Proceedings of the 2017 International Conference on Industrial Engineering and Operations Management (IEOM)
Bristol, UK, July 24-25, 2017

Quality Control in a University Laboratory: Evaluating the Gap between ISO/IEC-17025 Requirements and the Thin Section Laboratory's Processes.

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Abstract

The benefits that the implementation of quality management systems bring to testing and calibration laboratories make a compelling case for their deployment in teaching and research laboratories. The Thin Section laboratory, based at a South African university is a research and teaching laboratory currently facing funding and quality challenges and has to find ways of supplementing the grant it receives from the University. One of the ways is providing commercial testing services. Testing and calibration laboratories are required to conform to ISO/IEC 17025:2005 which is the general requirements standard for competence of calibration and testing laboratories. The Thin Section laboratory compliance to this standard can improve the quality of its services to compete with other testing laboratories.
Using laboratory experiments, surveys and interviews, this study aimed to evaluate the gap between the Thin Section laboratory processes and ISO/IEC 17025:2005 requirements, assess the ISO/IEC 17025 implementation challenges for such laboratories and evaluate the possible benefits of implementing such a system. The study found the gap between ISO/IEC 17025:2005 requirements and laboratory procedures to be wide but recommended solutions to narrow it. The findings of this study can be utilised by other teaching and research laboratories with intentions of implementing ISO/IEC 17025.

Keywords
Quality, Quality Assurance, Quality Control, Quality Management Systems, ISO/IEC 17025

1. Background
The Thin Section Laboratory produces polished thin sections, used for petrographic studies, thick sections, used in fluid inclusions analysis, and ore blocks for research and teaching purposes. The thin sections and other specimen types prepared in the laboratory can be used for a number of different applications and supplementary analysis which include X-ray diffraction (XRD); and Scanning Electron Microscope (SEM). Preparing good quality thin sections is very important for the above-mentioned studies and many other applications. Most of these analyses depend on the precision of the size and thickness of the section as minerals' optical characteristics sometimes change with size.
Housed in an academic institution, the laboratory's primary objective is producing good quality thin sections for academic research and students' practical work. The price adjustments at the laboratory are always kept minimal to enable laboratory users to have as much analytical data available to them as possible and at reasonable costs. An upward surge in student numbers and research activity has led to an increase in the number of sample submissions and the amount of work that has to be processed through the facility. That coupled with increases in consumables prices and funding challenges has placed added pressure on the laboratory's financial wellbeing. The laboratory

needed to investigate alternative methods of funding the facility other than increasing prices and relying on university grants. Accepting contractual work from other sectors and charging commercial rates will enable the laboratory to create a separate income stream for its operations. The capital generated from commercialising some of the laboratory's services means the laboratory can fund its own minor equipment needs and also offer a percentage contribution when applying for major equipment funding.
University laboratories providing testing services have to commit to offer society their facilities and knowledge to provide solutions to existing problems on the basis of the results they provide. And this can only be done by confirming the quality of results, for which it is essential to have a quality system (QS) implemented and in many cases to be accredited to ISO 17025 (Zapata-Garcia, Llaurado, &Rauret, 2007). This study will explore the gap between the laboratory's procedures and ISO/IEC 17025 requirements, assess the suitability and applicability of the standard to teaching and research laboratories and evaluate the benefits and limitations of its implementation.

2. Literature Review

2.1 Quality Systems in University Laboratories

Grochau and Ten Caten (2012) state that the introduction of formal quality management systems (QMS) and getting ISO/IEC 17025 accreditation for laboratories are not simple tasks, even more so for laboratories situated in teaching and research institutions. The university environment has different settings to other laboratories which present some challenges: not having conventional organisational structures and laboratories being, and at most times, staffed by student technicians are just some of the examples of those challenges. The motivation for implementing a QS at a university laboratory may also not be very clear and there is a difficulty in trying to measure the impact of accreditation of such laboratories on the quality of human resources education, their innovation capacity, the results of their research, and the quality and quantity of their publications. Such systems also require a lot of resources invested in them which universities seldom have.

2.2 Reasons for Implementing QS in University Laboratories

The implementation of a formal QMS in any organisation could result out of internal desire, external pressure or even institutional strategic planning Grochau et al. (2012). Mathur-De Vre (2000) posits that there is a need to respond to the changing trends in working practices. To meet the requirements for transparency, the need for a QA system in research and development (R&D) is becoming increasingly apparent. The needs are largely created by the globalisation phenomenon, i.e. socio-economic factors (efficiency, cost-effectiveness, client satisfaction, transparency, etc.), that emphasise competitive and productive scales, and require the criteria and definable "indices" for an objective evaluation.

