Attaining Laboratory Accreditation to ISO 15189:2012 – Bomu Hospital Laboratory Experience

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Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the funding agencies.

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Acronyms, abbreviation, and definition of terms

Accreditation - Accreditation is procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

CDC – U.S. Centres for Disease Control and Prevention - Kenya

Certification - Certification is procedure by which a third party gives written assurance that a product, process, or service conforms to specific requirements.

CLSI – Clinical and Laboratory Standards Institute

CLIA – Clinical Laboratory Improvement Amendments

ISO – international standards of organizations

KENAS – Kenya accreditation service

MCS – Mkomani Clinic Society

MOH – Ministry of Health

Non-conformity – No fulfilment of a requirement

QMS – Quality management system

SLMTA - Strengthening Laboratory Management Towards Accreditation

TBEA - Training, Building, Evaluation and Accreditation

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- Bomu Hospital Management

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Executive Summary

Background

Achievement of ISO 15189 accreditation in a medical laboratory demonstrates the competency of the laboratory staff to conduct testing. Different approaches to attain accreditation can be used, some of which are time-consuming while others require checklists that are not directly compliant with the requirement of ISO 15189. It is prudent that a simple approach is used to develop, align, and implement the requirements of ISO 15189 documentation.

Objectives

To come up with a quick approach to attaining laboratory accreditation under ISO 15189:2012 as well as complying with good laboratory practices.

Methods

Bomu hospital laboratory used an onsite tailor-made approach – the Training, Building QMS, Evaluation and Evaluation (TBEA) to achieve accreditation. The trainings improved staff knowledge evidenced in both pre and postmarks. Process mapping enabled the laboratory to lay down the laboratory testing process, and develop documents aligned with the laboratory process flow. The entire system was further evaluated through audits conducted by trained internal auditors meant to show that the pre-examination, examination, post-examination, and other supporting processes were conducted in a manner that met the needs and requirements of the laboratory users as well as ISO 15189. Internal audits are ongoing activities that are meant to continually improve the effectiveness of an established quality management system.

Results and Conclusion

There was an overall improvement in knowledge gained from the trainings. Building the quality management system as well as its evaluation by internal audit made it possible to attain accreditation in the shortest period.

Training using the best tools simplifies the understanding of ISO 15189 and assists in document development thereby assisting in building a strong quality management system. A team of highly motivated staff as well as well-trained internal auditors competent to pick problems in the quality management system and continually improve the system is required. A strong management commitment plus stable financial assistance with budget allocation is required to achieve the desired results.

1.0 INTRODUCTION

The "ISO 15189 Standard: Medical Laboratories–Requirements for Quality and Competence" is an internationally accepted accreditation standard based on a series of requirements which encompasses all the assessment criteria specified in the policy of quality (Richardson, 2002). Like other ISO Standards, ISO 15189 identifies what laboratories need to do, but not how to do it. Each laboratory specifies the "how" for its situation using knowledge thought to be acquired through college training or various mentorship programs available in a particular country.

Internationally-accredited laboratories are recognized for their superior test reliability, operational performance, quality management and technical competence (Viegas et al., 2017). Implementation of quality management systems (QMS) ensures that laboratory services meet international standards and that results are accurate, reliable and timely, representing a vital role in diagnosis, monitoring of disease treatment, training, surveillance and disease prevention (Aslan, n.d.).

One of the key priorities in laboratory medicine is improvement of quality management system for patient safety. Quality in health care is tightly connected to the level of excellence of the health care provided in relation to the current level of knowledge and technical development. Accreditation is an effective way to demonstrate competence of the laboratory, a tool to recognize laboratories world-wide, is linked to periodical audits, to stimulate the maintenance and improvement of the quality, which leads to high standard of services for clients.(Williams et al., 2019).

Although the benefits of accreditation are numerous, the journey toward accreditation has several challenges. Establishing the various standard quality requirements is expensive and labor-intensive. Lack of trained personnel especially in quality system essentials and good clinical laboratory practices, coupled with the lack of professional trainers in the country, require contracted mentors. In addition, all equipment needs to be placed on preventive and corrective maintenance service contracts, which is also costly. There are challenges in implementing safety standards such as waste management owing to the absence of or unclear government policies on disposal of certain waste products. A major hurdle was the nurturing of a quality culture (Zeh et al., 2010).The Strengthening Laboratory Management Towards Accreditation (SLMTA) program was launched in 2009 and adopted in Kenya in 2010 was designed to address expenses and challenges laboratory faced while implementing quality systems. Bomu was a beneficiary of the SLMTA. Bomu attained 4 stars at the end of the SLMTA process but used the ISO 15189:2012 approach for training and organizing all its documents until it attained the accreditation. Different laboratories use different approaches to attain accreditation some of which are time consuming and expensive. Some laboratories hire consultants to prepare the QMS documents while others copy existing QMS of other facilities (Zima, 2017). Laboratories often find it difficult to follow established testing algorithms and quality control protocols, specific guidelines, workplace health regulations and instrument maintenance controls. In addition, there are few resources to conduct periodic competency testing and continuing education to assure that technologists retain core knowledge of authorized procedures and remain abreast of international and national standards (Oliver et al., 2021).

