بسم الله الرحمن الرحيم

Sudan University of Science and Technology

College of Graduate Studies

Impact of Implementation of ISO/IEC 17025 In DNA Laboratory in Sudanese Forensic Laboratories

أثر تطبيق الأيزو 17025 على معمل البصمة الوراثية في المعامل الجنائية السودانية

A Dissertation Submitted to Sudan University of Science and Technology
in Partial Fulfillment of the Requirements for the Degree of Master in
Total Quality Management and Excellence

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December 2018

إستهلال

قال الله تعالى :

بسم الله الرحمن الرحيم

" الرحمن (1) علم القرآن (2) خلق الإنسان (3) علمه البيان (4) "

سورة الرحمن

" اقرأ باسم ربك الذي خلق (1) خلق الإنسان من علق (2) اقرأ وربك الأكرم (3) الذي علم بالقلم (4) علم الإنسان ما لم يعلم (5) "

سورة العلق

صدق الله العظيم

Dedications

To my mother...

To my wife...

To my lovely daughter...

I dedicate this work

ACKNOWLEDGEMENT

- First of all, I would like to express my deepest and warmly thank to my Supervisor Professor. Amel Omer Bakhiet for her generous guidance and patience during the period of my thesis writing. Her inspiring advices are extremely essential and valuable for me to finish my thesis.

- I would also like to show my sincere gratitude to all members in Sudanese Forensic Laboratories for their great help and support.

- Special thanks to my lovely Family, friends, my colleagues who helped me so much to finalize the questionnaires, giving good suggestions and advices for my thesis.

ABSTRACT

Standard ISO/IEC 17025 has been applied in many Laboratories worldwide for the past years. This descriptive study was carried out in the DNA laboratory at Sudanese Forensic Evidence Department - General Directorate of Criminal Evidence, during the period from June 2018 to November 2018. The objectives of the present study were to evaluate implementation of a quality management system in compliance with the requirements of ISO/IEC 17025:2005 at DNA Department in Sudanese Forensic (SFED) involving the identification and assessment of the various aspects to be considered for the implementation of a QMS based on the ISO/IEC 17025:2005 standard and to enumerate the practical benefits derived from laboratory accreditation. The methodology of the study based on statistical survey using questionnaire that was developed and distributed to the employees working in DNA laboratory and then was collected and analyzed using SPSS program. Frequencies and percentages were calculated. The main results of the study are 45%of workers has working experience up to 10 years and 20% has more than 5 and less than 10 years and 35% has more than 1 and less than 5 years,12.5% of workers has diploma and 50% has bachelor degree and 37.5% has post graduate degree, 17.5% of workers are unaware to ISO/IEC 17025 and 50% are aware and 32.5% are strongly aware to ISO/IEC 17025, 55.6% of workers are agreed that there is a defect in staff competency and 24.4% are disagreed with it and 20% are neutral, 45% of workers are in agreement with the service provided by DNA laboratory is poor with low quality and 30% are disagreed with it and 25% are neutral, 51.9% of workers are agreed that there is no clear management system with known responsibility and 21.3% are disagreed with it and 26.8% are neutral, 60% of workers are

in agreement with the working environment is suitable and helps in correct testing results and 17.5% are disagreed with it and 22.5% are neutral, 46.9% of workers are agreed that the top management is not committed to improving the management system and 23.8% are disagreed with it and 29.3% are neutral. The study concluded that the service provided by DNA laboratory is partially good and with high quality and the top management is committed for improving the management system and the working environment is suitable for work, but the training method need some improvement process with no clear management system inside DNA department.

المستخلص

خلال السنوات الماضية قامت العديد من المختبرات بمختلف البلدان بتطبيق نظام إدارة الجودة ISO/IEC 17025 لتحسين و تطوير الخدمات المقدمة بواسطتها.أُجريت هذه الدراسة في مختبر البصمة الوراثية (DNA) بالمختبرات الجنائية السودانية في الفترة من يونيو 2018م و حتى نوفمبر 2018م. هدفت الدراسة إلى تقييم تطبيق نظام الجودة ISO/IEC 17025 في معمل البصمة الوراثية و ذلك بتحديد و تقييم مختلف الجوانب الهامة في تطبيق نظام الجودة ISO/IEC 17025و أيضاً تحديد الفوائد العملية من إعتماد المختبر. إعتمدت منهجية الدراسة على المسح الإحصائي بإستخدام الإستبيان حيث تم إعداد الإستبيان وتوزيعه على العاملين بمعمل البصمة الوراثية و من ثم جمعه و تحليله بإستخدام البرنامج الإحصائي الحاسوبي (SPSS). من أهم النتائج التي توصلت لها الدراسة أن 45% من العاملين بمعمل البصمة الوراثية لديهم خبرة أكثر من 10 سنوات و20% خبرتهم أكثر من 5 وأقل من 10 سنوات و 35% خبرتهم أكثر من سنة و أقل 5 سنوات. 12,5% من العاملين حاصلين درجة دبلوم جامعي و 50% حاصلون على درجة البكلاريوس و 37,5% لديهم دراسات عليا. 17,5% من العاملين لا يعرفون ما هي المواصفة ISO/IEC 17025 و 50% مدركون لأهميتها و 32,5% مدركون بشدة لهذة المواصفة. 55,6% من العاملين يشيرون إلى أن هنالك نقص في كفاءة العاملين و 24,4% يختلفون معهم في الرأي و 20% محايدين. 45% من العاملين يشيرون إلى أن الخدمة المقدمة بواسطة معمل البصمة الوراثية غير جيدة و ذات جودة منخفضة و 30% يختلفون معهم في الرأي و 25% محايدين. 51,9% من العاملين يوافقون على أنه ليس هنالك نظام إدارة واضح بالمعمل و 21,3% يخالفونهم في الرأي و 26,8% محايدون.60 % من العاملين يتفقون على أن بيئة العمل مناسبة في المعمل و 17,5% مخالفون لهم في الرأي و 22,5% محايدين. 46,9% من العاملين يشيرون إلى أن الإدارة العليا غير ملتزمة بتحسين نظام إدارة الجودة و 23,8% يتختلفون معهم في الرأي و 29,3% محايدين.خلُصت الدراسة إلى أن الخدمة المقدمة بواسطة معمل البصمة الوراثية جيدة جزئياً و أن الإدارة العليا بالمعمل ملتزمة بتحسين نظام الجودة و بيئة العمل جيدة, و لكن نظام التدريب يحتاج لبعض التحسين مع عدم وجود نظام إدارة واضح.

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CHAPTER ONE

INTRODUCTION

Introduction:

Nowadays, a wide range of socio-economic activities depends on measurements. Food safety, health and environmental protection are dependent on chemical analyses. As we rely heavily on them, our confidence in chemical measurements can only be boosted by their accuracy. Laboratory accreditation, achieved through the implementation of the ISO/IEC 17025:2005 standard is the process which determines the competence of laboratories in delivering accurate results. On the global scale, with the economic crisis, manufacturers and suppliers need to reduce their operating costs. Using accurate and reliable data, emanating from internationally recognized accredited laboratories, eliminates the need for retesting, thus, reducing costs and minimizing technical barriers to trade.