2.2.1 External Pressure

Grochau et al. (2012) states that the greatest motivation for the implementation of a formal quality management system and accreditation of laboratories in teaching and research institutions is the external pressure, which often comes from an external customer or from regulatory agencies. Hullihen and Fisch (2009) state that university laboratories are increasingly being asked to perform testing for outside companies which increases scrutiny and exerts added pressure on them to obtain ISO certification. Add to that the accelerating need for industries to prove that their services match or exceed a measurable standard. Fernandez, Bacchi, Tagliaferro, Gonzaga, De Franca, Favaro and Fogaca (2006) state that test services for external customers are usually provided to generate additional capital and to create clear awareness about the need for systematic quality assurance/quality control actions.

2.2.2 Internal Desire and Institutional Planning

Nara (2003) states that researchers usually exchange, not only their papers but different test results with their collaborators on projects which necessitates that those tests be performed under the same conditions and using similar facilities to allow for fair comparisons. This makes it imperative that the laboratory aligns its methods to those of its partners and collaborators in research projects. Fajgelj (2003) expressed the reasons for the implementation of a formal QS in their faculty. Implementation was part of a much bigger project that incorporated health and safety and environmental projects. Quality management was merged with environmental care and health and safety at the work place into an Integrated Management System of Quality. The Thin Section Laboratory, at the request of the University's Health and Safety Directorate, is also involved in environmental initiatives to reduce/reuse waste. Implementing ISO/IEC 17025 will streamline the laboratory's processes and reduce the amount of waste produced.

2.3 Benefits of Implementing a Quality Systems

Hullihen et al. (2009) expressed that one of the primary benefits of implementing a quality system at the university laboratory was having documented procedures because that isolated the institution from a knowledge discontinuity if a trained or knowledgeable member leaves the faculty. It also created uniformity as everyone would perform the same test in the same way and training methods are standardised. Also, having students work on a quality system, and gain hands on experience of working in a laboratory with an ISO/IEC 17025:2005 program is different from just doing theoretical work in a quality course. This is one of the significant non-financial benefits teaching laboratories stand to gain from implementing a QS; the assurance that even if the anticipated economic growth does not occur, the quality system implementation would still be worth the time and effort. Having standardised procedures also assists with training modules for staff, which are mostly student technicians, minimizing the impact the high staff turn-over usually has on laboratory operations.

2.4 Limitations of a QS Implementation in Research/Testing Laboratories

2.4.1 Time constraints

Mathur-De Vre (2000) states that research, in its nature, is a continuously evolving process which can vary and change in form and approach over a period of time. There can be unexpected results, unpredictable occurrences and fascinating questions that arise during the course of a research project that would require further exploration. That more often than not leads to difficulties in fixing the targets, and to stick with the pre-approved schedules and resources. It would be very challenging for the laboratory to implement ISO/IEC 17025:2005 because the nature of the work processed in the lab is inconsistent and requires constant deviation from set procedures. There would also be the challenge of balancing the day-to-day activities of the laboratory, the tests and ISO/IEC 17025:2005 implementation requirements. The thin section laboratory would need to continue producing samples while finding ways to implement the quality management system. Explaining how much time and resources implementation planning or preparation takes, Halvey (2003) cited cumbersome documentation among other time-consuming activities as one of the major difficulties in the process of building the quality system.

2.4.2 Financial Constraints

Abdel-Fatah (2011) counted financial constraints as one of the major drawbacks of implementing a quality management system. That stems from the high cost of building the system, calibrating the equipment, complying with environmental conditions, staff training, updating standards, etc. The cost of ISO certification which varies with the manufacturing operation and quality control practices can be another deterrent. Hullihen et al. (2002) lamented the long-term commitment of financial and personnel resources to a quality system but also stated that while certification may be too expensive to consider for most university organisations, experience also indicates that there are heavy costs associated with running a lab that is compliant, but not certified. From upgrading laboratory equipment and conditions, training personnel on quality to utilising the human capital equally ensuring that the resources for implementation are made available and spread evenly to ensure that day-today activities of the laboratory are not adversely affected by ISO/IEC 17025 implementation.

