours from preparation to the point where a sample extract can be analysed either on an ICP/OES or GC/MS which to analytical staff members that did not understand the reasons and benefits behind system, was viewed as an unnecessary delay and extension of analysis turnaround times of otherwise simple and short laboratory activities.

2.3.2. Staff turnover and high training costs

The biggest challenge that EnviroServ's Rietfontein laboratory and many other laboratories are facing is high staff turnover. In order to ensure successful implementation and continuous adherence to the requirements of ISO 17025, a laboratory needs a team of competent, committed and stable personnel. EnviroServ have lost key laboratory personnel to competitors after significant investment in time, training and mentoring of personnel.

Laboratory personnel were trained internally as well as attended the SANAS ISO 17025 systems and auditing courses. However, this did not bring any benefits as high staff turnover ensued in the following years.

The statistics show that in the years between 2010 and 2014, 30% of EnviroServ's Rietfontein laboratory personnel resigned. The main reasons for losing key personnel were to a single competitor also seeking to establish an accredited laboratory facility, higher salary offers from the competitor and unwillingness of laboratory personnel to change and adapt to the requirements in ISO 17025. To mitigate the risk of losing personnel, management introduced regular performance management reviews with personnel and provided employee assistance programmes that helped to address personal and financial issues experienced by laboratory staff. Since 2014 to date EnviroServ have seen stability with laboratory personnel.

A key element of quality assurance and credibility of results is personnel competence. Training programmes for laboratory personnel are therefore very important in reaching and maintaining the required level of competence. Training helps maintain and improve quality and productivity. Providing training for laboratory personnel not only helps them develop their skills and knowledge, but it is also motivational and a building block to an organisation's success. Training needs to be for the right people, it needs to be the right type of training and it needs to be at the right time.

⁶ Minimum Requirements for the Handling, Classification and Disposal of Hazardous Waste, 2nd Edition 1998

Unfortunately, many companies do not have adequate budgets to allow them to have their employees trained adequately. The investment in training is not merely financial, but also in terms of time. Figure 1 below shows the average number of years it took Enviroserv laboratory analysts to become fully competent in various laboratory activities, especially if they were recruited from outside the organisation with no or minimal experience.

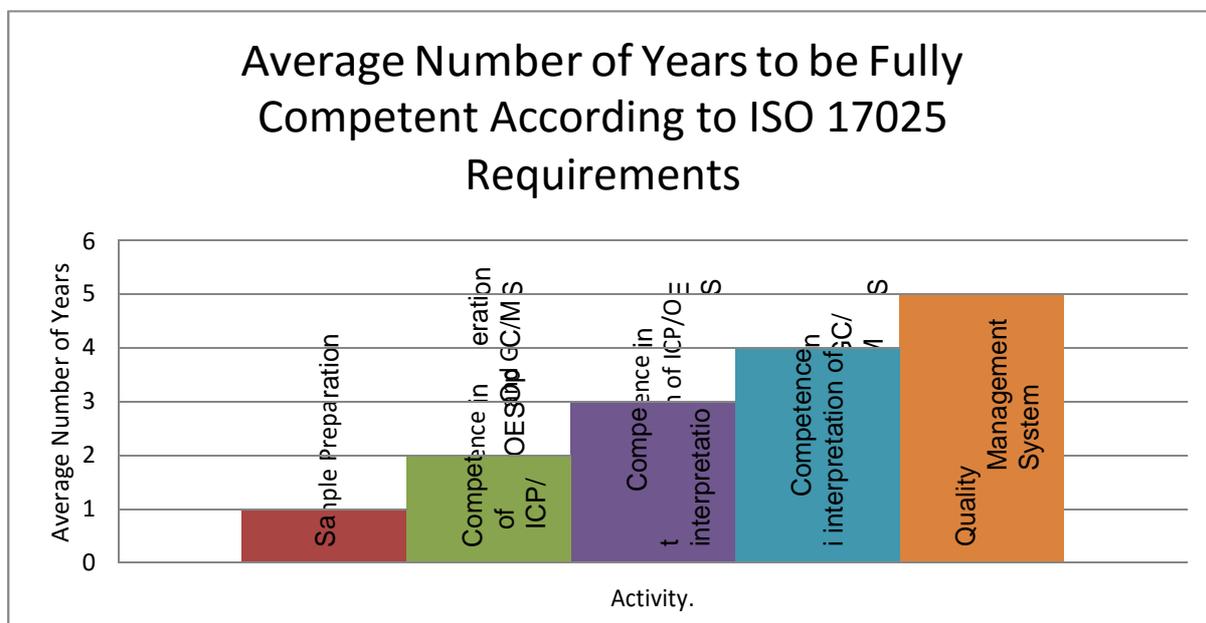


Fig. 1 Average number of years it took Enviroserv's Rietfontein Laboratory personnel to become fully competent in different Activities.