Growth in the use of quality management standard generally has increased the need to ensure that laboratories can operate to a quality management system that is seen as compliant with ISO 9001 as well as demonstrating technical competency. Therefore, ISO 17025 was written to incorporate all the ISO 9001 requirements that are relevant to the scope of testing and calibration services as well as specifying the technical requirements for technical competence. Testing and calibration laboratories that comply with ISO 17025 will also operate in accordance with ISO 9001 (Michalska & Szewieczek, 2007).

For laboratories, understanding measurement uncertainty is key. Laboratories carry out testing, calibration or both. Testing relies upon a measurement system using calibrated equipment to determine characteristics in relation to a target. Measurement uncertainty is quantified as the observed process variance attributed to the measuring system. The measuring system is the combined effort of controls, resources, information and material used to assign values to measured characteristics. A measuring system is part of an organizations overall management system, and for laboratories, the measuring system is often the most significant part of that system. Laboratories develop, implement and continually improve their process-based management systems to ensure they understand, quantify, control and continually improve the quality delivered by their measuring processes. ISO/IEC 17025 has been developed and agreed as the international laboratory management system standard. This standard recognizes the importance of how competent individuals contribute to controlling measurement uncertainty through their interaction with measuring equipment. ISO/IEC 17025 provides a framework of good management practices for laboratories performing testing and calibration, but conforming to the standard does not guarantee operational excellence. The best laboratories in the world not only seek accreditation to ISO/IEC 17025, they also develop their process-based management systems to ensure continual process improvement. One of the factors deciding about the competitive advantage of the research laboratories on the market is the quality of the delivered services, which influences directly on the success of these organizations (Karkoszka & Szewieczek, 2007).

Qualitative demands, sharply rising competition as well as the increase of the expectations concerning the technical competences make the

laboratories search the different solutions in the range of the improvement of management, they contribute significantly to seek for the new ways of confirming the abilities in the range of provided services, as well (Krupinska *et al*, 2007).

ISO/IEC 17025 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification. When a laboratory does not undertake one or more of the activities covered by ISO/IEC 17025, such as sampling and the design/development of new methods, the requirements of those clauses do not apply. It is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. ISO/IEC 17025 is not intended to be used as the basis for certification of laboratories (Huong *et al*, 2011).

Justification:

According to the efforts of the SFED to develop the quality system especially in the Forensic Laboratories Bureau to meet the international standardization, the quality administration was established recently on 2014 to deal with the quality affairs, this lead the researcher to focus in the guideline to apply the best international standards worldwide in forensic

DNA analysis hoping to be a member in international accreditation body and gaining ISO/IEC 17025 as the best reference in Standardization

General Objective:

The aims of the project to evaluate the implementation of a quality management system in compliance with the requirements of ISO/IEC 17025:2005 at DNA department in SFED involving the identification and assessment of the various aspects to be considered for the implementation of a QMS based on the ISO/IEC 17025:2005 standard and to enumerate the practical benefits derived from laboratory accreditation.

Specific objectives:

1. Evaluation of the existing quality system in DNA department in SFED through questionnaire.
2. Interpretation of the benefits of accreditation and assessing the feasibility of the accreditation process.
3. Develop an implementation guideline for the DNA department in SFED laboratory.

CHAPTR TWO

LITTERATURE REVIEW

2.1 History and definition of Quality:

Since the topic of my research is mainly concerned with the concept of quality and its applications worldwide essentially in different work organization sectors and types, the author finds it necessary to briefly write down what has been said about quality by practitioner and researchers before introducing the ISO 9001 quality standard system. Quality is considered to be a competitive weapon in the marketplace. Quality engenders competitive advantage by proving products that meet or exceed customer needs and expectations (Lee & Zhou, 2000). Quality is defined using different perspectives as it is still a subjective goal that has indefinable characteristics (Kazan *et al*, 2006). An early definition for quality is presented by (Juran *et al.*, 1979) who defines quality as "fitness for use". This definition originates mainly from customer's perspective in defining quality. It is the customer who determines whether the received products or services satisfy his or her needs. (Reeves & Bednar, 1994) similarly agrees with this definition and define quality as excellence, value, conformance to specifications, and meeting or exceeding customers' expectation. The term "fitness for use" defined by (Juran *et al*, 1979) is also included in the quality definition presented by (Reeves & Bednar, 1994). Thus, the customer perspective with respect to quality is the master key that should be understood while determining any term for quality or definition of quality. (Garvin, 1987) sees quality as a multidimensional construct. He describes quality as having eight dimensions which include:

performance, features, reliability, conformance, durability, serviceability, aesthetics, and perceived quality. These dimensions originally match with the definition of quality as seen by the customer.

If the above arguments about the various definitions of quality are considered, it can be concluded that quality provides competitive advantage for an organization through satisfying the customer needs. (Prajogo, 2007) considers quality as a strategic performance which is a reflection of a competitive strategy of the firms. He agrees with the notion that the quality definition has been gradually developed from an operational level to a strategic level. This concludes that a work organization should strongly consider quality as its strategic objective when fulfilling customer requirements. Therefore, quality should help work organizations enhance their competitiveness and lead to or even improve customer loyalty through meeting customers' requirements and expectations. (Collis & Montgomery, 1997) suggested that the implementation of practices (i.e., quality) such as ISO 9000 can raise organizational performance and result in real competitive advantage. This makes the organization to view quality as a very competitive weapon that should be adopted and implemented as a competitive strategy for playing a major role in creating, sustaining, and maintaining the competitive advantage of a given work organization.

2.2 The Role of implementing ISO/IEC 17025 in Testing Laboratories:

Implementing ISO/IEC 17025 has benefits for laboratories, but the work and costs involved should be considered before proceeding.

Implementing ISO/IEC 17025 as part of laboratory quality initiatives provides both laboratory and business benefits such as:

- Having access to more contracts for testing and/or calibration. Some public and private organizations only give contracts to accredited laboratories. Accreditation will also help to get more contracts from organizations that don't mandate accreditation, but do give preference to accredited laboratories in competitive situations.
- Improved national and global reputation and image of the laboratory.
- Continually improving data quality and laboratory effectiveness.
- Having a basis for most other quality systems related to laboratories, such as Good Manufacturing Practices and Good Laboratory Practices.
- Analytical testing laboratories seeking ISO/IEC 17025 will be impacted in multiple areas. The main difference between good analytical practices and formal accreditation is the amount of documentation to be developed. There is no doubt that any good analytical laboratory uses qualified analysts, checks the performance of equipment used for testing, and validates analytical methods. However, many times the outcome of the tests is not fully documented. ISO/IEC 17025 accreditation requires formal documented environment – 'what is not documented is a rumor,' and is viewed by assessors as 'not being done (Huong *et al.*, 2011).

2.3 History and status of ISO 17025:2005:

Prior to the issuing of ISO 17025:1999 there was no internationally accepted standard for laboratory quality systems that could provide a globally accepted basis for accreditation.