2.5 Contrasting Implementation Drawbacks against Implementation Benefits

Abdel-Fatah (2011) posits that the implementation of ISO 17025 should be a well prepared for process. The process can have high costs but it also brings big benefits. A careful assessment of the balance between costs and benefits should be conducted and documented. Hullihen et al. (2009) also stated that even with the escalating costs and time consuming activities, establishing a quality system at a university laboratory has great advantages. University laboratories that have undertaken formal QMS implementation and ISO accreditation processes believe that the benefits of implementing such a system are greater than any of the challenges they encountered. They have also documented ways of overcoming some of the most prevalent challenges with the implementation process.

3. Research Methodology

It is envisaged that ISO/IEC 17025:2005 implementation can provide answers to the thin section laboratory's financial and operational challenges. And that it can also expose other university research and teaching facilities to the possibility of generating additional income using techniques employed in the private research/testing facilities. Identifying quality management systems' shortfalls and benefits for teaching and research laboratories will add to the existing body of knowledge and help create new contexts in which quality management systems can be deployed.

The research topic and the primary research questions provide the basis of how the research will be conducted. This study adopted a mixed research approach with both non-sequential and sequential data collections. The survey and

cause analysis results were what informed the laboratory of what experiments to conduct which made the data collection from these two sequential.) Mixed methods research is the class of research where the researcher combines quantitative and qualitative research techniques, methods, approaches, concepts or language in a single study (Johnson et al., 2004). It is also an attempt to legitimately employ multiple techniques in an effort to provide answers to research questions and not constrain researchers to a single method or technique.
Hoshmand (2003) posits that research approaches must be mixed in a way that would provide opportunities for research questions to be adequately answered. In this study, qualitative interviews supplemented the questionnaires as a form of manipulation check and as a way to discuss the issue being investigated and get an understanding of participants' perspectives which will help the laboratory avoid repeating the mistakes those organisations made.

3.1 Data Collection Instruments

Sandelowski (2000) states that combination or mixed-method studies are concretely operationalized at the shop floor level of research. In this study a survey, questionnaire, laboratory experiments and interviews were used to gather information relevant to the case being studied. The survey was used to gather information from laboratory personnel and clients about the observed defects in the laboratory products and investigate possible causes of those defects. Laboratory experiments, informed by the results of the survey, were conducted as a means to provide possible solutions to the product failures. Both the survey conducted and laboratory experiments were part of the internal investigations of means to simplify and streamline the processes to ensure better quality control while questionnaires and interviews were part of external processes investigating how implementing ISO/IEC 17025:2005 could provide lasting solutions to the challenges the laboratory was facing.

3.3 Data Analysis

Johnson and Onweugbuzie (2004) state that the most common forms a of mixed methods studies entail using different data components to complement or build on what might have been learned from any of those data types independently. The selection of these data is based on the understanding that they possess complementary strengths and that their weaknesses do not overlap and that a combination of them would yield stronger outcomes. Sandelowski (2000) advises that the linking of results of qualitative and quantitative analysis techniques can be accomplished by analysing each data set with the techniques usually used with that data. That means using qualitative techniques to analyses qualitative data and quantitative techniques to analyse quantitative data.
Qualitative data from interviews was deductively categorised according to themes identified in literature and inductively according to common themes that developed from different respondents. Descriptive statistical analyses of the data from the questionnaires and survey were requested. Narrative analysis of qualitative data obtained from the structured interviews were given. Using grounded theory, groups of qualitatively similar experiences were brought together in one category that had either been deduced from literature or developed from responses.

4. Results

The reviewed literature assisted in creating categories for deductive analysis of the interview data. The analysis and interpretation of research data form major part of any research (Amaratunga et al., 2002) and as noted by Johnson and Onwuegbuzie (2004), finding the right analytical method and strategy is of utmost importance. Different types of methods like examining, categorising tabulating and or recombining data can be used to address the initial propositions of the study. Methodological triangulation was utilised to measure the degree of confirmation or disparity between questionnaire data (n = 20) and data obtained from the interviews (n = 10). These were designed to explore the question of why and how to implement a formal quality system in a testing laboratory, the system's benefits and limitations, and users' experiences with maintaining it. Qualitative data provided some completeness by giving contextual representation of requirements, challenges and benefits, and greater depth of understanding to the entire study. The reviewed literature provided support for developing themes and categories from the qualitative data and it assisted in developing categories for quantitative data (questionnaire).