Bomu hospital laboratory used an onsite tailor-made approach – the Training, Building QMS, Evaluation and Evaluation (TBEA) to achieve accreditation in the shortest period. The trainings improved the staff knowledge as evidence in both pre and post marks. Process mapping enabled the laboratory to lay down the laboratory testing process so that all documents developed aligned

with the laboratory process flow. This was a simple way of building the quality system as well as developing the necessary documentation. The entire system was further evaluated through audits. Internal audit which was conducted by trained internal auditors was meant to show that the pre-examination, examination and post examination and other supporting processes were conducted in a manner that met the needs and requirements of the laboratory users. The audits were also used to ensure conformity of the established quality management system as well.

The overall goal is to demonstrate how tailormade approaches can be used to attain laboratory accreditation under ISO 15189:2012 as well as complying with good laboratory practices in the same setting.

2.0 METHODS

2.1 Study Setting

The study was conducted at Bomu hospital in Mombasa County, Kenya. The hospital is a not for profit, registered and recognized non-governmental healthcare organization that provides general medical, pediatric, antenatal, family planning, and HIVtesting and care services established through PEPFAR funding under a cooperative agreement with the US Centers for Disease Control and Prevention (CDC) in Kenya. Bomu hospital is in Mombasa County, Mombasa west in Changamwe sub-County. Bomu Hospital serves all categories of patients ranging from the - middle-income earners to the lower income earners. It also offers high quality services at an affordable price.

Bomu hospital has a state-of-the-art laboratory divided into six key departments namely microbiology, biochemistry, haematology, immunology, serology, and parasitology. The laboratory has two sample collection sites (phlebotomy) within the hospital. The laboratory is equipped with automated analysers including the microbiology laboratory. In additional to internal test requests from Bomu hospital, the laboratory receives external or referral requests for testing from all healthcare centres within Mombasa. Furthermore, Bomu hospital laboratory is a backup for Coast General Teaching and Referral Hospital (CTGRH) Laboratory in Mombasa County, Kenya.

2.2 Study Design

The study was a descriptive study design that looked at the approach adopted by Bomu hospital laboratory to attain ISO 15189:2012 accreditation status.

2.3 Assessment process

The Kenya Accreditation Service (KENAS), established in 2009 is mandated to inspect and assess conformity to ISO standards and award accreditation to those meeting the minimum requirements for ISO accreditation. Respective standards include calibration, product testing, medical testing (pathology), and proficiency testing laboratories, inspection, verification, and certification bodies in all the economic sectors. It is a State Corporation re-established by the Kenya Accreditation Service Act 2019 (Act. No 17 of 2019) as the sole national accreditation body for Kenya (Republic of Kenya, 2019).

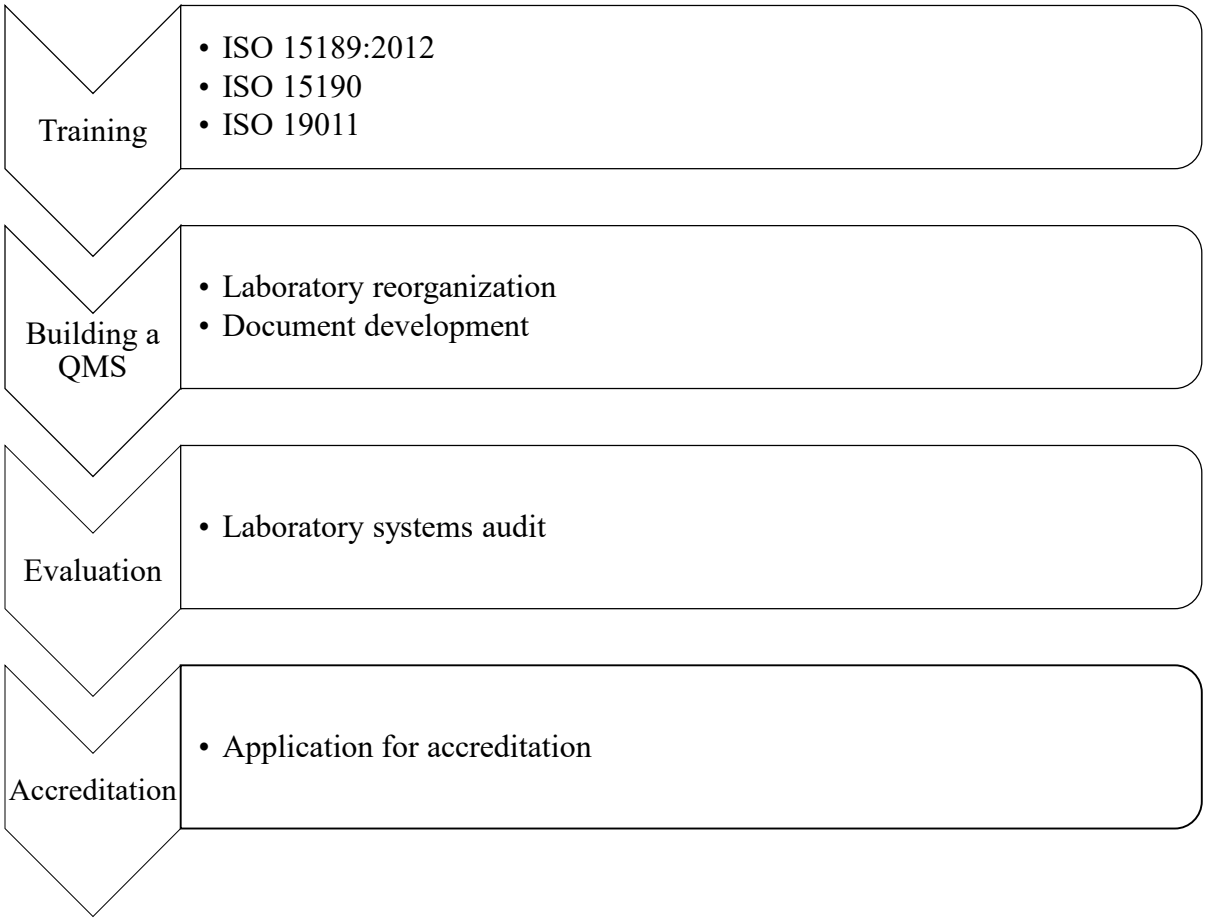
After a laboratory has fulfilled the requirements of ISO15189:2012, it will apply for accreditation. KENAS will send a formal response on the terms and references applicable applicable to the