Accreditation was based on national standards. However, there was considerable level of uniformity between the requirements expressed in these various standards due to the existence of ISO Guide 25, a document drawn up by the ISO Council Committee on Conformity Assessment (CASCO) in response to a request by the International Laboratory Accreditation Cooperation (ILAC) held in Auckland, New Zealand, in October 1988. The declared purpose of ISO Guide 25, taken from its foreword, is to establish the Principle that third party certification systems for laboratories should, to the extent possible, be based on internationally agreed standards and procedures. ISO guides are intended to be used by local standards institutions when preparing their own national standards. By this means, it is hoped to achieve a high degree of compatibility between standards prepared in different countries. The document now known as ISO 17025 began life as a revision of the third edition of ISO Guide 25, but during the revision process it was decided to convert the guide to a standard, so providing a truly global basis for accreditation. It was also decided to introduce as much compatibility as possible between ISO 17025 and the generic quality management system standard ISO 9001, which was also under revision at the same time. The objective appears to have been to create a logical connection between ISO 9001 and ISO 17025 such that the former would be seen as a master standard with ISO 17025being a specific application of that standard to testing and calibration laboratories. ISO 17025: 1999 was accepted by ISO subscribing countries

in late 1999 and came into effective use during the first quarter of 2000 after its adoption as a national standard by most countries around the world. The new version of ISO 9001, the 2000 edition, was accepted at a later date. The exercise intended to harmonies ISO 17025 and ISO 9001 was, in the event, regarded as imperfect, especially in that ISO 9001 placed great emphasis on continual improvement in the quality system. Although this was included in ISO 17025, its importance as a part of the standard was not strongly emphasized. Hence a revision of ISO 17025 was undertaken and this led to ISO 17025:2005 which was adopted as an ISO standard in late May of 2005 (Complying with ISO 17025, 2009).

There are no fundamental differences between ISO 17025:1999 and ISO 17025:2005 and nothing which impinges essentially on the technical requirements. The main differences .can be summed up as follows:

1. Insistence on a demonstrated commitment to continually improve the quality management system and identified mechanisms for achieving this.
2. Greater emphasis of the need to communicate with customers and, especially, to actively solicit feedback on service quality and ensure the resulting information is used as the basis of action to improve the management system.
3. Greater emphasis of the need to use information from quality control data to evaluate the performance of the quality system and to identify opportunities for Improvement.

The transitional period between ISO 17025:1999 and ISO 17025:2005 lasted two years, with the two standards running together. In May 2007 ISO 17025:1999 became defunct and existing laboratories that had not

been assessed against the 2005 version ceased to be accredited (Complying with ISO 17025, 2009).

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories sets out the criteria for laboratories wishing to demonstrate that they are technically competent, operate an effective quality system, and are able to generate technically valid calibration and test results.

The standard will form the basis for the accreditation of competence of Laboratories by accreditation bodies (L-A-B, 1999).

A transition period has been established during which laboratories currently operating to the preceding standards ISO/IEC 17025:1999 change to operating to the requirements of ISO/IEC 17025:2005. Similarly, accreditation bodies may need to adapt existing assessment and accreditation practices in order to minimize the period during which accreditation to different standards may exist.

The International Laboratory Accreditation Cooperation (ILAC) has confirmed that there will be a transition period of two years for full implementation of ISO/IEC 17025:2005. Accreditation bodies shall require that the laboratories for which they grant and maintain accreditation comply with the requirements of the

Standard within not more than two years from the date of publication of the standard, this was May 15, 2005. Accreditation bodies shall confirm that the laboratories comply with the standard at the next surveillance activity following this period (L-A-B, 1999)

2.4 The key factors of implementing ISO/IEC 17025:

2.4.1 Leadership:

This is an important factor in establishing the quality management system in accordance with the requirements of ISO / IEC 17025. If leaders of the laboratories do not see benefits from the application of quality management system standard ISO/ IEC 17025, the management will not create conditions for investment and operation and evaluation Quality laboratory. Thanks to the assessment and recognition of the quality of the laboratory has established a routine scientific work, discipline, unity and synchronization. All activities of the Laboratories are documented in the Quality Management System, is headed for approval and reviewed annually. Management standards also help the management to reduce laboratory time incident handling work assignments clearly and specifically through the job description (Huong *et al*, 2011).

When leaders are aware of the need to develop and apply quality management system and improving the technical capacity to meet the requirements of ISO/ IEC 17025, the management will conduct the review meeting of leaders to control review the annual quality objectives and quality policy has been built to suit the realities and requirements of standards and accreditation reviews. When the laboratory leaders realize the importance and benefits of the assessment and recognition, leadership laboratories will facilitate maximum of resources to help laboratories improve operational efficiency testing. The selection of personnel required to have expertise related to the calibration test, testers were trained to understand the ISO/IEC17025 well as how to do internal audits to find the suitability of required standards of testing and calibration, training and

knowledge of evaluation of uncertainty of measurement, operation of equipment and perform tests. For external resources (Outsource) when using the organization itself must be held Outsource also conducted capacity assessment. Besides the management structure, organization also needs to appoint positions such as management and technical management, quality management and the deputy to take charge when needed replacing (Huong *et al,* 2011).

2.4.2 Staff's participation:

All personnel who have a direct effect on the validity of the test results should demonstrate their competence to perform specific tasks. Personnel records for education, training, technical knowledge and experience should indicate that the person is competent, as defined in their job descriptions. The laboratory should evaluate the competence of all personnel and ensure that training is kept up-to date. Personnel are also required to contribute to meet the quality policy statement and the quality objectives of the management system.

The important factor of the management systems integration success is the commitment of all workers in the organization. The present enterprises couldn't function without knowledge by the workers of the management system principles and requirements of individual norms.

The necessary condition is the individual and group ability of the workers to finding the ways of achieving improvement and progress in the organization activity. The quality of the integrated management system concerns to article, information, service, process, knowledge, management, life, but it has to take into account the indispensability of changes and courage to theirs implementation (Paliska *et al.*, 2007).

2.4.3 Technology support:

Information used in the unit including documents, catalog, database software or device driver software, user manual in the work of testing and calibration. The exchange of information internal/external should be built into the specific provisions for the security, storage monitoring data base (e.g. baseline comparison, data recorded during testing calibration), the test results and calibration to avoid loss or change data in the process of doing or transferred to other goods. The construction of goals and plans of the organization of work activities related to testing and calibration needed done so as to ensure consistency as well as convey to all content test members.

Equipment must conform to the purposes and methods of testing, calibration methods, appropriate sensitivity to achieve detection limits and make the appropriate re-iteration of results. Equipment must be well maintained and efficient to each stage to always have proof of their stability. Employees understand what equipment or measuring something. The substitution of reagents or errors in the operation process of implementation methods can affect the final result.

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Several other issues also need to consider attention to the device:

- The installation of equipment and methods to control them during use.

- The control and driver software for the device.

- The work environment of the device.

- Shipping and portable equipment maintenance.

- Calibration, calibration and check between two calibrations.

- The use of overload.

- Control parameters were set and edit them.

- Control and user training.

- Develop and apply the correction factor if necessary.

- Request achieved after repair of equipment failures.

Major obstacles encountered, during implementation and maintenance of implementation, by the laboratories was: lack of suppliers of calibrated equipment, non-existence of accredited metrology laboratories for calibration of equipment, and unavailability of proficiency testing providers. Moreover, despite more responsibilities, employees claimed that implementation did not benefit them financially. In addition, the majority agreed that there was a lack of communication from management. But yet they were satisfied to work in an accredited laboratory and has improved the level of employees satisfaction. The most pressing ones being that calibration laboratories should be implementation to ISO/IEC 17025 at the

earliest as well as driven campaigns by Government to boost national awareness on the economic and social benefits of accreditation (Huong *et al.*, 2011).

