Sudan University of Science and Technology

College of Graduate Studies

Impact of ISO-IEC 17025:2017 Accreditation on Laboratories Performance (A Case Study: Nano for Measurement and Calibration Center, Khartoum State- Sudan)

أثر اعتماد ISO-IEC 17025:2017 على أداء المختبرات (دراسة حالة: مركز نانو للقياس و المعايرة، ولاية الخرطوم– السودان)

A dissertation submitted for partial fulfillment for the requirements of M.Sc. degree in Total Quality Management and Excellence

By

Shareef Mahmoud Hassan Mohamed

B.Sc. in Physics and Mathematics, Shendi University, 2011

Supervisor

Dr. Tayseer Elamin Mohamed Elfaki

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الآيـــــة

قال تعالى:

بسم الله الرحمن الرحيم

﴿أَمَّنْ هُوَ قَانِتٌ آنَاءَ اللَّيْلِ سَاجِدًا وَقَائِمًا يَحْذَرُ الْآخِرَةَ وَيَرْجُو رَحْمَةَ رَبِّهِ ۗ قُلْ هَلْ يَسْتَوِي الَّذِينَ يَعْلَمُونَ وَالَّذِينَ لَا يَعْلَمُونَ ۗ إِنَّمَا يَتَذَكَّرُ أُولُو الْأَلْبَابِ﴾

صدق الله العظيم

سورة الزمر: الآية ٩

Dedication

To my family, my father, my mother, my brother and sisters.

To my beloved wife for her moral support

To my beloved daughter

To the soul of my beloved sister.

To everyone who contributed to my education even by one letter.

To my friends and colleagues in Nano for Measurement and Calibration Center and Sudan University of Science and Technology

I dedicate this work.

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Abstract

This descriptive case study was conducted in in Nano for Measurement and Calibration Center, Khartoum State- Sudan to assess the impact of accreditation on laboratories performance regarding ISO/IEC 17025:2017 during the period from November 2020 to March 2021. A questionnaire was used as data collection tool to achieve the study objectives. Thirty four questionnaires were distributed to all laboratory employees in Nano for Measurement and Calibration Center. All laboratory employees were responded with percentage of (100.0%). The data were analyzed using Statistical Package for Social Sciences (SPSS); the methodology used was the descriptive correlation by using Chi-square test. The study showed that there was a statistically significant relationship between accreditation and validity of results issue by laboratory. The study reflected that there was a statistically significant relationship between accreditation and the performance and efficiency of employees. In addition to, there was a statistically significant relationship between accreditation and customer satisfaction. The study revealed that there was a statistically significant relationship between accreditation and financial returned to the laboratory. The study concluded that accreditation improved laboratories performance regarding ISO/IEC 17025:2017 in Nano for Measurement and Calibration Center, Khartoum State- Sudan.

المستخلص

أجريت دراسة الحالة الوصفية في مركز نانو للقياس والمعايرة ، ولاية الخرطوم– السودان لتقييم أثر الإعتماد على آداء المختبرات فيمايتعلق بالمواصفة آيزو 17025:2017 في الفترة من نوفمر 2020م إلى مارس 2021م. استخدمت الإستبانة كآداة لجمع البيانات لتحقيق أهداف الدراسة. أربع و ثلاثون إستبانة وُزعت على جميع العاملين في مركز نانو للقياس والمعايرة. استجاب كل العاملين بنسبة (١٠٠%). حُللت البيانات باستخدام الحزم الإحصائية للعلوم الإجتماعية (SPSS)، المنهجية التي استخدمت كانت التحليل الوصفي الارتباطي باستخدام مربع كاي. اظهرت الدراسة أن هناك علاقة ذات دلالة إحصائية بين الإعتماد وصحة النتائج الصادرة من المعمل. عكست الدراسة أن هناك علاقة ذات دلالة إحصائية بين الإعتماد و آداء و كفاءة العاملين. بالإضافة إلى، أن هناك علاقة ذات دلالة إحصائية بين الإعتماد ورضا العملاء. كشفت الدراسة أن هناك علاقة ذات دلالة إحصائية بين الإعتماد و العائد المادي للمختبر. خلصت الدراسة إلى أن الإعتماد طَوّر آداء المختبرات وفقاً لمتطلبات ISO/IEC17025:2017 في مركز نانو للقياس والمعايرة، ولاية الخرطوم– السودان.

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CHAPTER ONE

Introduction, Research Problem, Rationale, Objectives and Hypotheses

Chapter 1

Introduction, research problem, rationale, objectives and hypotheses

1.1 Introduction:

International organization for standardization/international electro technical commission (ISO/IEC 17025) is the global quality standard for testing and calibration laboratories. ISO/IEC 17025 was developed by laboratory experts from all over the world, along with 18 liaison organizations, such as the international laboratory accreditation cooperation (ILAC), and many associations representing laboratories (Kim-Soon, 2012). ISO is an independent, non governmental international organization with membership of 162 national standards bodies. ISO has published international standard and related documents, covering almost every industry, from technology, to food safety, to agriculture and health care (Hahn and Christian, 2016). ISO/IEC 17025 was first issued in 1999 by the international organization for standardization (ISO) and the international electro technical commission (IEC). It is the single most important standard for calibration and testing laboratories around the world (Kim-Soon, 2012). There have been three releases; in 1999, 2005 and 2017. The most significant changes between the 1999 and 2005 release were a greater emphasis on the responsibilities of senior management, explicit requirements for continual improvement of the management system itself, and communication with the customer. It also aligned more closely with the 2000 version of ISO 9001 (SAI GLOBAL, 2012). The two main sections in ISO/IEC 17025 are management requirements and technical requirements. Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements include factors which determine the correctness and reliability of the tests and calibrations performed in laboratory (Honsa