provision of accreditation services. The laboratory is required to follow the KENAS accreditation process, which will eventually lead to an laboratory assessment. The outcome of the assessment will be determined by closure of the identified non conformities and the decision of the accreditation committee from KENAS.

2.5 Accreditation approach - TBEA approach

The Training, Building, Evaluation and Accreditation (TBEA) was a toiler made approach which Bomu hospital laboratory used to attain the accreditation in the shortest possible time since it was taking too long to understand the requirements of ISO 15189:2012.
See below a flow chart.

Figure 1: A process flow chart showing Bomu TBEA Approach in attaining laboratory accreditation, XXX,2014 -2015 (two years) Bomu hospital, Mombasa



The process flow describes the steps the laboratory took to attain accreditation.

2.6 Training

All 14-laboratory staff attended QMS training sessions that were organized by CLSI in collaboration with Ministry of Health (MOH). A series training for all staff that covered all elements of ISO 15189:2012 were done by the CLSI experts. This training was followed by awareness meetings that involved hospital management so that they understood the processes and to ensure the availability of resources required to enable the QMS implementation process. The hospital management was supportive and committed to supporting the accreditation process. The

training involved covering all aspects of management and technical requirements under ISO 15189:2012.

2.6.1 Method Validation Training

A total of fourteen laboratory staff were trained on validation/verification of laboratory methods so that they demonstrate that the analytical procedures used are suitable for the intended use.
All laboratory methods require to be verified or validated before being used to analyze patients' samples. Quantitative methods required precision, accuracy, and linearity studies at a minimum whereas the verification of qualitative methods involved a better understanding of specificity, sensitivity and the predictive values as given by the manufacturers.

2.6.2 ISO 15190 Safety Training

This document specifies requirements to establish and maintain a safe working environment in a medical laboratory. As with all other guidelines, ISO 15190 guides laboratory staff to take personal responsibility for their own safety at work and the safety of others. ISO 15190 is a safety standard, a key component of ISO 15189. In addition, a biosafety and biosecurity training were conducted by African Medical and Research Foundation (AMREF).