2.4.4 Process control and Improvement:

Quality control is of paramount importance in laboratory accreditation. It gives confidence in the work performed by the laboratory. The validity of results should be rigorously monitored through quality control checks, which may be internal or external. Internal quality control usually is done using statistical techniques to detect trend in the results. External quality control is done either through proficiency testing program or inter-laboratory comparison to compare results obtained by the laboratory. According to ILAC-P9 (2005), proficiency testing and inter-laboratory comparison are defined as:

- Proficiency testing is the determination of the calibration or testing performance of a laboratory or the testing performance of an inspection body by means of inter-laboratory comparison.

- Inter-laboratory comparison is the organization, performance and evaluation of calibrations/tests on the same or similar calibrations/tests items by two or more laboratories in accordance with predetermined conditions.

The modern organization directed to the quality is one which is able to create the knowledge. According to Japanese approach creating the knowledge is not only "processing" of objective information, it is also creating the new knowledge being based on reaching to latent and often of very subjective observations of employees, their intuitive beliefs and

premonitions and making these reflections available to the entire company so that it is possible to verify them and to use. A man is always the source of the new knowledge (Dudek-Burlikowska, 2006).

2.4.5 Service quality:

According to the requirement concerning the client's service, laboratory should owe internal procedures guaranteeing proper cooperation not only in the aspect of fulfilling their requirements but also - in the aspect of capability to monitor the research commissioned to the laboratory. Laboratory is also obliged to estimate the clients' satisfaction; any positive as well as negative information from the clients should be analyzed by laboratory to prevent repeating the same incompatibilities in the future and - what is the most important - to improve the system and services offered by the laboratory.

You face a special challenge: Meet customer needs while remaining economically competitive. Automated processes can make an impact, but services are still labor-intensive. There can be no substitute for high-quality personal interaction between service employees and customers (Huong *et al.*, 2011).

2.4.6 Performance:

Laboratory implementation QMS ensures that laboratories perform their work correctly and to appropriate standards. It provides them with a benchmark for maintaining that competence. In addition to commercial testing and calibration services, manufacturing organizations may use laboratory accreditation to ensure the testing of their products by their own in-house laboratories is being done correctly.

Testing of products and materials can be expensive and time consuming, even when they are done correctly the first time. If not done correctly, then the cost and time involved in re-testing can be even higher if the product has failed to meet specifications or expectations. Not only costs go up, but reputation as a supplier or manufacturer can go down. Thus, a product tested in a particular country by an accredited laboratory minimizes the chances of retesting and reducing chances of additional financial burden and time delays.

Performance is focused behavior or purposeful work. That is, jobs exist to achieve specific and defined results (outputs) and people are employed so that organizations can achieve those results. This is performed by accomplishing tasks.

Managing performance has the dual purpose, the first is arranging situations (environment) so that employees can do their best, and the second is growing the employees by educating, enlightening, and appreciating them. Its purpose is to achieve specific and defined results from people so that the organization can achieve its goals and objectives.

It is much easier to fix situations by making structural changes to the organization, rather than trying to fix or change people. These include such means as changing reporting relationships, enlarging the job, improving a process, or opening lines of communication.

Once performance barriers have been removed, employees can be educated, enlightened, and appreciated. This assumption is based on the premise that most employees try to do their best. They prefer harmony over conflict, action over inaction, and productivity over delays. We often refuse to believe this as most studies on human behavior are performed on

people when they are not at their best, such as in school, clinics, or prison. Thus, most studies on human behavior are performed in the process of trying to reform people (Huong *et al*, 2011).

2.5 The Accreditation Process:

(Abdulraheem & Bakheit, 2017) summarize the testing laboratory, accreditation is the formal recognition that the laboratory possesses the necessary competence to carry out specific tests As it is delivered by an independent, national or international body by using data from an accredited laboratory are as follows:

1. Increase in public confidence.
2. Assurance that quality data is being used to establish baselines for key analyses and decisions.
3. Reduced uncertainties associated with decisions that affect the protection of human health and the environment.
4. Improved efficiency of assessment process.

Accreditation of laboratories plays an essential role on the international stage as it minimizes barriers to trade. With accreditation, test results produced in one country is accepted in another country. The data generated by accredited laboratories is more readily acceptable on the overseas market. By reducing or eliminating the need for retesting in the importing country, manufacturers and exporters can reduce costs (ILAC, 2001). In order to obtain accreditation, a laboratory must be assessed by a third party independent body. The assessing body must itself conform to ISO/IEC 17011:2004, which specifies the general requirements for accreditation bodies accrediting conformity assessment bodies.

Accreditation can be assessed by either national bodies or international ones. On an international level ILAC is the organization responsible for assessing National Accreditation bodies and MAURITAS is an associate member of ILAC. Moreover, if a laboratory wants to receive an accreditation which is recognized internationally, it can apply to any National Accreditation body which has been accepted as a signatory to the ILAC Mutual Recognition Arrangement (ILAC MRA) such as:

1. Singapore Accreditation Council (SAC)
2. South African National Accreditation System (SANAS)
3. United Kingdom Accreditation Service (UKAS)

For a laboratory, operating a QMS based on ISO/IEC 17025:2005, wishing to achieve an accredited status, the first step is to contact the accreditation body. In the local context, the laboratory should apply to MAURITAS. The laboratory will send its manual for review. If the manual does not require any modification, MAURITAS will contact the laboratory in order to conduct an on-site assessment. Qualified assessors will assess the QMS and operations of the applicant body. Technical assessment will involve spending time with the staff to check their technical knowledge, observe calibrations, and check whether test procedures are respected.

The final product of the assessment is a detailed report highlighting nonconformities.

The appropriate corrective actions need to be implemented before accreditation is delivered. It is to be pointed out that the accreditation granted is for specific tests and that the MAURITAS Accreditation Logo can only be used for test reports containing test results of the methods included in the Accreditation Scope (Abdulraheem & Bakheit, 2017).

2.6 ISO/IEC 17025:2005 in a Testing Laboratory:

Figure (2.1) denotes the general requirements which a laboratory has to abide by to demonstrate, its competence in the fields of testing and calibration (ISO/IEC 17025, 2005).

2.7 Relationship between ISO 17025 and ISO 9001:

ISO 9001 is the general standard which specifies the requirements for a quality management system (QMS). ISO 17025, as opposed to ISO 9001, include participation in proficiency testing, adherence to documented, validated, methodology and specification of technical competence, especially on the part of senior laboratory personnel. There is also a difference in the method of scrutiny of laboratories under ISO 9001 as compared to ISO 17025 assessments. ISO 9001 is the overall standard for quality management systems and ISO 17025 provides specific guidance on the application of the ISO 9001 principles to laboratories. This correspondence is becoming increasingly apparent with the development of both standards, especially as the language and terminology is converging (Complying with ISO 17025, 2009).

