

Pathway to Accreditation of Medical laboratories in Mauritius

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Paper Accepted on 11 August 2009

Abstract

This research presents a study of Laboratory Accreditation in the health sector in Mauritius and its impacts with emphasis on ISO 15189: 2007 standards for Medical laboratories – From the findings of a survey conducted in four private medical laboratories, the impact of accreditation was analysed. Results showed that despite the disadvantages that come with accreditation (higher workload and more paperwork), the majority of personnel preferred to work in an accredited laboratory.

The feasibility of accrediting a medical laboratory was discussed. Accreditation is a lengthy and demanding process but still feasible since it offers many advantages to the medical society i.e., the laboratory, its personnel and clients. The cost issue associated with lab accreditation is briefly discussed.

Finally the pathway of how to move towards accreditation in a medical laboratory needed utmost consideration has been devised.

In this context, a holistic approach was undertaken in order to avoid piecemeal solutions such that accreditation is obtained at one go. Henceforth the concern to gear towards the improvement of quality and competence should pervade the whole laboratory and the organisation to which it is attached.

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1.0 INTRODUCTION

Throughout the world, many countries now rely on a process called Laboratory Accreditation to determine the technical competence of their laboratories. The laboratory accreditation process is generally completed by one accreditation body within a country. Some developing economies, without established accreditation bodies, can seek to have their laboratories accredited by an established system in another country.

The issue of quality management systems and accreditation is gaining increasing interest in the health sector in Mauritius. Since more than ten years, medical laboratories have been working without norms. This situation gave rise to certain practices that are far from satisfying customers. In 2006, around 6.7 million pathological tests were carried out in the public laboratories. (*Mauritas 2007*) Important decisions about diagnosis, prognosis and treatment are frequently based on the results and interpretations of these laboratory tests, and irreversible harm may be caused by erroneous results.

Moreover, Mauritius is already providing medical health facilities to foreigners, especially with the emergence of multi-specialised hospitals and specialised centres. This concept of medical tourism, which provides for a diversified tourist product, is increasingly in demand and is expected to grow. With the policy to allow retired non-citizens to become residents in Mauritius, there is an increasing demand for services.

Thus, the Ministry of Health and Quality of life in collaboration with the Ministry of Commerce is enforcing that all medical laboratories have to accredit themselves. Consequently, medical laboratories of the public as well as of the private sector are preparing for accreditation. Laboratory accreditation is a means to improve customer confidence in the test reports issued by the laboratory so that the clinicians and through them the patients shall accept the reports with confidence.

1.1 Aims of Study

The aims of this study were two fold viz:-

- 1 To decide on the international standard that needs to be followed for the accreditation of medical laboratories.
- 2 To make a study of the laboratory accreditation process and its impacts in Mauritius.

1.2 Objectives

The objectives of the study were to

- Work out an initial review of medical laboratories in Mauritius and to select the appropriate international standard i.e. ISO 17025 or ISO 15189.
- Undertake a survey to learn about the attitude of laboratory personnel towards, and the impacts of accreditation in Mauritius.
- Develop a model for the implementation of ISO 15189 in a medical laboratory in Mauritius.

- Assess the feasibility of the accreditation process.

1.3 Quality in a medical laboratory

The definition of quality requires definition of the need which a medical laboratory has to satisfy, and these are explored in the section below.

The overall mission of a medical laboratory is to provide the customer with clinically effective information in a cost-efficient manner. The purpose of this information is to reduce the uncertainty of decisions taken in relation to diagnostic, prognostic and monitoring questions concerning the health or disease status of the patients. The information is usually based on examinations of an individual's samples of body fluids or tissues.

The medical laboratory has therefore to satisfy the needs and expectations of at least three parties: the owner(s), customers (patients, physicians) and staff, who may place a different emphasis on various aspects of the mission statement. Thus, the owner might highlight the cost-efficient use of the resources and effective cooperation with the customers and other parties (e.g. of the hospital or clinic), whereas the customers might emphasize acceptability of the examination to the patient (e.g. convenience of sampling), clinically effective and timely information, and staff safety, stress-free working conditions, training and education, and job security.

1.4 Quality Assurance in the Medical Laboratory

Quality assurance "in laboratory medicine is the process of assuring that all pathology services involved in the delivery of patient care have been accomplished in a manner appropriate to maintain excellence in medical care".