2.6.3 Internal audit training

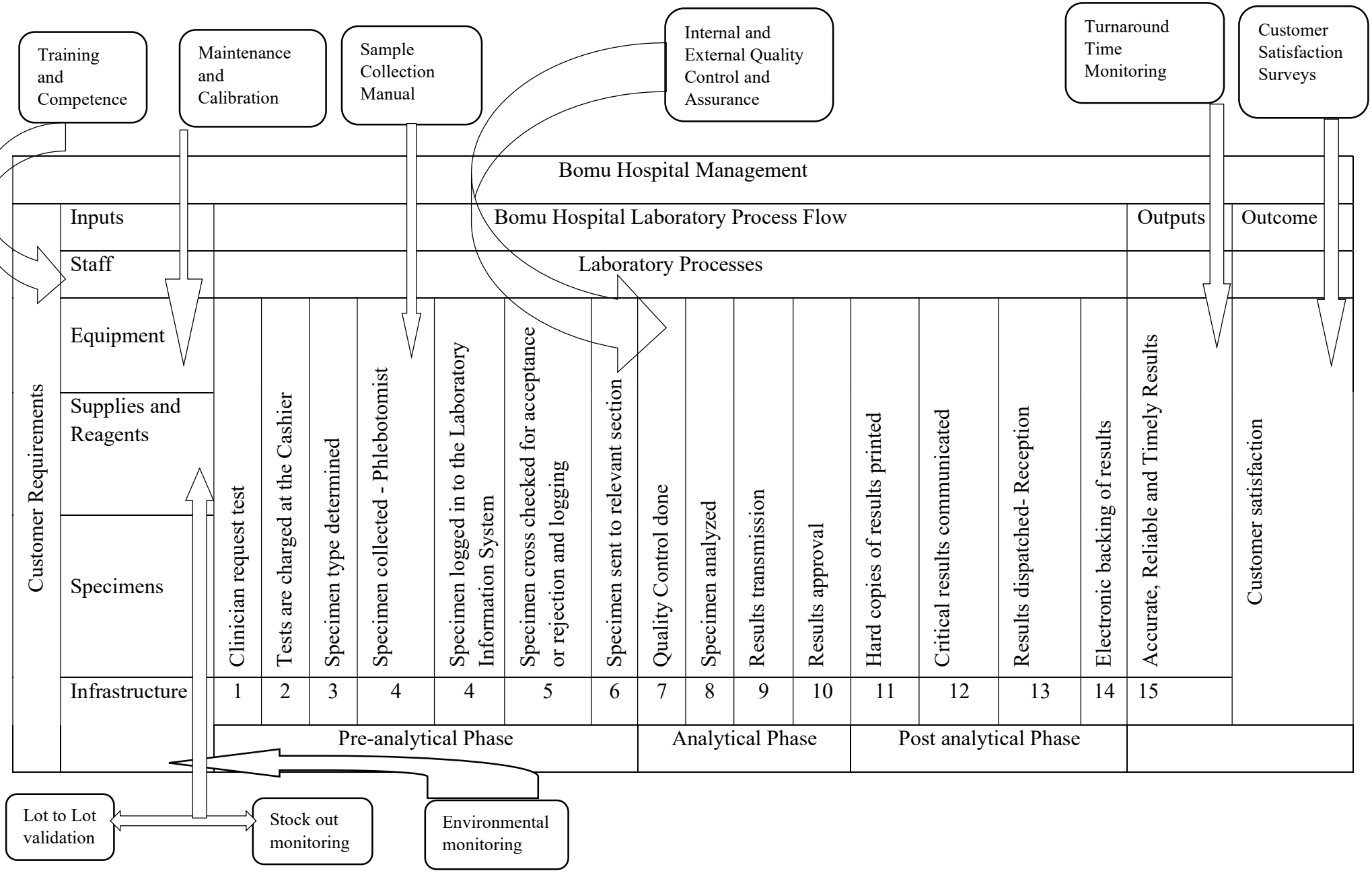
Internal auditing is fundamental to any quality improvement initiative where trained auditors carry out audits using a process-based approach to measure system and process performance. Staff were trained on internal audit skills using both ISO 19011 and ISO 15189 standards.

2.7 Building QMS

This process involved setting up a holistic system that outlined the requirement of the whole cycle. In addition, a documentation structure was developed that comprised of a three-level system of policies, procedures, and records. A quality system culture was instilled among all laboratory staff. The policies were built in the laboratory quality manual where each staff was involved. Procedures required to be developed by ISO 15189:2012 were documented as required by ISO 15189:2012. Technical procedures which guide the laboratory staff to do their specific tasks were also written. Furthermore, registers and forms were also developed.

Figure 2: Bomu Laboratory Process Flow, Bomu hospital

The table below shows the flow of all the laboratory processes at Bomu hospital laboratory. The processes are monitored with the various quality indictors as shown below.



A layout of the Bomu hospital laboratory process flow, inputs and outputs, the phases of examination as well as the quality indicators.

The following procedures were developed to address the policies in line with the requirements of ISO 15189:2012**.** Procedures show step by step what is supposed to be done.

1. Procedure for document control
2. Procedure for establishment and review of service agreements
3. Procedure for selection and evaluation of referral laboratories
4. Procedure for selection and purchasing of reagents.
5. Procedure for resolution of complaints
6. Procedure for identification and control of non-conformities
7. Procedure for corrective action and Preventive action
8. Procedure for control of records
9. Procedure for internal audit
10. Procedure for personnel management
11. Procedure for equipment management
12. Procedure for verification of examination methods
13. Procedure for verification of calibrated equipment
14. Procedure for estimating uncertainty of measurement.
15. Procedure for reporting and releasing results.
16. Procedure for reviewing internal control and external quality control results.
17. Procedure for sample management
18. Procedure for ensuring confidentiality of patient information, ethical code, and conduct.

2.8 Evaluation

An internal audit was conducted to check whether all activities in the quality management system, including pre-examination, examination and post examination conformed to the requirements of ISO 15189:2012 versus the requirements established by the laboratory. Two internal audits were conducted, the second done after closure of the nonconformities identified in the first internal audit. The internal audit also checked if the requirements of ISO 15189:2012 were implemented, effective and maintained. All laboratory staff ensured that appropriate action was promptly undertaken where nonconformities were identified. The internal audit was conducted by the same laboratory staff who had undergone an internal audit training as required by ISO 15189:2012 and ISO 19011.

2.9 Accreditation

The laboratory team discussed with the hospital management about its readiness to apply for KENAS accreditation. The laboratory then applied to KENAS for accreditation. All key documents which had been developed underwent a desk review before an onsite initial assessment. An application was sent to KENAS. All quality management system documents were sent for initial document review by the KENAS team.