4.1 Survey Results

The survey was the first data collection instrument used. Subsequent laboratory tests and experiments depended on the results of the survey. The aim of the survey was to identify the defects in the specimen and to gauge the prevalence of those defects in completed specimen. In that way, the causes of the most prevalent defects and their effects on the quality of the specimen could be identified. From those defects a cause and effect diagram was drawn to try and identify the source or sources. After the sources were identified, laboratory experiments were conducted to try and correct part of the procedures that led to those defects. This part of the study aimed to provide a response to

the research question of whether there are parts of the thin section making process that can be improved to ensure better quality products. The results also provided a response to the question which asked if there is a method of standardising quality control measures in the laboratory. Sixty survey forms were sent out to laboratory users after their samples were processed through the laboratory. Thirty-five (58.3%) people responded to the survey.

Figure 1 Percentage Distribution of Defects.

Figure 1 shows the distribution of the observed defects on thin sections. Thin section thickness plays an important role in properly identifying the minerals within the sample. Minerals under microscope emit different transition colours at different thicknesses. Colour matching standards are available for minerals at different sizes and standardising thin sections to the recommended (30 microns) simplifies both the preparation and teaching processes. Bubbles affect the optical properties of the thin section under microscope. This survey was crucial in pointing the laboratory towards the type of investigations needed to devise the necessary remedies and the laboratory had to find a way of correcting/preventing them in order to improve the quality of the thin sections.

Guided by the survey outcomes, a cause and effect diagram of the identified defects was drawn. The aim of drawing a cause and effect diagram was to analyse the effects of each defect on the overall quality of the Thin Sections produced. The diagram assisted laboratory personnel in identifying possible sources of the defects and how they affect specimen quality. ISO/IEC 17025:2005:6 - Cause analysis, posit that the procedure for corrective action should start with an investigation to determine the root cause(s) of the problem. Root cause analysis are the key and the most difficult aspect in the development of the corrective action procedure. At most times the root cause is not obvious and it takes very careful analysis of all potential causes of the problem to identify it.

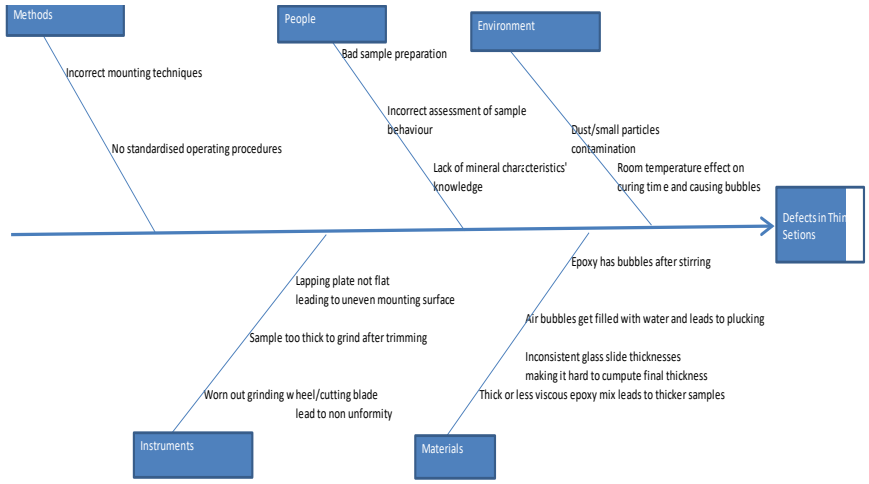

Figure 2 Cause and Effect diagram of defects thin sections

Figure 2 above shows a cause-and-effect diagram of what was identified as causes of defects in thin sections identified by respondents to the survey. The cause and effect diagram, also known as Ishikawa diagram, was developed in 1943 and is one of the seven basic tools of quality (Kenett, 2007). It is the flexible nature of the cause and effect diagram that makes it easier to employ in a number of different environments to extract valuable information on process failures and quality improvement projects. For example, the complex nature of the samples that the lab is requested to make thin sections from, led to there being no standard operating procedures in place for

the thin section making process. The lab receives rocks, sand, concrete, aggregates, grains, soils, etc. which all have varying qualities and must be handled differently. It was left to the technician to assess and decide on the method of preparation. Hence therefore standardising the procedure was a challenge. The solution was to write a Standard Method document for solid rocks and a separate one for treating soft rocks, loose soils, sands, aggregates and grains.

The cause and effect diagram illustrated that there may be more than one cause for certain defects and therefore a need to take a holistic approach to resolving them. The findings from the survey and the root cause analysis led to a number of changes and improvements in the thin section making process. An effort to standardise methods led to a selection of a single supplier for the critical consumables used in the thin section making process. This removed the variation in mixing proportions introduced by using different suppliers and helped eliminate air bubbles forming in the sample. The root cause analysis assisted the laboratory by revealing the technical aspects that needed improvement if the laboratory were to align their processes with ISO/IEC 17025:2005 requirements.