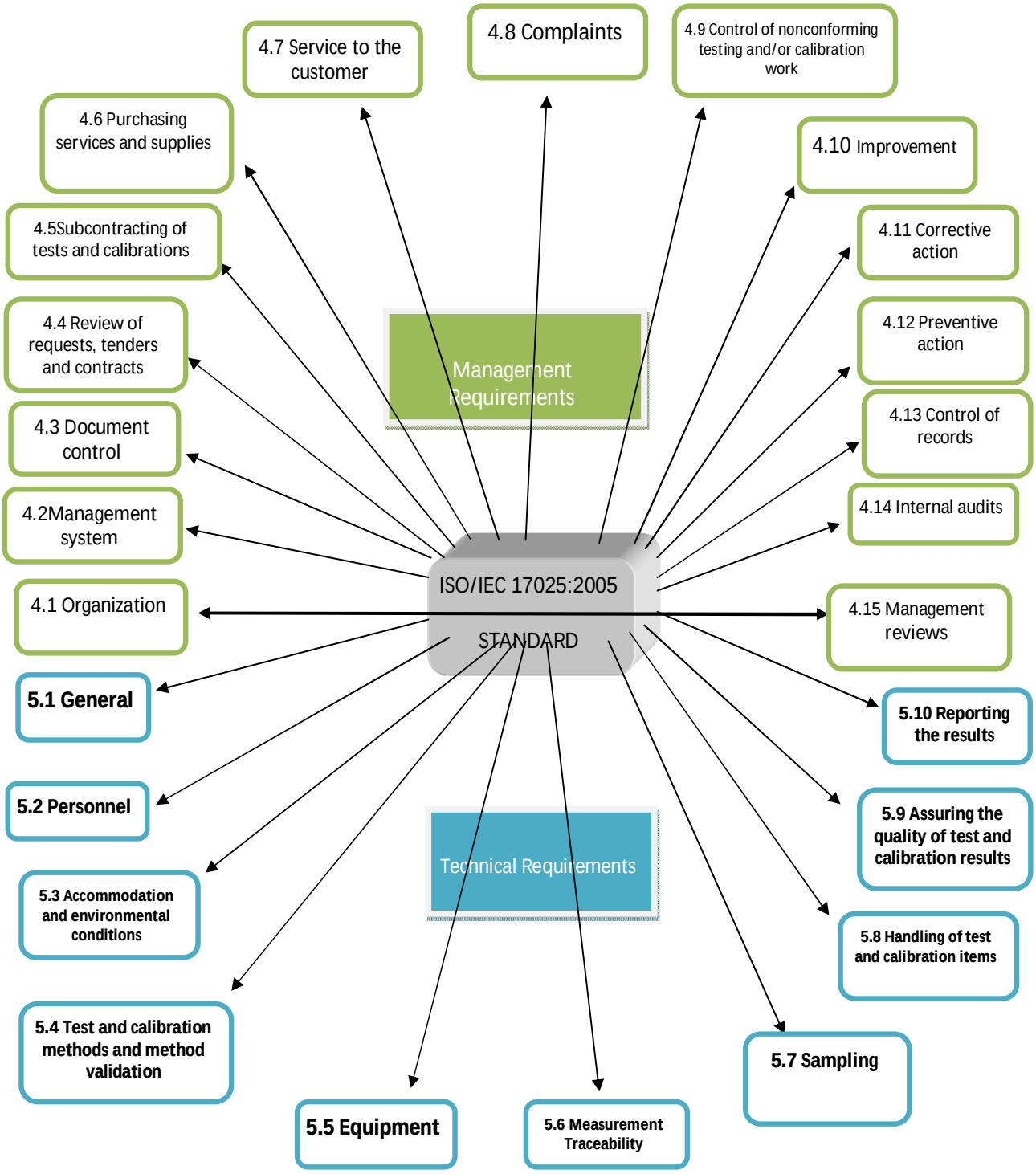

Figure (2.1): Management and Technical Requirements of ISO/IEC 17025:2005

Source: (Khodabocus & Balgobin, 2011)

2.8 The Sudanese Forensic Evidence Directorate (SFED):

SFED founded under the name of the unit of technical assistance in 1967 and was to head directly to the Police Head Quarter, then became administration of technical forensic evidence belonging to the criminal investigation. Change its name in the mid-nineties to the administration of forensic evidence, then later became the Forensic Evidence Bureau under the General Directorate of criminal investigations (Hamid & Yousif, 2017).

In date 25/08/2010 SFED upgraded to a General administration specialist to head directly to the Police Head Quarter and became consist of four specialized Bureau:

1. Forensic laboratories Bureau.
2. Crime Scene Bureau.
3. Fingerprint Bureau.
4. Police Dogs Bureau.

2.8.1 Forensic laboratories Bureau:

Specializes in forensic laboratories examination, analyses, and comparison of all the vital, physical, and chemical evidence related to criminal action (Hamid & Yousif, 2017).

The Forensic Laboratories Bureau Divided into the Following:

1. Forensic Chemistry Administration.
2. Forensic Biology Administration.
3. Arms and Mark Tools Administration.
4. Detect counterfeiting and Forgery Administration.
5. Physical Testing Administration.

6. Exhibits Administration.

Forensic Biology Administration Composed of Four Departments:

1. Serology Department.
2. Spermatozoa Department.
3. Hair and Fibers Department.
4. DNA Fingerprinting Department.

2.8.2 DNA Fingerprinting Department in SFED:

The DNA Laboratory was established in 2003, machines, Equipment, Chemicals, and reagents were imported in three stages. The first Case was successfully announced in December 2007 (Hamid & Yousif, 2017).

The DNA Department consists of the following sections:

1. Sampling Area section.
2. Extraction section.
3. PCR section.
4. Genetic Analyzer section.
5. Samples and Reagents Store.

2.8.2.1 Tasks and Duties:

1. Identification of Persons through the Analysis of Genetic profile for different biological samples related to forensic cases.
2. The establishment of DNA Database for both the criminals and unknown persons.
3. Genetic profile for non-forensic cases such as immigration cases.

2.8.2.2 Standards and Steps Currently used in the DNA Analysis in DNA Department:

The forensic laboratories applied the international standards especially in the Forensic Biology Administration because the sample examinations are very sensitive. This lead the EAPCCO countries in 2008 (astern Africa Police Chiefs Cooperation Organization) which is the regional response to fight traditional and organized crime, to select the Sudan to be premises of Regional Forensic Laboratories (New Building) which Inaugurated in 17/12/2015 as the biggest forensic laboratories in Africa and Arabic states, with international standards and applicable with ISO 17025 and WHO laboratory safety manual.

The forensic Biology laboratories designed in separation the sample test from crime scene in line and reference samples in other line to avoid contamination and supported with the latest versions of extraction, amplification, genetic analyzer instruments and the facilities of laboratories.

Steps of examination followed as most used in international forensic laboratories example the Interpol as following:

1. Simple trace evidence examinations of serology, spermatozoa, body fluids, hair and fibers…..etc.
2. DNA fingerprint examinations (from extraction to DNA profiling) (Hamid & Yousif, 2017).

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study methodology:

This study based on theoretical background of methodology and the quantities design using a hypothesis testing approach.

3.2 Study population:

The study population consisted of samples of Forensic laboratory Bureau of Sudanese Forensic Evidence Directorate.