The outcome of the initial document review was satisfactory hence an onsite assessment was conducted. KENAS conducted an internal peer review where the laboratory was given a formal communication about the accreditation decision. This followed the issuance of the accreditation certificate, accreditation marks as well as the accreditation program.

Table 1 Non-conformities identified during the initial KENAS assessment, and closure status at final assessment, Bomu hospital, April to August 2012,

Gap identified in initial audit	Root cause	Corrective action	Outcome on Final Audit
No records of reconstitution for control and calibrators	The laboratory did not have a tool to record in house prepared reagents	Revised the SOP to include in house reagent preparation then trained staff	Closed
No records of verification of biological reference ranges	Lack of suitable standard or guide for establishment of reference range	Revised the procedure on verification of methods to include verification of biological reference interval	Closed
No acceptability criteria for verified methods	No reference standard	Adopted CLIA guidelines to serve as reference levels	Closed
Trainings evaluation is not done for laboratory staff	Staff did not understand how to fill in the evaluation form	Trained staff on training policies as well as filling in forms. Regular reviews by the laboratory manager	Closed
Obsolete documents available at the point of use	File containing the obsolete documents had been stamped yet the original document not stamped	All documents in the obsolete file were stamped and dated	Closed
Results released yet there was a quality control failure	The procedure for quality control was inadequate	Trained staff on quality control including the Westgard rules and Levy Jennings charts	Closed
Referral laboratory was not evaluated	Lack of knowledge	Created a check list and a quality plan to evaluate referral laboratory	Closed
Staff not trained on ethics and confidentiality of patient information	The procedure lacked ethics and confidentiality aspects	Revised procedure to include ethics and confidentiality	Closed

Laboratory did not monitor the temperature for transported samples	The procedure did not capture the need to document temperature	Revised the procedure and trained staff to record temperatures for transported samples to ensure integrity	Closed
No reviews for effectiveness for previous nonconformities	Effectiveness of a non-conformity was not captured in the non-conformity form	Revised the non-conformity form to capture the effectiveness of the non-conformity	Closed
Failure of EQA in three consecutive cycles yet corrective action was implemented	Inadequate root cause	Troubleshooting guide for EQA failure	Closed
No bias in estimation of uncertainty of measurement	The SOP did not include bias when estimating uncertainty of measurement	Revised SOP to include bias as required by the accreditation body	Closed
Incoming laboratory reagents and consumables not inspected	Lack of communication between the laboratory and the central store	Trained the procurement staff on inspection and documentation of laboratory supplies	Closed

Table 2 above shows the nonconformities identified during the initial KENAS assessment. The root causes and the corrective action done.

2.10 Ethical Considerations

We used data from routine laboratory QMS operations. The study was reviewed in accordance with the U.S. Centers for Disease Control and Prevention (CDC) human research protection procedures and was determined to be non-research. No sample or patient information was used; therefore, no ethical review was required for this article.

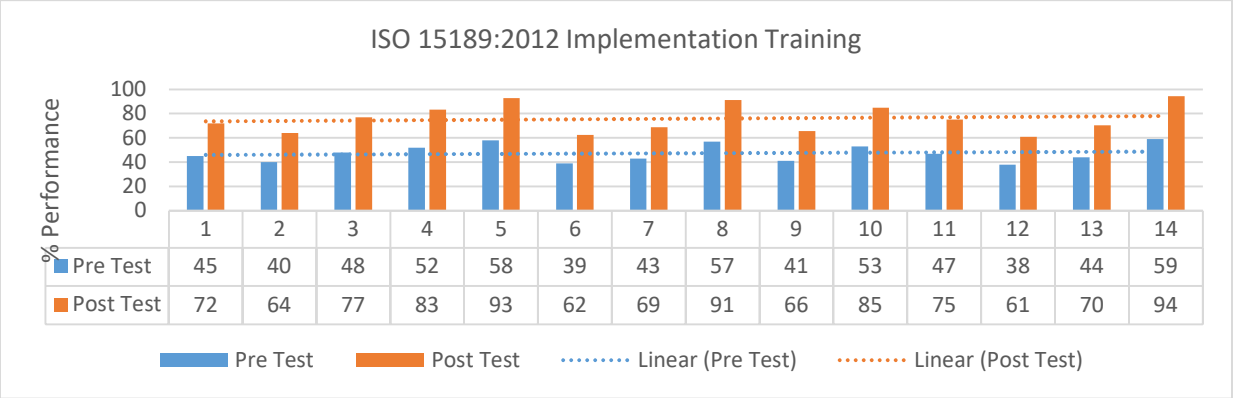
3.0 RESULTS

This section describes the results of the evaluation, highlighting results for ISO 15189 Implementation Training, Building Quality Management System, and description of nonconformity trends.

3.1 ISO 15189 Implementation Training

This training was intended to help staff understand to answer what the requirements of ISO 15189:2012.