4.3 Laboratory Results

Based on the outcomes of the survey and the subsequent root cause analyses exercise, the laboratory conducted experiments in an attempt refine the sample preparation procedures and eliminate variation and defects in the process.

4.3.1 Sample Thickness

The laboratory receives microscope glass slides from a supplier with thickness ranges between 1,400mm and 1,600 mm. The glass slides are hand pressed on a flat surface with silicon carbide powder to grind one side of the slide (frosting) to enable easier mounting. Hand-pressed slides have varying and inconsistent thicknesses after frosting. The varying thicknesses of glass slides made it difficult to standardise the desired final thickness of the sample mounted on to the glass slide. To counter that, a new method of frosting glass slides was investigated. The machine, Discoplan TS, which the laboratory already had, has a function that allows the operator to pre-set the settings to desired parameters. This only required the procurement of a finer grinding wheel (80 microns) to be attached to the instrument. Samples were then prepared using the hand-pressing method and the machine preparation method. Comparative tests of the two preparation methods were carried out. Slides received from the supplier were prepared using both methods. In one batch of thirty samples, the slides were hand-pressed and frosted on one side. In another batch, they were frosted on one side, using the grinding wheel in the machine with a pre-set thickness of +/- 1,3000mm. Using a digital micrometer, the standardised slides were measured after frosting to ensure that they are as close to 1,300mm as possible.

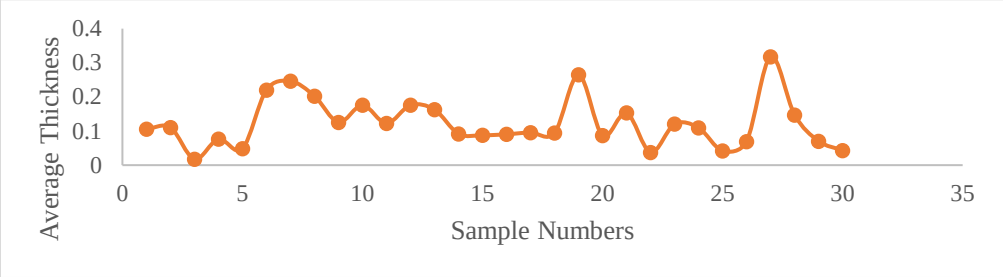

Figure 2: **A line graph representing thickness distribution from manually-prepared slides**

Figure above depicts the results that were obtained after the first part of the experiment. The points in the line graph represent the calculated final sample thicknesses. Bearing in mind that the theoretical thickness of a thin section should be 30 microns +/- 0.03mm, it was observed that besides the fact that those thicknesses did not exhibit any precision, very few were close to the required accuracy as well. Descriptive statistics analysis of the experiment data shows an average sample thickness of 0.124 mm was achieved at a standard deviation on 0.0718, which indicates poor accuracy and precision respectively.

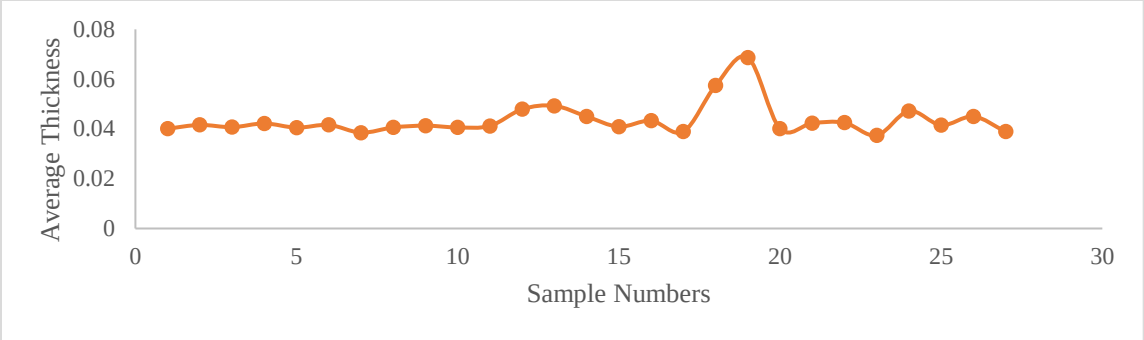

Figure 2: A line graph representing thickness distribution from manually-prepared slides