In the initial stages of ISO 17025 implementation at Enviroserv's Rietfontein laboratory it was found that most laboratory personnel remained employed with the organisation on average for three to four years. The short time spent at Enviroserv was therefore not contributing significantly to the growth and stability of the laboratory and the organisation at large. The lack of stability and the requirement to have a minimum of two approved SANAS technical signatories placed the laboratory at risk of either losing their accreditation or applying for voluntary suspension in the event of having only one technical signatory in the laboratory. Enviroserv have since appointed additional laboratory personnel and have in their employ three technical signatories. This reduces the risk of losing accreditation or being suspended due to the laboratory not meeting the criteria for minimum number of technical signatories.

3. EQUIPMENT

ISO 17025 effectively requires a complete history of each piece of equipment. This should start with details of the checks and calibrations carried out before the equipment is placed in service and continue with a detailed record of all calibrations, repairs, and routine maintenance and performance checks. In this context, 'equipment' should be understood to encompass any items which may affect the validity of measurements or calibrations, including reference standards of measurement, such as standard weights and reference thermometers.

Enviroserv's laboratory was a small laboratory with a small budget for equipment maintenance and repairs. The laboratory was not familiar with having a schedule in place for regular maintenance and service of their equipment. Since the implementation of an ISO 17025 system equipment logbooks and registers needed to be maintained as part of the system requirements which increased the running costs of the laboratory. It was also found historically that equipment in the laboratory had

been purchased without service contracts. This meant that emergency repairs or breakdowns had to be carried out at higher costs. With the implementation of ISO 17025 this had to be addressed.

4. TIMEFRAME FOR DEVELOPMENT AND IMPLEMENTATION OF AN ISO 17025 SYSTEM

Once approval to implement ISO 17025 at the Enviroserv laboratory had been granted there were other challenges which surfaced. Due to the small staff complement, all laboratory personnel were asked to be part of the initial development. The system implemented needed to be simple enough to work with yet complete and comprehensive enough to comply with the ISO 17025 standard and SANAS requirements. The system had to also accommodate both the quality manager requirements in terms of a reasonable timeframe for development and implementation as well as the laboratory manager requirements for laboratory production, i.e. customer requirements had to be met while developing and implementing the system.

A reasonable timeframe for development of a system and implementation for an average sized laboratory is between twelve and eighteen months. During the development and implementation stage of the system there were many challenges which the laboratory had to overcome such as changing the mind-set of personnel and getting their commitment or buy in to quality, increase in laboratory costs and the pressure of getting the laboratory ready for assessment in a reasonable time frame. Figure 2 below gives a summary of the timeframes and duration for implementation of the ISO 17025 system at Enviroserv's laboratory.

The system was developed and implemented over a period of approximately 13 months starting in July 2010. The application for assessment, quality manual, and application for technical signatories, CV's, validations and uncertainties of measurement were submitted to SANAS around August 2010.