Quality assurance covers a broad spectrum of plans, policies and procedures that give an administrative structure for a laboratory to achieve its quality goals. These include procedures that influence the laboratory test procedure, quality of analysis, quality control, quality assessment, external quality assessment (EQA), quality audit and laboratory accreditation. (*K. W. Davies, 1999*)

1.5 Laboratory Accreditation

Accreditation is defined as the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. (*MAURITAS, 2007*)

Laboratory accreditation is a means of determining the technical competence of laboratories to perform specific types of testing, measurement and calibration. It also provides formal recognition to competent laboratories, thus providing a ready means for customers to identify and select reliable testing, measurement and calibration services able to meet their needs. (*ILAC, 2006*)

1.6 Accreditation Bodies

The only accreditation body in Mauritius is MAURITAS, Mauritius Accreditation Service which is a governmental body established in 1998. The aim of MAURITAS is to provide accreditation services to testing/calibration laboratories; inspection bodies; and certification bodies operating certification of products, personnel, quality systems and environmental management systems. NAMAS, UKAS and SANAS are among the international accreditation bodies.

1.7 The accreditation procedures for medical laboratories in the European Union (EU)

According to a survey launched by the Federation of European Societies of Clinical Chemistry (FESCC) in July 1998, the number of accredited laboratories was the highest in the two countries which started accreditation the earliest (*i.e.* Sweden and UK, 1992). Moreover in 2005, the EC4 (European Communities Confederation of Clinical Chemistry and Laboratory Medicine) carried out a survey to explore the status of accreditation in EU countries and part of the results published is shown as follows:

EU country	Accreditation to	
	ISO 15189	ISO 17025
Belgium	22 (10%)	
Czech Republic	3 (0.3%)	2
France		90 (3%)
Netherlands	122 (30%) + 98 applied	
Norway		15
Sweden		85%
United Kingdom	101 (9%) fully, 116 partially; Old CPA: 606 (55%) fully, 276 partially	

Table 1: Accredited laboratories in the EU

Results are presented as number of laboratories (% of total)

(Source: Huisman et al. 2007)

The number of accredited laboratories varies between EU countries. In 20% of the countries, EN/ISO 15189 was used exclusively, while in the remaining countries both standards (*i.e.*, ISO 15189 and 17025) were available (Table 1). In the UK, the original CPA standards was replaced by the new EN/ISO 15189-aligned CPA

guideline. The total number of accredited laboratories was relatively high, and the proportion accredited according to ISO 15189 is already 9%. In The Netherlands, 30% of all types of medical laboratories and 70% of clinical biochemistry laboratories were accredited to EN/ISO 15189. In Sweden, the rate of accredited laboratories was even higher at 85%, most of which were accredited to ISO/IEC 17025, but some also to EN/ISO 15189.

1.8 Standards for Quality Management in the Medical Laboratory

1.8.1 ISO/IEC 17025: 2005 – Its Assurance to the Customer

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, is the main standard used by testing and calibration laboratories. Originally known as ISO/IEC Guide 25, ISO/IEC 17025 was initially issued by ISO in 1999. Laboratories accredited to ISO 17025 are normally assessed every four years. In addition the standard requires that the laboratory carries out its own, internal, audits on a regular basis and record the results for scrutiny by the external assessors. Where problems are revealed by internal and external audits the laboratory must take prompt and effective corrective action to ensure, as far as possible, that the problem is not likely to recur. This will thus provide a mechanism for continuous quality improvement and which assures the customer that the laboratory quality management system is under constant scrutiny both internally and, crucially, by an independent third party. ISO 17025 provides defined requirements which must be met by the laboratory's quality management system. Compliance to ISO 17025 provides assurance to the customer that, test work will be conducted by validated, recognised, technical methods suitable for the purpose required and of established performance characteristics.

The work will be carried out by trained and qualified personnel. There must be a formal programme for training staff that will perform the test work and work with customer samples. Moreover, staff competence will be reviewed and reassessed on a regular basis.

Laboratories accredited to ISO 17025 must have planned maintenance and calibration schedules for their equipment. They must present evidence to assessors that such schedules are rigorously followed and that any equipment malfunctions are detected before they affect client's data. Calibration of all key equipment must be such as to establish traceability to the relevant industry or international standards. This means that any measurement made on equipment in an accredited laboratory has global credibility and should be reproduced to known levels of uncertainty by any laboratory in the world operating to similar rigorous levels of traceability for its calibrations.

Overall the laboratory is expected to be highly active and responsive in maintaining and improving its quality management system to the highest practicable standards and to minimise the likelihood of suspect data being produced and released. The laboratory should also be seeking to continually improve its performance and be responsive to any information which enables it to identify problems with its quality system and carry out appropriate corrective and preventive action. ISO 15189:2007 is also a laboratory standard with similar

requirement to ISO 17025 but it addresses the needs for medical laboratories accreditation much better with much more emphasis for the medical environment.