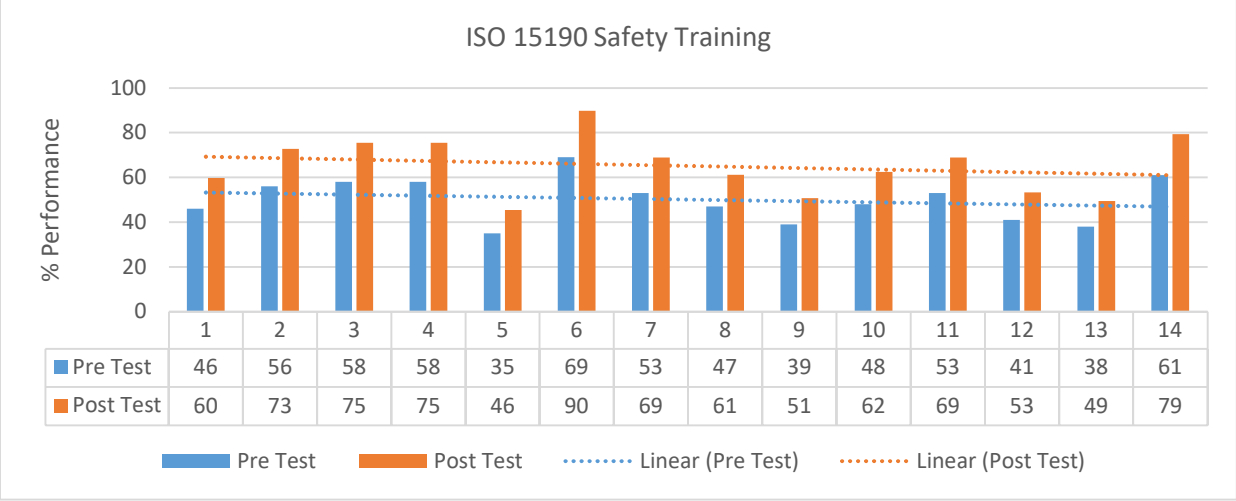
Figure 3: Pre and Post Test Results of the ISO 15189 Implementation Training, Bomu hospital, March 2012



	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Pre Test	45	40	48	52	58	39	43	57	41	53	47	38	44	59
Post Test	72	64	77	83	93	62	69	91	66	85	75	61	70	94

Figure 3 shows the Pre and Post Test results of the ISO 15189:2012 training for laboratory staff demonstrating the knowledge gained after the training. The staff demonstrated a better understanding of ISO 15189:2012 after the training.

Figure 4: Pre and Post Test results of the ISO 15190 Safety Training, Bomu hospital, March 2012



	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Pre Test	46	56	58	58	35	69	53	47	39	48	53	41	38	61
Post Test	60	73	75	75	46	90	69	61	51	62	69	53	49	79

Figure 4 shows the Pre and Post Test results of the ISO 15190 Safety training for Laboratory staff. There was an increased knowledge as well as understanding of all the safety requirements in the laboratory.

Figure 5: Validation/Verification Process Training, Bomu hospital, April 2012

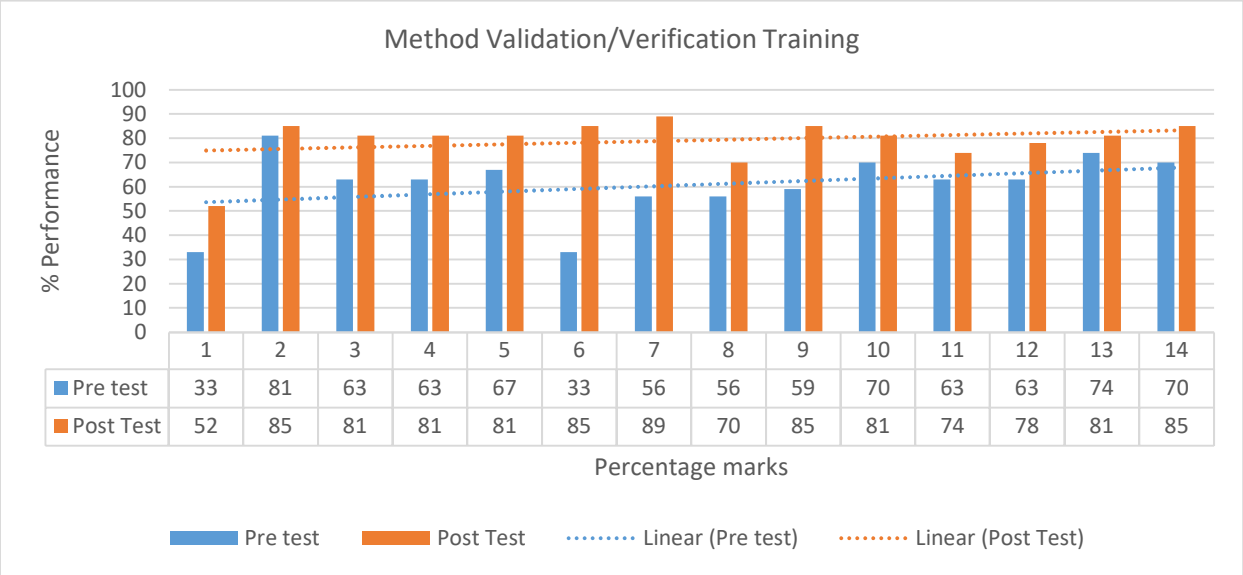


Figure 5 shows performance in both pre and post test results in the method validation/verification training. There was an increased knowledge as well as understanding of all the safety requirements in the laboratory.