Figure 4 above depicts the result of the second part of the experiment. The glass slides thicknesses were kept standard and as a result the figures on the final thicknesses observed on the line graph are less scattered. The desired accuracy was still not achieved but the experiment did yield positive results. It has eliminated some of the variation observed on the first set of results and which will assist in improving the quality of the final specimen. A comparative look at both these sets of results shows the improved precision. Technicians gave varying reasons for the variation observed in the first set of results. Not being able to quantify the amount of epoxy in the final thickness was one of those reasons and an attempt to eliminate that uncertainty was made and will be dealt with later in this report. The average sample thickness, computed from the experiment data above, is 0.0431mm at a standard deviation of 0.0063. The reduced standard deviation illustrates the improvement in precision. The thinking behind standardising glass slides thicknesses was that it would be easier to formulate a way of computing the final thickness of the sample mounted on the slide if the glass slide thickness is known. The sample thickness can then be determined by using the formula below:

Sample Thickness = Total Thickness – Glass slide thickness.

Using this formula would be a tedious exercise if the glass slides thickness is not kept standard. A technician would have to track individual glass slides thickness before doing the calculations to record the final sample thickness. If the machine is properly set up for glass slide preparation the variation in their thicknesses is greatly reduced making it easier to perform the final calculations thus saving a lot of time and increasing productivity. Standardising the glass slides led to a big reduction in variation which made calculating the final sample thickness less complicated and reduced complaints. The achieved precision points to an elimination of a major source of variation in the sample thickness computation.

To further improve and streamline the specimen production method, the laboratory attempted to introduce one uniform sample preparation procedure. It was difficult to sift through all the different mounting techniques and come up with one that will be able to fit all or most of the client's needs. The results of the standardisation of glass slides removed some of the variation in final thin section thickness but also created an opportunity for further investigations. This led to an observation that thickness added on by the epoxy layer that binds the sample onto the glass slide was unaccounted for. ISO/IEC 17025 requires the estimation of uncertainties in the process and a decision to apply equal amounts of pressure on sample during curing was made. The application of pressure sought to (1) squeeze out any air bubbles that may appear when the sample is bonded to the glass slide and (2) to maintain a very thin and uniform layer of epoxy throughout the sample.

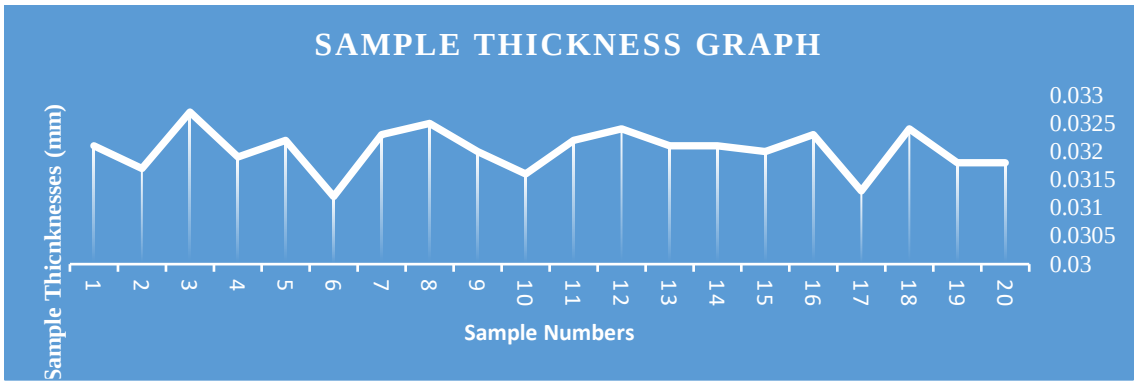

Figure 3 Line Graph of Sample Thicknesses after Pressurised Mounting

Figure 3 above depicts a line graph obtained from the calculated thin section thicknesses after pressurised mounting. Using 0.03mm as the baseline then taking the epoxy contribution into consideration, getting an average thickness of 0.03203mm was a big improvement. Also worth noting that without an accurate estimation of the epoxy thickness, a sample thickness of exactly 0.03mm was impossible to compute using thickness as a guide. What the line graph above also allows the lab is the use of it as a run chart. Each technician can evaluate whether they are using too much epoxy compared to other technicians. This will help in streamlining the method and improve the overall product. Statistical analysis of the data above was conducted. Of particular interest was the standard deviation, the mean and the median. The standard deviation proves how much precision was achieved with this method. The median was used, in this instance, because the data was skewed and did not display normal distribution. Using the median also allowed the lab to reduce the importance of any outliers observed. Removing the highest and the lowest values, as outliers, leaves a very close cluster of values. That would enable for a much more accurate estimation of the epoxy thickness in thin sections. What the calculated median of 0.0321mm informs the laboratory of is that; if the sample is 0.03mm and +/-0.002mm attributed to the amount of epoxy in the sample then a final thickness of 0.0320mm should be the target. To further simplify this, the glass slide thickness could also be added and the desired final thickness of the whole section should be +/-1.3320.