1.8.2 ISO 15189:2007 – The Preferred Standards for Medical Labs.

ISO 15189:2007 *Medical Laboratories- Particular requirements for quality and competence* specifies the quality management system requirements particular to medical laboratories. The standard was developed by the International Organisation for Standardisation’ Technical Committee 212 (ISO/TC 212). Its development was strongly influenced by the EC4 Essential Criteria for Quality Systems in Medical Laboratories. While the standard is based on ISO/IEC 17025 and ISO 9001, it is a unique document that takes into consideration the specific requirements of the medical environment and the importance of the medical laboratory to patient care. The following table gives the main requirements of this document:

4. Management Requirements	5. Technical Requirements
4.1 Organisation	5.1 Personnel
4.2 Quality Management System	5.2 Accommodation and environmental conditions
4.3 Document Control	5.3 Laboratory equipment
4.4 Review of contracts	5.4 Pre-examination process
4.5 Examination by referral laboratories	5.5 Examination process
4.6 External services and supplies	5.6 Assuring the quality of examination procedures
4.7 Advisory services	5.7 Post-examination process
4.8 Resolution of complaints	5.8 Reporting of results
4.9 Identification and control of non-conformities	
4.10 Corrective action	
4.11 Preventive action	
4.12 Continual improvement	
4.13 Quality and technical records	
4.14 Internal audits	
4.15 Management reviews	

Table 2: Main requirements of ISO 15189

This process based quality management system for medical laboratories is based on ISO 9001:2000 and is represented in the diagram below:

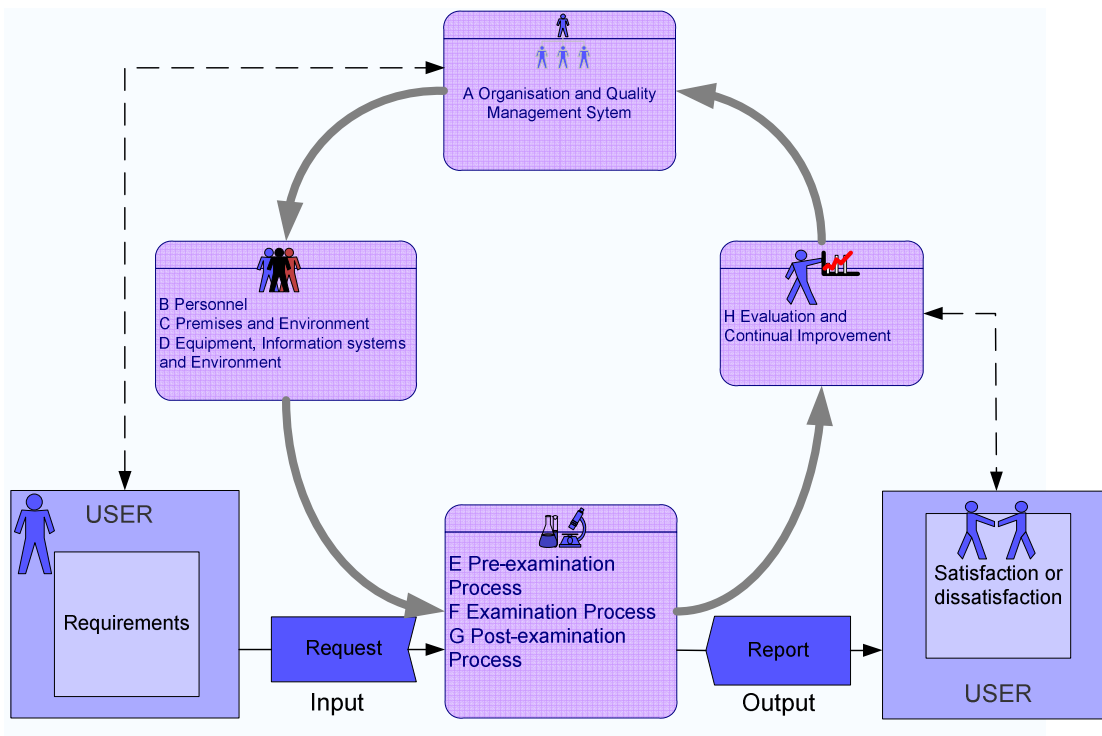


Figure 1: Quality Management System for Medical Laboratories

(Source: CLAS Accreditation Guidelines, 2004)

1.8.3 Comparison between ISO 15189 and ISO 17025

A comparison is made of ISO 15189 and the ISO 17025 and sections where there are differences are discussed below.

Premises and Environment

- Attention is paid in the ISO 15189 document to the requirements for space, for personnel as well as for patients. It is not addressed in ISO 17025.
- Requirements for computer facilities are available in the annex of ISO 15189 but are not considered in ISO 17025

Pre-analytical phase

The pre-analytical phase is extremely important for the interpretation and outcome of medical laboratory data.

- Aspects regarding this phase are practically not addressed at all in the ISO 17025 document in contrast to the ISO 15189 document.
- There is, in the ISO 15189 document, an annex included on ethics in laboratory medicine. Although not mandatory, issues are addressed here such as the

informed consent of the patient, collection of information and access to medical records.

Post-analytical phase

The post-analytical phase includes reporting procedures.