Figure 6Internal Audit Training

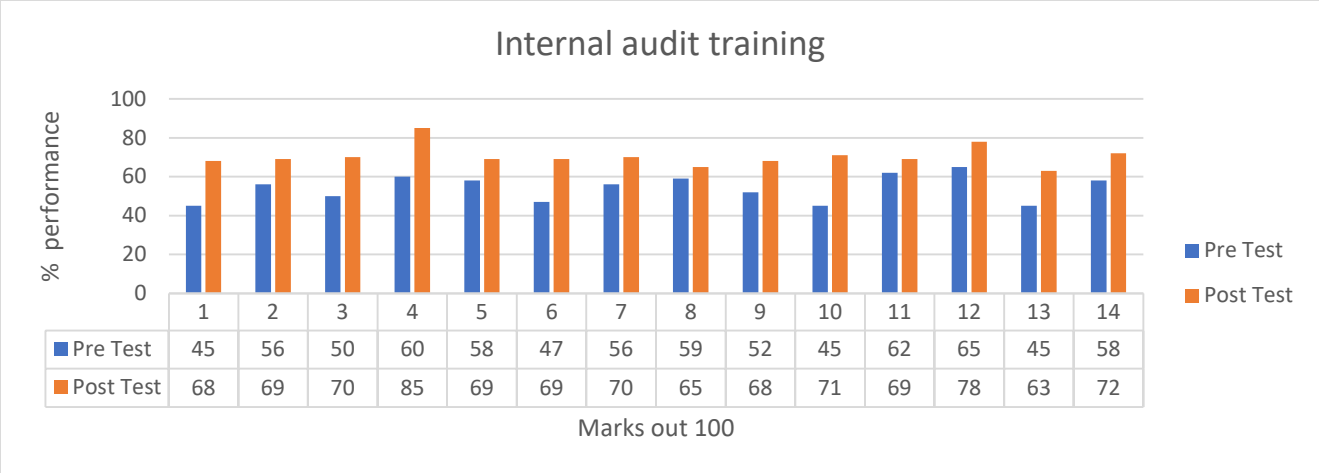


Figure 6 shows performance in both pre and post test results in the internal audit training. Internal auditing is a key component in the implementation and maintenance of ISO 15189. There was an increase in knowledge on internal audit after the training.

3.2 Building Quality Management System

Figure 7. Below shows the Quality Management System documentation.

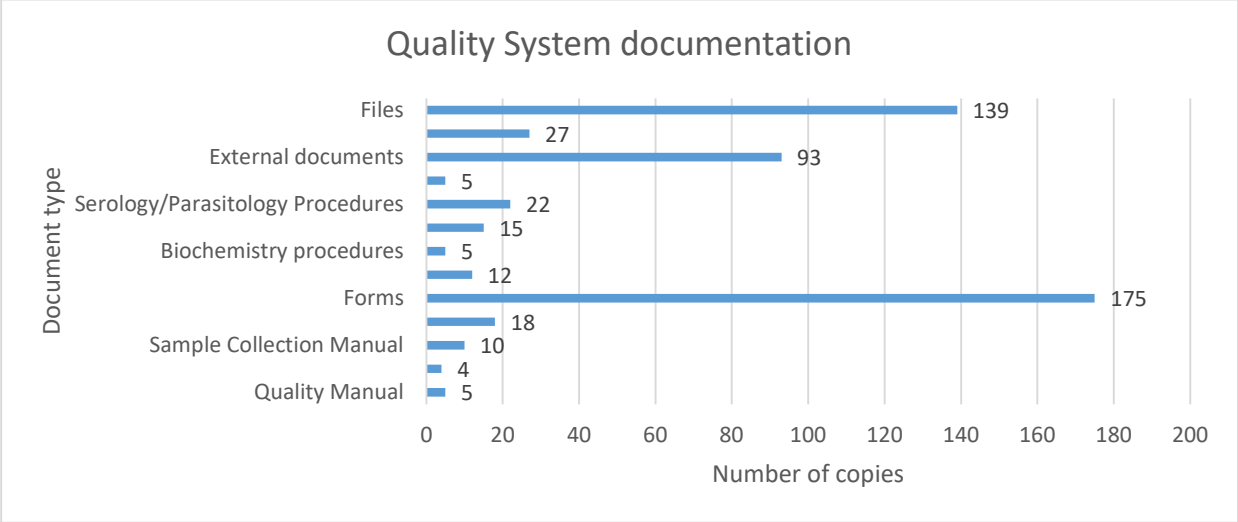
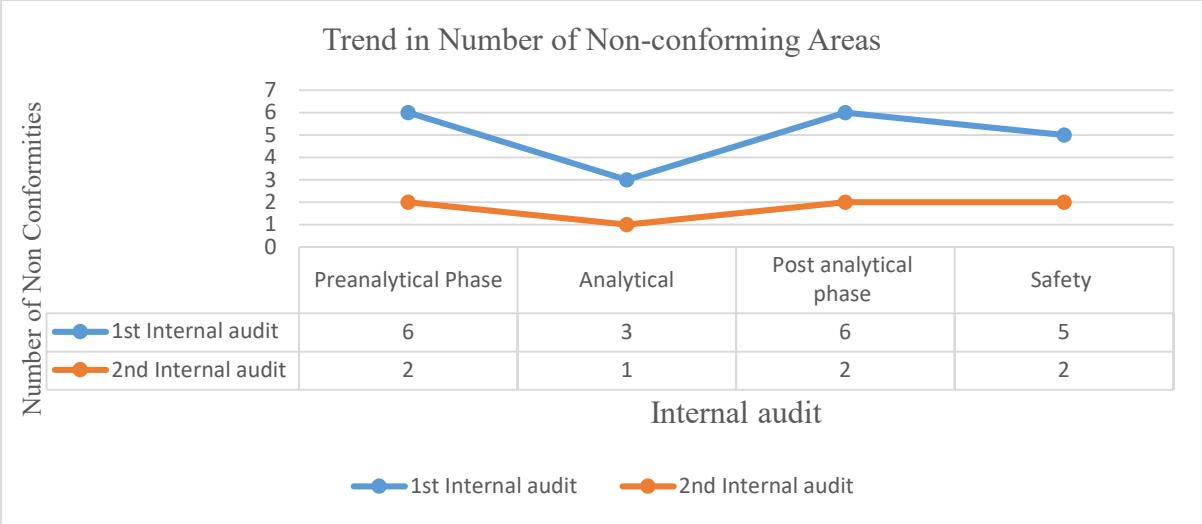