3.3 Sample size:

The study sample consisted of (40) workers from DNA department of Forensic laboratory Bureau of SFED and divided to 28 of male and 12 of female. The sample size divided to 6 mangers, 9 experts, 17 assistants, and 8 technicians.

3.4 Questionnaire

The questionnaire was designed to consist information about the following sections:

1. Demographic information about the workers.
2. Staff competency.
3. Quality of the service provided by DNA laboratory
4. Management system.
5. Working environment.
6. Top management.

The answer of the questions of the study was closed, except section one the answer was given grade (1) as a weight for each answer "Strongly agree", grade (2) as a weight for each answer "Agree", grade (3) as a weight for each answer, " Neutral", grade (4) as a weight for each answer "Disagree", and grade (5) as a weight for each answer "Strongly disagree"

3.5 Statistical analysis:

Data was expressed as Chi-square and P values. Differences between questionnaire phrases were compared by Chi-square test using statistical software SPSS (Statistical Package for Social Sciences) version 23. The result was considered statistically significant when $P \leq 0.05$.

CHAPTER FOUR

RESULTS

4.1 Reliability and Validity:

Table (4.1) showed that all reliability and validity coefficients for questionnaire is greater than (50%) and close to the one, This indicates that the questionnaire is characterized by high reliability and validity, and makes statistical analysis acceptable.

Table (4.1): Reliability and Validity

Reliability coefficient	Validity coefficient
0.71	0.84

4.2 Demographics:

4.2.1The sample distribution by gender:

Table (4.2) showed that 70% of workers are male and 30% are female.

Table (4.2): The sample distribution by gender

Gender	Frequency	Percentage (%)
Male	28	70
Female	12	30
Total	40	100

4.2.2 The sample distribution by work experience:

Table (4.3) showed that 35% of workers has working experience from one and less than 5 years, 20% has experience from 5 to 10 years, and 45% has experience up to 10 years.

Table (4.3): The sample distribution by work experience

Work Experience	Frequency	Percentage (%)
1----5	14	35
5----10	8	20
Up to 10	18	45
Total	40	100

4.2.3 The sample distribution by educational level:

Table (4.4) showed that 12.5% of workers has diploma degree, 50% has bachelor degree, and 37.5% has postgraduate degree.

Table (4.4): The sample distribution by educational level

Educational level	Frequency	Percentage (%)
Diploma	5	12.5
Graduate	20	50
Post graduate	15	37.5
Total	40	100

4.2.4 The sample distribution by job level:

Table (4.5) showed that 15% of workers are managers, 22.5% are expert, 42.5% are assistant, and 20% are technician.

Table (4.5): The sample distribution by job level

Job level	Frequency	Percentage (%)
Manager	6	15
Expert	9	22.5
Assistant	17	42.5
Technician	8	20
Total	40	100

4.2.5 The sample distribution by ISO 17025 awareness:

Table (4.6) showed that 32.5% of workers are strongly aware about ISO 17025, 50% are aware, 12.5% are unaware, and 5% are don't hear about ISO 17025.

Table (4.6): The sample distribution by ISO 17025 awareness

ISO aware	Frequency	Percentage (%)
Strongly aware	13	32.5
Aware	20	50
Unaware	5	12.5
don't hear about it	2	5
Total	40	100

4.3 Staff competency:

Table (4.7) showed that 22.5% of workers are strongly agreed with the staff are competent and qualified, 32.5% are agreed with it, 20% are neutral, 15% are disagreed, and 10% are strongly disagreed. 10% of workers are strongly agreed with the staff are trained periodically and when need when needed, 25% are agreed, 22.5% are neutral, 30% are disagreed, and 12.5% are strongly disagreed. 20% of workers are strongly agreed with any one of the staff know his responsibility, 40% are agreed, 22.5% are neutral, 12.5% are disagreed, and 5% are strongly disagreed. 30% of workers are strongly agreed with the implementation of international standards like ISO 17025 can enhance the competence of the staff, 42.5% are agreed, 15% are neutral, 10% are disagreed, and 2.5% are strongly disagreed.

Table (4.8) showed the chi-square values of each phrases and all values of P are less than 0.05 that mean there is significantly difference in all phrases.

Table (4.7): Frequency distribution of Staff competency phrases

Answers

Phrases	Frequency and Percentages				
	S. agree	Agree	Neutral	Disagree	S. Disagree
The staff are competent and qualified	9 22.5%	13 32.5%	8 20%	6 15%	4 10%
Staff are trained periodically and when need when needed	4 10%	10 25%	9 22.5	12 30%	5 12.5%
Any one of the staff know his responsibility	8 20%	16 40%	9 22.5%	5 12.5%	2 5%
The implementation of international standards like ISO 17025 can enhance the competence of the staff	12 30%	17 42.5%	6 15%	4 10%	1 2.5%

Table (4.8): Chi-square test results for Staff competency

Phrases	Chi-square value	P-value
The staff are competent and qualified	46.839	0.000*
Staff are trained periodically and when need when needed	36.624	0.002*
Any one of the staff know his responsibility	53.556	0.000*
The implementation of international standards like ISO 17025 can enhance the competence of the staff	20.750	0.000*

*Means there is significantly difference when $P \leq 0.05$.

4.4 Service Quality:

Table (4.9) showed that 15% of workers are strongly agreed with the DNA Labs has leading position in the competitive market in Sudan, 22.5% are agreed with it, 32.5% are neutral, 20% are disagreed, and 10% are strongly disagreed. 20% of workers are strongly agreed with there is increasing in the range & availability of service provided by DNA Labs, 35% are agreed, 20% are neutral, 17.5% are disagreed, and 7.5% are strongly disagreed. 5% of workers are strongly agreed with the testing time is adequate and there is no delay in the service provided by DNA Labs, 15% are agreed, 35% are neutral, 32.5% are disagreed, and 12.5% are strongly disagreed. 25% of workers are strongly agreed with the implementation of international standards like ISO 17025 can increase the quality of services, 42.5% are agreed, 17.5% are neutral, 10% are disagreed, and 5% are strongly disagreed.

Table (4.10) showed the chi-square values of each phrases and P values of phrases 1, 2, and 3 are up to 0.05 less than 0.05 in phrase 4. That mean there is significantly difference in phrase 4 and significantly no difference in phrases 1, 2, and 3.

Table (4.9): Frequency distribution of service quality phrases Answers

Phrases	Frequency and Percentages				
	S. agree	Agree	Neutral	Disagree	S. Disagree
The DNA Labs has leading position in the competitive market in Sudan	6 15%	9 22.5%	13 32.5%	8 20%	4 10%
There is increasing in the range & availability of service provided by DNA Labs	8 20%	14 35%	8 20%	7 17.5%	3 7.5%
The testing time is adequate and there is no delay in the service provided by DNA Labs	2 5%	6 15%	14 35%	13 32.5%	5 12.5%
The implementation of international standards like ISO 17025 can increase the quality of services	10 25%	17 42.5%	7 17.5%	4 10%	2 5%

Table (4.10): Chi-square test results for the service quality.

Phrases	Chi-square value	P-value
The DNA Labs has leading position in the competitive market in Sudan	13.186	0.659
There is increasing in the range & availability of service provided by DNA Labs	19.076	0.256
The testing time is adequate and there is no delay in the service provided by DNA Labs	19.518	0.243
The implementation of international standards like ISO 17025 can increase the quality of services	17.250	0.002*

*Means there is significantly difference when $P \leq 0.05$.