- Internal ideas and complaints form input for continuous improvement and motivation of staff. There should be a low threshold for reporting such remarks from the laboratory personnel, and a recording and evaluation system should be in place. It is addressed to some extent in ISO 15189, but not in ISO 17025.

2.0 METHODOLOGY OF THE STUDY

This section will give an overview of the general method that has been used to carry out this study research. The methodology covers a four stage structured approach as illustrated below:

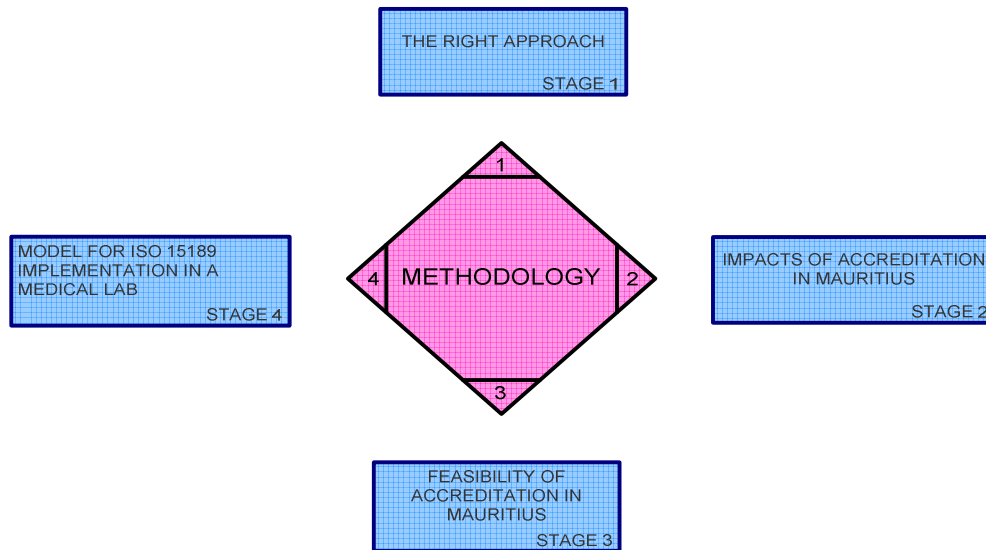


Figure 2: Methodology

2.1 Stage 1: Decide on the right approach

The required international standard, ISO 17025 or ISO 15189; that suits a medical laboratory is selected by a benchmark study with the EU countries.

2.2 Stage 2: Impacts of the accreditation process

A three-page questionnaire comprising of two sections, was submitted to the personnel in four private medical laboratories; approximately three months after they started the process. The survey form consisted of 2 sections:

- a) The right approach towards accreditation
- b) Impacts of accreditation

Objectives of the survey

Laboratory personnel play a critical role in the success of a quality system by performing according to standard operating procedures. One would expect that the introduction of a quality system with all the inherent changes in the way of working, the additional paperwork and the stiffening-up of the procedures would not be welcomed by these personnel. So, the survey was conducted in order to learn:

1. How laboratory personnel react to the accreditation process, and
2. What are the impacts of such a process

2.3 Stage 3: Feasibility of the accreditation process

The practical feasibility of this process is analysed as well as the difficulties that creates obstacles for the implementation process. In addition, the time frame and the types of cost implied are investigated.

2.4 Stage 4: Model for ISO 15189 Implementation in a Medical Laboratory in Mauritius

Not all laboratories have the resources to secure the assistance of quality consultants. For those laboratory managers who have to find their way towards quality management on their own, some recommendations are given for a pathway towards laboratory accreditation.

The major factors that need utmost consideration for ISO 15189 implementation process are analysed.

In this section, the results and findings of the survey conducted among laboratory personnel are elaborated. At the same time, the impacts of laboratory accreditation in the health sector in Mauritius are discussed. Finally, feasibility of the accreditation process is assessed.

3.0 SURVEY: THE ATTITUDE OF LABORATORY PERSONNEL TOWARDS AND THE IMPACTS OF ACCREDITATION IN MAURITIUS

3.1 Survey results and discussion

For reasons of confidentiality, the private laboratories are randomly designated as A, B, C and D. The number of respondents was 5, 4, 5 and 6 in labs A, B, C and D respectively.

Which standard will be appropriate for a medical laboratory in Mauritius

Personnel were asked to choose between ISO 17025 and ISO 15189 standards. 100 % affirmed that ISO 15189 was the right standard; however 75 % of them commented that guidelines for its implementation was required; the main reason being that the majority of laboratories in Mauritius are not familiar with this system.

3.2 Impacts of Accreditation

Has work load increased with accreditation?

An overwhelming majority (as illustrated in Figure 3) of the personnel considered that their workload had increased. The reasons for this increase being

- an increase in documentation and records,
- regular monitoring of calibration,
- and setting up Internal Quality Control

Only a minority had no opinion or thought that the workload remained the same.