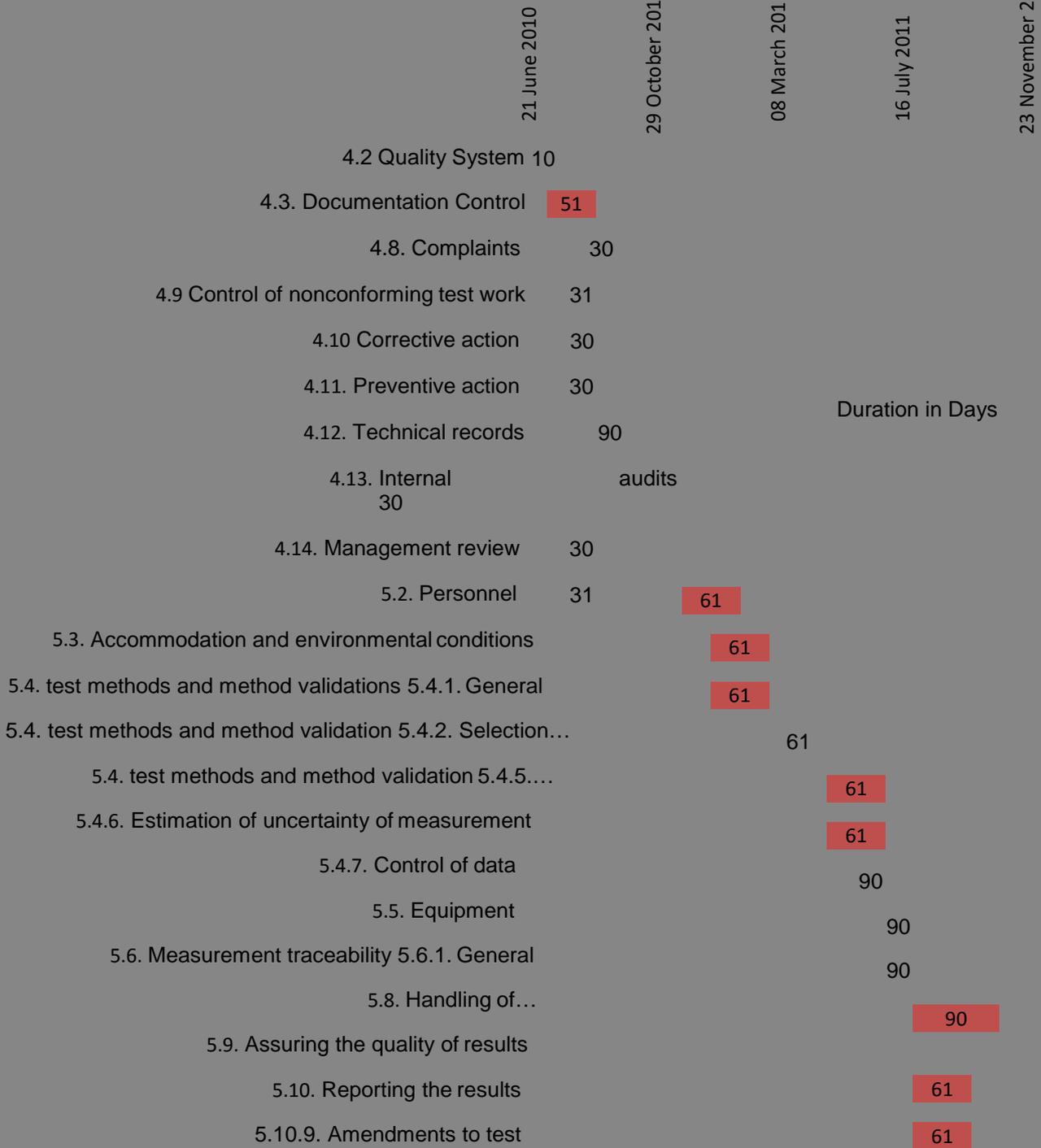


Figure 2. Timeframe for ISO 17025 Implementation_Enviroserv Rietfontein Laboratory

After reviewing Enviroserv’s application for assessment SANAS conducted an initial assessment in November 2011. The assessment was positive with a few non-conformances which the laboratory had to close out within the required timeframes. These non-conformances were cleared as required and Enviroserv received the desired certification and schedule of accreditation in February 2012. Enviroserv was the first waste testing chemical laboratory to be SANAS accredited in South Africa.

5. SUPPLIERS OF CALIBRATION SERVICES AND CRITICAL CONSUMABLES

The ISO 17025 requirement is that, where the quality of any outside services or supplies may have an impact on the quality of the data or calibrations emanating from the laboratory, there must be procedures to ensure that the quality of the services or supplies is adequate and consistently so. The two extremes of an approach to quality of supplies and services are for the laboratory to check

everything on receipt or for only approved, preferably certified or accredited suppliers to be used and checks to be dispensed with. In practice, elements of both extremes will be used. Laboratories have approved and trusted suppliers but also carry out checks, often as an integral part of methods, for example reagent blanks or calibration checks.

In order to comply and meet the standard requirements, the onus to verify suppliers and sub-contracted laboratories rests with Enviroserv. Prior to implementation of the ISO 17025 system, no consideration was given to audit and verify suppliers and sub-contracted laboratories. Legacy suppliers and sometimes suppliers that were the cheapest were used as basis of approval of suppliers and placed as preferred vendors within the organisation whereas the ISO 17025 requirement places huge emphasis on quality criteria as their basis of approval. It was challenging to convince Enviroserv procurement management to change and move over to suppliers and sub-contractors that provide superior quality services or products or are accredited and even in certain instances more expensive.

Other challenges, especially in the waste arena, are the availability of certified waste reference materials which are not readily available in South Africa. Reference materials had to be imported either from Europe or the United States of America at significant cost and with extended delivery times.

6. METHOD VALIDATION AND PROFICIENCY TESTING

Method validation is the process used to confirm that the analytical procedure employed for a specific test is suitable for its intended use. Results from method validation can be used to judge the quality, reliability and consistency of analytical results; it is an integral part of any good analytical practice.