Figure 7 shows the number of documents developed and implemented in line with ISO 15189:2012

3.3 Evaluation – Trend in Number of Non-conforming Areas

Figure 8 below shows the trend in the number of nonconforming areas identified during the first and second internal audits.



There was a reduction in the number of non-conforming areas between the first and second internal audits (figure 8).

4.0 DISCUSSION

Bomu hospital laboratory implementation of ISO 15189:2012 based QMS was successful in preparing the laboratory for accreditation after 15 months of intense effort. A motivated team that had been trained on all aspects of ISO 15189:2012 plus strong management support was able put the laboratory to the standards of accreditation. The TBEA, a tailor-made approach used by Bomu hospital laboratory was useful in attaining laboratory accreditation. Training the laboratory staff in all the aspects of ISO 15189 was key in the implementation of the requirements of the standard.

Training of the various quality systems essentials under 15189:2012 was done by expert mentors from Clinical and Laboratory Standards Institute (CLSI) who used the CLSI documents to simplify the understanding of the standard. ISO 15189 does not specify how to address a particular requirement or clause. This approach was useful in the understanding of ISO 15189:2012.

Development of the key document as required by the standard was made easier following the better understanding of ISO 15189:2012 requirements. The Bomu laboratory quality manual was developed in line with its policy procedures. Technical procedures which guide the testing work were also developed. Registers, forms, and records that were used to show the work done were also developed. Each of the processed involved in the development of the procedures and forms was followed by a training. The process flow was useful in mapping the pre-examination, examination and post examination phases and thereafter develop the required documents.

To ensure that the laboratory was compliant with its process, two internal audits were done. ISO 15189 accredited laboratories must perform internal audits of their QMS regularly as part of the requirement. Bomu hospital laboratory performed two internal audits. It was essential to critically check the entire system. Increased frequency of audits may be required depending on the risk and occurrence management outcomes (Msemwa et al., 2022). Gap analysis was done and resulted in a corrective action. It was important to evaluate the entire quality system to check for compliance

of the requirements. The lessons learned from ISO 19011, guidelines for auditing managements system were useful in conducting an objective audit based on ISO 15189:2012 requirements.

Accreditation offers an overarching structure to laboratory operations which applies to all laboratory departments regardless of the services it provides. The attainment of accreditation gave the Bomu hospital laboratory the opportunity of giving reliable results to its customers. Furthermore, it gave the laboratory the opportunity to identify its own problems and come up with ways to continually improve the Quality Management System.

4.1 Dissemination plans

Bomu shared findings of this research with Bomu staff, County leadership and MOH teams, and stakeholders during a stakeholders meeting. Bomu plans to upload the report on the Bomu website and will prepare and submit the amanuscript to a journal/international conference.

4.2 Lessons Learnt

Accreditation require a better understanding of the ISO standards – ISO 15189:2012 and ISO 15190 as well as other national and regulatory requirements. This is made possible by an intensive training of all the laboratory staff working in the accredited laboratory as a strong support from the top management.

5.0 CONCLUSION

Training using the best tools that simplifies ISO 15189:2012 assists in better understanding in document development thereby assisting in building a strong quality management system. A team of highly motivated staff as well as that of well-trained internal auditors who can pick problems in the quality management system and continually improve the system would help the laboratory. A strong management commitment plus a stable financial assistance with budget allocation may achieve the desired results.

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APPENDICES

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