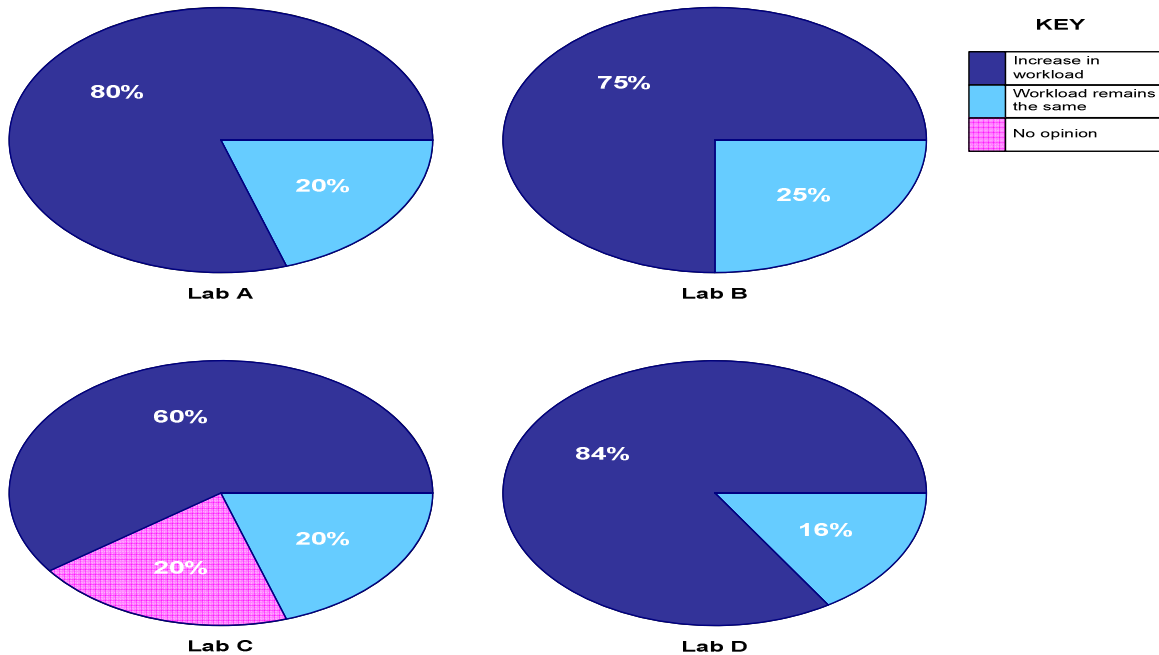


Figure 3: Pie-charts showing response of lab personnel towards workload

Has quality of test results improved?

Surprisingly, only a minority of staff considered that the quality of the laboratory results had improved (lab A: 20 %/ lab B: 25%/ lab C: 40%/ lab D: 33%).

- The first explanation for this would be that personnel will not happily acknowledge that the quality of results was bad before. In other words, they were convinced that the quality was already good before accreditation.
- Secondly, at the beginning of an accreditation process, much more emphasis is placed on the formalities (documentation of actions and initialling work lists

and printouts) than on the quality of results. After sometime, the attention shifts to the intrinsic quality as the formalities become more routine.

What are the advantages of working in an accredited medical laboratory?

The main advantages of working in an accredited laboratory, as viewed by its employees, were the better traceability of all things that happen in the laboratory (see figure 4), so that the cause of an error can more easily be traced and the fact that the personnel are more sure of the procedures to be followed.

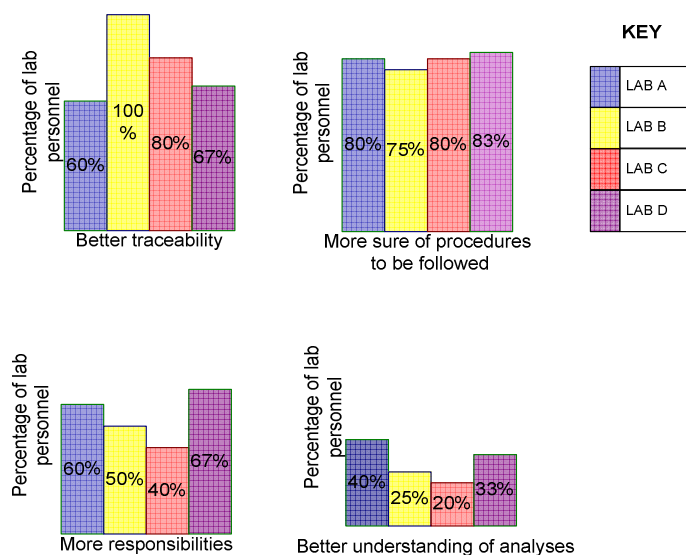


Figure 4: Bar chart representing advantages of lab accreditation as seen by lab personnel

The personnel appreciated that they were receiving more responsibilities, which can be explained by the fact that in the surveyed laboratories, they were actively involved in writing and revising the procedures. About 20 to 40 % of the respondents thought that they had a better understanding of the analyses they were performing. The reasons were divided as to the quality of the results, which was in agreement with the answers to the previous section.