The development, validation and transfer of analytical methods are crucial steps in a waste laboratory. Waste laboratories face many challenges during the method validation process. Waste streams and sample matrices are extremely diverse which makes validation a real challenge. More challenges typically exist for unknown waste streams. For example, validation of the extraction method in leach testing is matrix dependent. Enviroserv, the largest waste management company in Southern Africa, services more than 15,000 waste generators with a large diversity of waste streams. The diverse and complex waste make-up makes it impossible to validate the extraction method for every waste matrix received for disposal. Method validation consumes critical amounts of time and effort in any laboratory looking to validate their methods. The sooner methods are developed and optimized; the lower the risk will be to the environment.

The Waste Regulations have a comprehensive list of elements and chemical substances in the Norms and Standards needing both total and leach concentration analysis. Method development and validation for each element and chemical substance on every waste matrix is a daunting task.

Testing laboratories are accredited separately for each of the tests performed. The cost, time and sheer volume of work required to accredit each element and chemical substance for each of the preparation methods, i.e. leach and total, is challenging. Testing Laboratories develop and implement an ISO 17025 system for the entire laboratory and only accredit selected methods.

SANAS will not recommend accreditation to any testing laboratory if a validation does not meet the ISO 17025 requirements as well as the SANAS requirements for validation. Enviroserv's Rietfontein laboratory has successfully validated and is accredited for their ICP-OES method using various leach solutions.

Proficiency testing determines the performance of individual laboratories for specific tests or measurements and is used to monitor laboratories' continuing performance. Proficiency testing is also called inter-laboratory comparison.

There is currently no proficiency testing co-ordinating studies in South Africa for waste testing laboratories in South Africa to participate in. There are no waste studies available in South Africa currently. Europe, Australia and the United States have waste proficiency testing co-ordinating studies and Enviroserv currently participates in studies from Europe and the United States of America. Again, there is a cost associated in the participation of the foreign studies but remains a critical requirement in the ISO 17025 standard.

7. ACCREDITATION IS METHOD SPECIFIC

A certificate of accreditation is the fundamental document attesting to the organization's competence to perform tests as indicated on the scope of accreditation.

For testing laboratories, the scope of accreditation is the official listing of the various tests, or types of tests that the testing laboratory has been deemed competent to perform under the SANAS Accreditation. The testing scope identifies, wherever possible, the sample matrix on which the testing is being performed, and the specific test methods that apply to the accredited tests.

The testing scope of accreditation is normally identified in terms of standard test methods prepared by international organizations such as ISO, ASTM, etc. Specific reference in the Waste Regulations is made to the Australian Standards as a reference standard for leach analysis.

Because of the very many challenges and stumbling blocks many laboratories face when developing and implementing the ISO 17025 system, many laboratories use the few methods they are accredited for to market their testing services in the waste industry. Laboratory's where waste analysis is strictly not within their accredited range of methods or their core function incorrectly use their SANAS accreditation to leverage services into the waste management industry.

Laboratory's accredited for water, food, pharmaceutical, etc. that don't have the expertise, infra structure or experience in dealing with waste have pounced on an opportunity to service generators of hazardous waste following the promulgation of the Waste Regulations in August 2013.

Although it's not possible to accredit every method in a laboratory, laboratories should be required to demonstrate their competence in waste analysis before marketing themselves as proficient in this field. Having an ISO 17025 quality system in place does not make a laboratory proficient in waste analysis and their competence needs to be demonstrated via by participation in proficiency testing studies, inter laboratory comparison studies, method validation, etc.

Unlike the historic and now defunct Minimum Requirements where formal accreditation was seen only as a step to improving analytical quality control and not as a guarantee of correct analytical procedure the Waste Regulations are specific in that waste laboratories need to be SANAS accredited to perform analysis for waste.

8. CONCLUSION

SANAS accreditation for testing laboratories means the assessment and recognition of the technical competence and integrity of conformity assessment bodies to carry out their specific tasks. Accreditation has become "mandatory" in many regulated areas as more and more regulators appreciate the benefits that accreditation brings in assisting governments to meet their obligations and responsibilities to safeguard the public and the environment.

As a regulator, the Department of Environmental Affairs (DEA) greatest responsibility is to protect the health and safety of the public and the environment. The DEA's core function is to minimise risk by regulating the use technically competent laboratories for waste classification and assessment.

Finally, the question may be asked “how does Enviroserv know that its quality system is successful”? A successful quality system is one that seems natural to the user. The system has been set up so that while there are procedures, paperwork and calibrations they are seen simply part of the measurement and are not overwhelming or too onerous. The procedures make sense because laboratory personnel know why every step is necessary. The systems used make it straightforward and laboratory personnel understand the importance and significance of the results to the customer and authorities.

In spite of the challenges involved for accrediting a waste testing laboratory, Enviroserv’s Rietfontein laboratory has successfully worked through all of the ISO 17025 standard requirements to achieve accreditation. Enviroserv’s accredited laboratory provides formal recognition of competence and a means for industry and authorities to identify and select reliable testing.

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