ISO/IEC 17025:2005 requires corrective and preventive actions and continual improvement. Implementation of such a system would build on from what has been achieved and ensure that opportunities for improvement are always sought. Removing uncertainties and sources of variation from the process would lead to a reduced demand for reworks in the laboratory and optimal use of laboratory consumables which would save laboratory funds.

4.4 Interviews and Questionnaire Findings

Organisations that have implemented ISO/IEC 17025 can assist organisations that are in the process of implementation or still contemplating it. People's live experiences can provide valuable lessons on what implementing ISO/IEC 17025 entails, the challenges and how to overcome those and the benefits of implementation. The findings pertaining to ISO/IEC 17025 implementation lessons were that:

- Inadequate resources allocation (time, personnel and finances) can lead to failure of ISO 17025 implementation.
- Failure to select implementation champions and committees needed for the successful implementation can be hindrance to successful implementation of ISO 17025.
- Organisations must ensure that they have the required knowledge for successful ISO 17025 implementation. If that knowledge is not available internally, knowledgeable consultants can be utilised.

Qualitative analysis involved responses to four main sections soliciting for open-ended responses. Some of the interviews took place after some of the questionnaire responses had been received and those interviews were then used to confirm or refute the information obtained using triangulation. The aim was to get the views of the respondents in order to measure the impact of ISO 17025 system in university laboratories.

4.4.1 Education and work experience

Mann and Kehoe (1995) listed employees' skill levels, employees' length of employment (experience) and employees' educational levels as some of the factors that affect total quality management implementation. Highly educated and highly skilled employees are usually more receptive to change than their less educated and less skilled

counterparts. The highly skilled personnel also feel less threatened by proposals of implementing changes and understand why there is a need for change. It was based on this background that the respondents' skills and education levels were solicited. All of the interviewees had a QA/QC qualification and only one of the questionnaire respondents did not have a post high school qualification. All of the respondents had two or more years' experience with ISO 17025 in varying roles. The knowledge, education and skills of the interview respondents was also critical in ensuring the validity of the study.

4.4.2 Reasons for Implementing ISO 17025

The question on what were the main reasons for implementing ISO 17025 solicited the following response categories: (1) Improving the quality of the products and services (2) To streamline processes and simplify work procedures (3) To reduce customer complains (4) To get access to more work contracts. Respondents acknowledged the fact that there is pressure to get ISO 17025 accreditation because it gives you access to more contracts as some holding organisations prefer using accredited laboratories but improving the quality of the products and services was the main reason stated by respondents. What can be concluded from the responses was that most of the reasons furnished are somehow interconnected. Improved services would lead to less customer complains.

Challenges faced when implementing ISO 17025: Respondents stated the following as the main challenges they faced during ISO 17025 implementation: (1) Cumbersome Documentation (2) Time Constraints (3) Financial constraints (4) Lack of support/staff participation. There was a minor disparity between what the questionnaire respondents regarded as the major disadvantage and what the interviewees stated. Interviewees had financial challenges as their biggest disadvantage and questionnaire respondents stated that they often encountered cumbersome documentation as their biggest challenge. That is understandable because project owners, like quality assurance managers (who were the respondents in interviews), etc., would know more about budgetary limitations than any other team members. The information would then filter down to the rest of the organisation if management were not able to find solutions to the financial challenges.

4.4.3 Benefits of implementing ISO 17025

Respondents counted: (1) reduced customer complaints, (2) Improved process efficiency, (3) Improved quality of products and services and (4) Increased productivity and projects as the main benefits they observed after the implementation of ISO 17025. The benefits of implementing ISO 17025 stated by interviewees, questionnaire respondents and what is generally found in literature was more or less the same. Of course, the importance of each of those benefits differed from one organisation to another. One organisation might have product improvement as their major benefit and another organisation might have reduced customer complaints as theirs. The thin section laboratory's main focus is on improving product quality and the potential of securing new clients. The possibility of achieving other benefits is an added incentive.