What are the disadvantages of working in an accredited medical laboratory?

According to the employees surveyed, the biggest disadvantage of an accredited laboratory was the increase in paperwork (100% agreement in each lab). An important disadvantage was also the discrepancy between written procedures and the reality (as shown in figure 5); i.e. when procedures are not followed exactly or skipped, for example because of the breakdown of an instrument. Other disadvantages were:

- Greater emphasis on formalities
- Less adaptability
- Less possibility for personal initiative

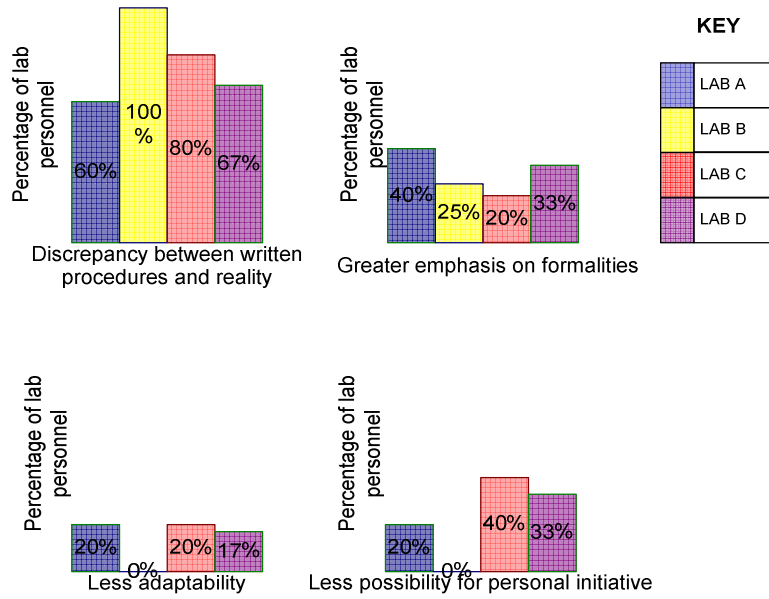


Figure 5: Bar chart representing disadvantages of lab accreditation as seen by lab personnel

What is preferred: working in an accredited laboratory or a non-accredited laboratory?

Finally despite the disadvantages, the majority of the respondents (lab A: 80% versus 20%/ lab B: 100%/ lab C: 100%/ lab D: 66% versus 17% with 17% without opinion) preferred to work in an accredited laboratory.

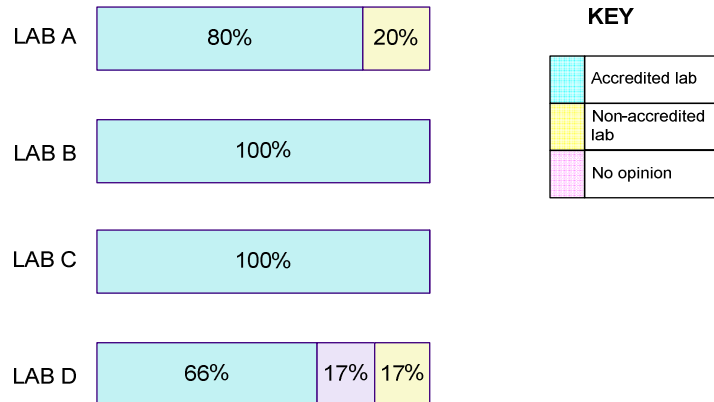


Figure 6: Bar chart representing percentage of lab personnel preferring accredited lab

3.3 Conclusion to survey

This survey describes the attitude of medical laboratory personnel towards accreditation in Mauritius. Results show that despite the disadvantages that come with accreditation (higher workload and more paperwork); the majority of personnel prefer to work in an accredited laboratory. The main reason for the positive attitude to accreditation process is that the employees were currently involved in the accreditation process. They were writing the standard operating procedures, testing them with their colleagues and modifying them. In this way, they were actively involved and were allocated more responsibility. This seems to have been appreciated and is critical to the success of the accreditation process.

4.0 FEASIBILITY OF MEDICAL LABORATORY ACCREDITATION IN MAURITIUS – COSTS IMPLICATIONS

The advents of accreditation would definitely increase the credibility of the laboratory vis-à-vis its customers. However though accreditation is workable, it will take some time for the laboratory to implement ISO 15189. A proper budget should be planned for the implementation process. Actually the medical laboratories in Mauritius have been given about 2 years for its preparation which is justified. In this respect, the documentation aspects; Quality Manual, Job Descriptions, Quality Plan, Records, must be carried out. In certain laboratories, the need for the recruitment of a consultant or additional personnel may arise; and responsibilities may have to be redistributed in order to tally with and maintain the QMS. Only after all the requirements of the ISO 15189, are fulfilled and suited to MAURITAS that the laboratory will obtain accreditation.