4.5 Management system:

Table (4.11) showed that 17.5% of workers are strongly agreed with all staff in DNA unit are well trained about application of safety measures, 20% are agreed with it, 45% are neutral, 12.5% are disagreed, and 5% are strongly disagreed. 15% of workers are strongly agreed with there is an internal management system and know for everyone, 32.5% are agreed, 25% are neutral, 20% are disagreed, and 7.5% are strongly disagreed. 17.5% of workers are strongly agreed with the internal system of the lab is the part of the overall system in SFED, 35% are agreed, 22.5% are neutral, 15% are disagreed, and 10% are strongly disagreed. 25% of workers are strongly agreed with the implementation of international standards like ISO 17025 can support the management system and improve it, 45% are agreed, 15% are neutral, 12.5% are disagreed, and 2.5% are strongly disagreed.

Table (4.12) showed the chi-square values of each phrases and P values of phrases 1, 3, and 4 are less than 0.05 and up to 0.05 in phrase 2. that mean there is significantly no difference in phrase 2 and significantly difference in phrases 1, 3, and 4.

Table (4.11): Frequency distribution of management system phrases Answers

Phrases	Frequency and Percentages				
	S. agree	Agree	Neutral	Disagree	S. Disagree
All staff in DNA unit are well trained about application of safety measures	7 17.5%	8 20%	18 45%	5 12.5%	2 5%
There is an internal management system and know for everyone	6 15%	13 32.5%	10 25%	8 20%	3 7.5%
The internal system of the lab is the part of the overall system in SFED	7 17.5%	14 35%	9 22.5%	6 15%	4 10%
The implementation of international standards like ISO 17025 can support the management system and improve it	10 25%	18 45%	6 15%	5 12.5%	1 2.5%

Table (4.12): Chi-square test results for the management system

Phrases	Chi-square value	P-value
All staff in DNA unit are well trained about application of safety measures	37.505	0.002*
There is an internal management system and know for everyone	19.760	0.176
The internal system of the lab is the part of the overall system in SFED	57.280	0.000*
The implementation of standards like ISO 17025 can support the management system and improve it	20.750	0.000*

*Means there is significantly difference when $P \leq 0.05$.

4.6 Working environment:

Table (4.13) showed that 12.5% of workers are strongly agreed with the work environment inside the lab is facilitate correct performance of the test, 47.5% are agreed with it, 22.5% are neutral, 12.5% are disagreed, and 5% are strongly disagreed. 25% of workers are strongly agreed with the implementation of international standards like ISO 17025 can enhance the good environmental condition inside the lab, which increases the quality of the results, 47.5% are agreed, 17.5% are neutral, and 10% are disagreed.

Table (4.14) showed the chi-square values of each phrases and all values of P are less than 0.05, that mean there is significantly difference in all phrases.

Table (4.13): Frequency distribution of working environment phrases

Answers

Phrases	Frequency and Percentages				
	S. agree	Agree	Neutral	Disagree	S. Disagree
The work environment inside the lab is facilitate correct performance of the test	5 12.5%	19 47.5%	9 22.5%	5 12.5%	2 5%
The implementation of international standards like ISO 17025 can enhance the good environmental condition inside the lab which increase the quality of the results	10 25%	19 47.5%	7 17.5%	4 10%	0 0%

Table (4.14): Chi-square test results for working environment

Phrases	Chi-square value	P-value
The work environment inside the lab is facilitate correct performance of the test	22.000	0.000*
The implementation of international standards like ISO 17025 can enhance the good environmental condition inside the lab which increase the quality of the results	12.600	0.006*

*Means there is significantly difference when $P \leq 0.05$.

4.7 Top management:

Table (4.15) showed that 17.5% of workers are strongly agreed with top management strongly encourages employee involvement in quality management activities, 32.5% are agreed with it, 20% are neutral, 17.5% are disagreed, and 12.5% are strongly disagreed. 17.5% of workers are strongly agreed with top management empowers employees to solve quality problems, 30% are agreed, 27.5% are neutral, 17.5% are disagreed, and 7.5% are strongly disagreed. 15% of workers are strongly agreed with top management discusses many quality-related issues in top management meetings, 17.5% are agreed, 47.5% are neutral, and 20% are disagreed. 22.5% of workers are strongly agreed with top management support the implementation of ISO 17025, 35% are agreed, 15% are neutral, 5% are disagreed, and 2.5% are strongly disagreed.

Table (4.16) showed the chi-square values of each phrases and P values of phrases 1and 2 are up to 0.05 and less than 0.05 in phrase 3 and 4, that mean there is significantly no difference in phrase 1 and 2 and significantly difference in phrases 3and 4.

Table (4.15): Frequency distribution of top management phrases

Answers

Phrases	Frequency and Percentages				
	S. agree	Agree	Neutral	Disagree	S. Disagree
Top management strongly encourages employee involvement in quality management activities	7 17.5%	13 32.5%	8 20%	7 17.5%	5 12.5%
Top management empowers employees to solve quality problems	7 17.5%	12 30%	11 27.5%	7 17.5%	3 7.5%
Top management discusses many quality-related issues in top management meetings	6 15%	7 17.5%	19 47.5%	8 20%	0 0%
Top management support the implementation of ISO 17025	9 22.5%	14 35%	9 22.5%	6 15%	2 5%

Table (4.16): Chi-square test results for top management

Phrases	Chi-square value	P-value
Top management strongly encourages employee involvement in quality management activities	4.500	0.343
Top management empowers employees to solve quality problems	6.500	0.165
Top management discusses many quality-related issues in top management meetings	11.000	0.012*
Top managers support the implementation of ISO 17025	9.750	0.045*

*Means there is significantly difference when $P \leq 0.05$.

CHAPTER FIVE

DISCUSSION

The most important goal of applying ISO/IEC 17025 is to prove reliability and capability of laboratories (Vlachos *et al*., 2002; Sari & Nurcahyo, 2018). The laboratory accreditation is required based on ISO / IEC 17025 standards to obtain accurate measurements (Khodabocus & Balgobin, 2011)

For the improvement of the quality management system, the testing laboratory uses the ISO / IEC 17025 standard as the reference of general requirements of competence to perform the test / calibration, including sampling test (ISO/IEC 17025, 2005). This standard is also used for quality, administrative and technical activities.

To achieving the quality objectives contained in the laboratory, application of standards in laboratory testing should be closely related. Application of the ISO / IEC 17025 standard, the testing result is secure, reliable and certainly has undoubted quality (ISO, 2017).

To run effectively Testing laboratory; the flexibility, accuracy, value-oriented, and main job of its employees should be managed (Bien *et al*., 2007; Sari & Nurcahyo, 2018). The laboratory effectiveness plays an important role in its development. It is necessary to know the key areas of employment and employee empowerment (Bien *et al*., 2007; Sari & Nurcahyo, 2018). A questionnaire is a qualitative data collection methodology to ensure consistency of data taken from respondents using the data collection (Boateng, 2012; Sari & Nurcahyo, 2018). Also it is allowing researchers to interview multiple respondents systematically and simultaneously (Babbie, 2011; Sari & Nurcahyo, 2018).