5. Conclusions

The objectives of the study were:

- To conduct a Gap analysis of quality management in the thin section laboratory in relation to the requirements of ISO 17025
- To assess whether there is scope for formal quality management system implementation in this type of laboratory
- To review quality control measures on thin section production and standardise them.

5.1 Gap Analysis

Grochau et al. (2012) listed aspects that needed to be checked in order to conduct an effective gap study for implementing ISO 17025 at a university laboratory. Those important aspects include (1) proper functioning and calibration status of equipment; (2) the staff's knowledge and skill; (3) the use of clearly described and validated analytical methods; and (4) the adequacy of the equipment. These aspects were used as a guide in examining the gaps between ISO 17025 requirements and the thin section laboratory's practices. The various gaps that were uncovered are summarised in the table below.

Table 1: Summary of Non-Conformances

ISO 17025:2005 TECHNICAL REQUIREMENTS		
Clause 5.2.1	Non-conformance:	Recommendation
Personnel: The laboratory management shall ensure the competence of all who operate specific equipment, perform tests	Use of student technicians who are not adequately trained	Ensure proper training and competence for lab personnel
Clause 5.4.5	Non-conformance	Recommendation
Validated Methods: The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope	Use of non-standard, lab-developed methods and no SOPs	Validate non-standard and lab-developed methods. Develop SOPs for all methods. Discuss with clients the utilisation of non-standard methods
Clause 5.5.3	Non-conformance	Recommendation
Equipment: Authorized personnel shall operate Equipment. Up-to-date instructions on the use and maintenance of equipment	No records of service to equipment and it is sometimes used by inadequately trained personnel	Train and ensure competency of personnel and ensure that equipment is properly maintained and records are kept.
MANAGEMENT REQUIREMENTS		
Clause 4.2.2	Non-conformance	Recommendation
Management System: The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual.	No structured quality management system.	Develop a structured quality control/management system.
Clause 4.2.6	Non-conformance	Recommendation
Define the roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with quality requirements.	The laboratory has unconventional management structure and duties often conflate.	Amend laboratory management structure to include a quality officer or manager, who will be responsible for quality control and improvement initiatives

These were some of the major non-conformities that made the gap between laboratory practices and ISO 17025 requirements very wide and, in some cases, it can be observed that possible remedies have already been recommended. The laboratory has already identified parts of the process that needed improvement and the gap between the laboratory's processes and ISO 17025 requirements can be narrowed further.

6 Recommendations

6.1 Technical Requirements

The laboratory must maintain the good condition of the facilities and the laboratory equipment they currently possess. Finding alternative funding streams will assist the thin section laboratory in servicing the equipment and, if the need arises, to purchase new equipment. Implementing ISO/IEC 17025 and competing for testing services contracts is one way of creating that additional income stream. The thin section laboratory will need to write SOPs for laboratory instruments and methods and conduct tests to validate those methods. This can be done internally as there is enough technical know-how already available at the laboratory's disposal.

6.2 Management Requirements

Changes to the laboratory's organisational structure would have to be made by the department. This may mean creating a position for a laboratory/technical manager to oversee the day-to-day operations of the laboratory. The manager can concentrate on technical and quality initiatives while the financial aspects are left with the departmental executive member. The laboratory manager will also help with writing proposals for new equipment funding and laboratory upgrades. Another option would be to train technicians on ISO standards and make them responsible for the technical aspects of the laboratory and ISO standards interpretation and implementation. This maybe a lengthy process but it has long term benefits for both the technicians and the department.
From literature and the conducted interviews, it was established that ISO/IEC 17025 implementation is a costly exercise. There is no doubt that ISO/IEC 17025 implementation will benefit the laboratory immensely but laboratory management will need to conduct a proper cost-estimation and ROI analysis. Abdel-Fatah (2010) states that it is not advisable to pursue implementation of ISO/IEC 17025 unless there are significant gains counteracting the cost of establishing the system, gaining accreditation and maintaining the standard.

6.3 Process Improvement

In an attempt to align its processes with ISO/IEC 17025 requirements, the thin section laboratory will have to improve its thin section-making process. The tests conducted in this study showed that there are changes that can be made to the preparation procedure to improve the quality of the thin sections. As the laboratory validates its methods, more improvement opportunities will be identified. Implementing ISO/IEC 17025 helps identify process improvement opportunities with corrective and preventative actions. The move towards implementation will also provide such opportunities as the review of the current processes is conducted. The laboratory technicians should conduct tests to determine the standard methods and validate them. Senior researchers can also be invited to give input on how to streamline the process to make it more efficient.

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Biography

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