Therefore accreditation is a lengthy and demanding process but still feasible since it will provide numerous advantages both to the laboratory and its customers. This is true however under the assumption that the particular medical laboratory can cover all the cost involvement associated with accreditation. The associated costs are:

Consultancy cost

The expert guidance for the preparation and implementation stages may be useful and desirable to ensure the success of the accreditation process.

MAURITAS application and assessment costs

An application and assessment fees are payable to MAURITAS. It covers the process of registering the organisation's application and auditing the quality system to assess the compliance with the standards. Furthermore, an annual registration and surveillance fees are paid to the accrediting body for periodic audits and assessments, and continued accreditation.

Calibration costs

Normally calibrations of analysers are performed by the use of reference materials (known as "calibrators"). The costs of these materials have to be included. Moreover, in those circumstances where the laboratory cannot undertake

calibration, it will have to forward the task to an external organisation or the manufacturing company; hence, generating additional cost.

Stationery and other materials costs

As discussed earlier, the quality system will require manuals, written procedures, work instructions and forms to be developed. In the implementation process, drafts are considered and amended so that paper will be required together with binders, filing cabinets, photocopies and others; whose costs have to be incurred.

In general, it is more practical to categorise cost areas as follows:

1. *Preventive costs:-*
 - Included here are such things as quality planning, documentation and its control and revision, quality training and preventive maintenance.

2. *Appraisal costs:-*
 - Internal quality control, costs of control materials.
 - Interlaboratory and proficiency testing costs
 - Internal audits costs

3. Failure costs
 - Cost of repeating analyses
 - Costs of corrective action efforts
 - Investigation or root cause efforts

Parts of these costs are already being sustained by some medical laboratory but to cover other expenses the laboratory, if it is part of an organisation (hospital or clinic), will have to gain financial support from its top management. Otherwise certain private laboratories affirmed that the cost of analysis will have to be increased after accreditation.

Recommendations for accreditation of medical laboratory in Mauritius are described in twofold in this study:

1. The right standard for Mauritius is suggested
2. A model for ISO 15189 implementation is provided

5.0 THE RIGHT STANDARD FOR MAURITIUS

ISO 15189 was accepted in all EU countries; revealed by the EC4 2005 survey (see Table 1), and as well as in India as the standard for medical laboratory services. The value of this International Standard is irrefutable. Medical laboratories are the first medical discipline for which a specific International Standard has been elaborated and delivered, linking the needs of quality management systems, according to the ISO 9001:2000 series, with technical requirements that determine competence in clinical laboratories.

So, ISO 15189 seems adequate for our medical laboratories in Mauritius and also for those who want to benchmark themselves to countries like UK and Sweden.

Moreover, of the medical lab personnel surveyed in Mauritius, 100 per cent agreed that ISO 15189 is the right standard for Mauritius.

6.0 A MODEL FOR THE IMPLEMENTATION OF ISO 15189 IN A MEDICAL LABORATORY IN MAURITIUS

One of the specific tasks of this model was to specify actions (“milestones”) needed to implement ISO 15189 in a medical laboratory, as a plan of “*how to proceed from here to there*”, i.e. a pathway as illustrated in the Table 3. The model is also based on the elements of ISO 15189 and is adapted to suit a medical laboratory.

Table 3: Model for ISO 15189 implementation in a Medical Laboratory in Mauritius

<i>Pathway</i>	<i>Action points</i>
	From now on, all actions must be documented!
1. Start	Scope: The medical laboratory needs to be able to show objective evidence that the tests were undertaken <ul style="list-style-type: none"> ■ in a proper manner ■ by appropriate tools and environment ■ with validated methods
2. Awareness	Building awareness: Awareness of the scope among staff is generated by <ul style="list-style-type: none"> ■ general information on quality ■ motivation by requirements from outside the laboratory and competition ■ motivation from inside the laboratory ■ discussion of problems being experienced ■ discussion to establish what is felt to be the minimum requirements for the laboratory
Awareness OK	✓ Awareness OK? Then proceed to the next step ◆ Milestone 1
3. Laboratory status document	Current status: Collect information on current status of the laboratory system. This is best done by those who actually do the work.