(Khodabocus & Balgobin, 2011) reported that "the application of standards to improve the quality of management systems is a way to show that the quality of test results is reliable". With a quality management system standard, the laboratory will have measurement traceability, error prevention, and corrective actions when an error occurs.

The ISO / IEC 17025 standards can be applied to all laboratories regardless of the number of personnel or the extent of the scope of testing and / or calibration activities (ISO/IEC 17025, 2005).

The ISO / IEC17025 standard has 15 management clauses and 10 technical clauses, which are used as reference by testing or calibration laboratories. Each clause contained in the management aspect requires clear procedures, policies, programs and instructions to maintain the management system. While in the field of technical itself, set various factors that determine the truth and reliability testing and / or calibration performed by the laboratory (ISO/IEC 17025, 2005).

Based on the questionnaire conducted in this study, the DNA Laboratory could run the quality system standard similar to most organizations which apply the management system standard by the standardization agency (Komite Akreditasi Nasional, 2016; Sari & Nurcahyo, 2018).

The implementation of a QMS based on ISO/IEC 17025:2005 will modify the actual system prevailing in the DNA laboratory and will also introduce new procedures. According to the results all the staff, workers and top management staff are ready for the implementation of this QMS. The alterations will generally have an effect on the laboratory, its personnel and the clients. It will increase paperwork and work load, internal quality control and running costs of operating the laboratory. There will be a need to maintain documentation procedures and records to operate the QMS, and the additional control of records to verify on tests carried out and

calibration results. The validation for test methods is another additional load for laboratory staff. Calibration of equipment requires the use of calibration standards and reference materials and these add up to the running costs of the laboratory (CITAC / EURACHEM, 2002).

The benefits associated to implementation of QMS can be analyzed from different angles; the laboratory's personnel, the laboratory itself, the top management and the clients. The use of appropriate procedures, staff will be more confident about their work. They can easily identify errors and can implement necessary corrective actions. QMS demonstrates the technical ability of a laboratory to carry out its specific tests and provides. The top management will be satisfied and looking for more development and job satisfaction. This recognition of the Laboratory will lead the customer to select it for its reliable testing services these different angles are in agreement with (ILAC, 2001).

The results of this study showed that implementation of a QMS based on ISO/IEC 17025:2005 is possible and it would increase its trustworthiness.

Training is an aspect that needs to be considered while implementing the QMS. The laboratory will need to recruit additional personnel in order to maintain the QMS and the guidance of a consultant will be a plus point for the implementation process (Khodabocus & Balgobin, 2011).

Results in this study indicate that although the laboratory does not operate the ISO 17025 standard in the DNA Laboratory, it does abide to most of the clauses to some extent. But it will face challenges of training and validation of tools and methods (Beckett & Slay, 2011).

Top management support is important to improve employee fulfillment, consistency, reliability and accuracy of laboratory measurements, quality performance and customer satisfaction (Khodabocus & Balgobin, 2011).

Providing necessary training to employees can increase awareness about and commitment to produce quality products. Therefore, adequate training on quality and management support should be given to DNA laboratory to improve quality and laboratory performance (Khodabocus & Balgobin, 2011).

The results of this research agreed with Sadikoglu, & Temur, (2012) in their study, which examined the effects of ISO17025 accreditation on laboratory performance in Turkey.

The results showed that when laboratory adopts ISO accreditation the laboratory could improve its performance.

CONCLUSION AND RECOMMENDATIONS

Conclusion:

1. The training method inside DNA laboratory needs an improvement process.
2. The service provided by DNA laboratory is partially good and with high quality, but it needs improvement process.
3. There is no clear management system with known responsibility inside DNA laboratory.
4. Working environment inside DNA laboratory is suitable and helps in correct testing results.
5. Top management partially committed for improving the management and technical system in DNA laboratories by implementing ISO/IEC 17025 quality system.

Recommendations:

DNA Laboratory should make use of the gap analysis to devise a plan for the implementation of the standard. The plan should address the preparation of documents related to procedures and work instructions and how the work will be distributed among the staff. The quality manager should coordinate all the work and find out what resources will be needed to implement the system. Other aspects that should be mentioned in the plan are:

1. The time expected to complete the implementation of the system.
2. The accreditation body to be chosen.
3. Training sessions, seminars or workshops for laboratory personnel.

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Total Quality & Excellence Center

MSc in Management of Quality Excellence

Mr. & Ms. / Worker on DNA department

I request you to kindly cooperate and answer all statements contained in questionnaire **about Implementation of ISO 17025 workers in DNA Laboratories** and assure that the information will be collected through your answers will be kept confidential and used for the purposes of scientific research so I hope your cooperation and answer these questions objectively.

The purpose of this questionnaire is to estimate knowledge & the aims will be achieved through the following objectives:

1. Evaluation of the existing quality system in DNA department in SFED.
2. Discuss the benefits of accreditation and assessing the feasibility of the accreditation process.
3. Develop an implementation guideline for the DNA department in SFED laboratory.

The researcher: Mohieldeen Diaeldeen Abualazaim

Which level of your satisfaction at the following statement of Organization? The level will be represented in the scale from 1 to 5.

1=Strongly agree; 2=Agree; 3=Neutral; 4= Disagree; 5=Strongly Disgree

Note: you only tick into each question

PART (A): Demographic		
1	**Gender**	Male ( ) Female ( )
2	**Work experience** (years)	1-5 ( ) 5 – 10 ( ) Up to 10 ( )
3	**Educational level**	Diploma ( ) Graduate ( ) Post graduate( )
4	**Current job**	Manager ( ) Officer ( ) Assistant ( ) Technician ( )
5	**What is the extent become aware of ISO**: strongly aware ( ) aware ( ) unaware ( ) don't hear about it ( )	

PART (B): Staff Competency	
6	**The staff are competent and qualified**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
7	**Staff are trained periodically and when need when needed**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
8	**Any one of the staff know his responsibility**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
9	**The implementation of international standards like 17025 can enhance the competence of the staff**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )

PART (C): Service Quality	
10	**The DNA Labs has leading position in the competitive market in Sudan**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
11	**There is increasing in the range & availability of service provided by DNA Labs**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
12	**The testing time is adequate and there is no delay in the service provided by DNA Labs**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
13	**The implementation of international standards like ISO 17025 can increase the quality of services**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )

PART (D): Management System	
14	**All staff in DNA unit are well trained about application of safety measures**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
15	**There is an internal management system and know for everyone**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
16	**The internal system of the lab is the part of the overall system in SFED**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
17	**The implementation of international standards like ISO 17025 can support the management system and improve it**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )

PART(E): Work environment	
18	**The work environment inside the lab is facilitate correct performance of the test**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
19	**The implementation of international standards like 17025 can enhance the good environmental condition inside the lab which increase the quality of the results**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )

PART(F): Top management	
20	**Top management strongly encourages employee involvement in quality management activities**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
21	**Top management empowers employees to solve quality problems**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
22	**Top management discusses many quality-related issues in top management meetings**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )
23	**Top management support the implementation of ISO 17025**: Strongly agree ( ) Agree ( ) Neutral ( ) Disagree ( ) Strongly disagree ( )

Thank you for your cooperation