- Flowchart your procedures
- Make a list of all procedures and actions for the current practices.
- Include the laboratory’s mission statement
- Be alert for completeness
- ✓ Check for completeness, have any deficiencies been corrected so that procedures reflect agreed current procedure

<i>Pathway</i>	<i>Action points</i>
Document completed	◆ Milestone 2
4. Evaluation	<ul style="list-style-type: none"> ✓ Perform a gap analysis between the identified current status and the requirements of ISO 15189 standards/ guidelines ✓ Decide whether compliance is acceptable or not (if “yes”, go to stage 8, otherwise continue)
5. Plan	<p>Prepare a plan for improvement: The purpose of the plan is to close the gap between the identified current status and the requirements.</p> <p>Actions to achieve this include:</p> <ul style="list-style-type: none"> ■ Form a steering group ■ Clarify responsibilities and authorities for the allocation of resources and setting the priority of work ■ Identify and allocate laboratory resources, personnel, equipment and work environment ■ Identify and request potential external assistance ■ Define the essential procedures to be improved and to what extent modification/ harmonisation/ documentation/ assurance is required. ■ Set time frame ■ Participate in proficiency testing ✓ Obtain approval from management
Plan completed	◆ Milestone 3
<i>Pathway</i>	<i>Action points</i>
6. Implementation	Bring plan into action: All actions shall be documented:

	<ul style="list-style-type: none"> ■ Harmonise procedures when necessary, that is, get everyone working the same way ■ Analyse and implement each clause of ISO 15189 ■ Pay attention to process situations of non-conformance ■ Ascertain statistical control and traceability ■ Participate systematically in proficiency testing and evaluate results as work proceeds ✓ Check improvements through internal audits ✓ Obtain verification by second opinion
Quality plan implemented	◆ Milestone 4
7. Assessment	Assessment of the current system against ISO 15189 <ul style="list-style-type: none"> ■ Compile quality manual ■ Have system assessed independently ✓ Is the laboratory operating according to ISO 15189?
ISO 15189 in place	◆ Milestone 5
8. Accreditation	Go for accreditation <ul style="list-style-type: none"> ■ Certificate of accreditation
Fully accredited laboratory	◆ Milestone 6

Validation of Test procedures

The objectives of analytical procedures used at the implementation stage should be clearly understood since this will govern the validation characteristics which need to be evaluated. Typical validation characteristics which should be considered are: accuracy, precision, repeatability, detection limit and linearity. The accuracy of the results will be determined by the comparison of the results of the proposed test procedure with those of the standard procedure identified. The precision is computed as standard deviation or coefficient of variation of the measurement results. And repeatability is a minimum of 9 determinations covering the specified range for the procedure (e.g. 3 concentrations/3 replicates each). Finally linearity is evaluated by visual inspection of signals as a function of analyte concentration (e.g. a minimum of 5 concentrations). Internal Quality Control (IQC) is very important for verifying control results, and, consequently, for accepting or rejecting a calibration or a series of measurements.

7.0 CONCLUSION

As the issue of ensuring best value for money with best treatment for the patient is becoming a priority, quality assurance system is becoming the norm. This is the case for Mauritius where medical laboratories are being enforced to set up a Quality Management System based on International Standards and finally to head towards accreditation.

There are several advantages to be gained in working in an accredited laboratory. Firstly, top laboratory management is highly committed to the accreditation process, the laboratory is well managed, examining procedures are in place and results are internally controlled and validated. There is better traceability of materials and results such that the root cause of an error can more easily be found. And the personnel are more confident in using the facilities provided. The major disadvantages of accreditation are higher workload and increase in paperwork and more training and awareness to be worked out for qualified personnel.

In Mauritius, so far, both the public and private laboratories have started implementing ISO 15189 which is the right direction, since the benchmark study in this project showed that ISO 15189 is the right standard for Mauritius. Pro-Medical Laboratory and Green cross Medical Laboratory are among the private laboratories that affirmed to be ready for accreditation by December 2008. Calibrations of the automatic analysers are being done by the use of reference materials. Internal Quality Control has been set up since three months, through which the quality of analysis are detected immediately. However, the main limitation to accreditation in Mauritius is the absence of a national body that can provide Proficiency Testing schemes. Our medical laboratories will have to make recourse to external facilities which will incur high costs.

Accreditation is a lengthy, and demanding process but still feasible since it offers many advantages to the medical society i.e., the laboratory, its personnel and clients. However, there is a cost issue associated which will require financial support and commitment from top management when the laboratory is attached to a hospital or clinic. Otherwise the laboratory will have to recourse to loan facilities which is being offered by the government. Nevertheless, medical laboratory personnel affirm that the cost of analyses may rise after accreditation.

In general, the scheme towards accreditation based on ISO 15189 requires commitment from top management and staff, effective communication, appropriate education and training of all staff, and well-organised implementation and monitoring.

Finally, it is hoped that this study will provide impetus for medical laboratory accreditation in Mauritius. Accreditation should be recognised as a strategic decision and will trigger major behavioural and cultural changes in the sense that policies will change; it will require implementation of more rigorous procedures for testing of experiments and for verification and validation of results. It is also

hoped that, further research in this field will be pursued with rigor. The following are some future works that are suggested

- To identify the non-conformances that will arise after the first assessment by MAURITAS and hence find the root causes and propose corrective actions.
- To investigate the performance of a medical laboratory after its accreditation to ISO 15189.

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