and Deborah, 2003). Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an accreditation body. Since the standard is about competence, accreditation is simply formal recognition of a demonstration of that competence. A prerequisite for a laboratory to become accredited is to have a documented quality management system. The usual contents of the quality manual follow the outline of the ISO/IEC 17025 standard (Honsa and Deborah, 2003). Accreditation is an objective way to assure customers that technical competence has been fully implemented to provide reliable and accurate test or calibration results (Borsting *et al.*, 2009). ISO/IEC 17025 is an ideal management system model for laboratories because it aims to control quality costs, improve measurement accuracy and guarantee consistency of results. It is also customer-driven when implemented correctly. Furthermore, when your company achieves ISO/IEC 17025 accreditation, you will be presented with a certificate of accreditation. This certificate can be used in advertising, promotional literature and stationary to show current and potential customers that your laboratory is committed to quality and has demonstrated technical competency to perform calibration or testing services (Metha, 2013).

1.2 Research problem:

The accreditation is very importance to the laboratory performance and improves the service delivery. Lack of the accreditation leads to lack of the technical competence of testing and calibration report. However, this will both employee and customer dissatisfaction in the measurement of instruments and also will lack competitive advantage on technical skills and equipments competency for the laboratory. So, this study tried to answer the following questions:

- What is the impact of accreditation on validity of results issued by laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center?
- What is the impact of accreditation on the performance and efficiency of employees according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center?
- What is the impact of accreditation on customer satisfaction according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center?
- What is the impact of accreditation on financial returned to the laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center?

1.3 Rationale:

Accreditation is an important tool in the performance of the laboratory and helps in accepting the results issued by the laboratory locally and international. It also helps in establishment national references for measurement, which contribute significantly to building the national economy. The Nano for Measurement and Calibration Center was chosen to try to understand the accreditation and its effect on the performance of laboratory according to ISO/IEC 17025:2017. So, the study helps in the process of continuous improvement of the activities of the center and motivation of the accreditation of the other activities on the laboratories in the center.

1.4 Objectives of the study:

1.4.1 General objective:

To assess the impact of accreditation on laboratories performance regarding ISO/IEC 17025:2017 in Nano for Measurement and Calibration Center, Khartoum State- Sudan.

1.4.2 Specific objectives:

- To identify a relationship between accreditation and validity of results issued by laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.
- To identify a relationship between accreditation and the performance and efficiency of employees according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.
- To identify a relationship between accreditation and customer satisfaction according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.
- To identify a relationship between accreditation and financial returned to laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.

1.5 The hypotheses:

- There is a statistically significant relationship between accreditation and validity of results issued by laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.
- There is a statistically significant relationship between accreditation and the performance and efficiency of employees according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.
- There is a statistically significant relationship between accreditation and customer satisfaction according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.
- There is a statistically significant relationship between accreditation and financial returned to laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.

CHAPTER TWO

Literature Review

Chapter 2

Literature review

2.1 International organization for standardization and the international electro technical commission (ISO/IEC 17025):

ISO is based global consortium in Geneva and has a membership of more than 90 national standardization body, was shortened (ISO) based on the Greek word "ISOS" which means "Equal". ISO creates documents that provide requirements, specification, guidelines or characteristics that can be used consistently to ensure that materials, product processes and services are fit for their purpose (Hahn and Christian, 2016). ISO/IEC17025 standard used by testing and calibration laboratories to provide a basis for accreditation of laboratory quality systems. There are many commonalities with the ISO 9000 family of standards, but ISO/IEC 17025 adds in the concept of competence to the equation, applying directly to those organizations that produce testing and calibration results (Kim-Soon, 2012). Laboratories that are accredited to this international standard have demonstrated that they are technically competent and able to produce precise and accurate test and/ or calibration data. In most major countries, ISO/IEC 17025 is the standard for which most laboratories must hold accreditation in order to be deemed technically competent. In many cases, suppliers and regulatory authorities will not accept test or calibration results from laboratories that are not accredited. Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results (Kim-Soon, 2012).

2.1.1 History of ISO/IEC 17025:

ISO/IEC 17025 was originally known as ISO/IEC Guide 25, first released in 1978, with subsequent editions following in 1982 and 1990. Guide 25 was created with the belief that third party certification systems (for

laboratories) should, to the extent possible, be based on internationally agreed standards and procedures. In the mid-to late 1990s, an update to Guide 25 was required. However, the ISO decided to convert the guide into a standard and introduce tight compatibility with ISO 9001, which was also being revised, such that ISO 9001 would be treated as a master standard and the next evolution of Guide 25 to be treated as a standard to be specifically applied to testing and calibration laboratories (UNIDO, 2009). ISO/IEC 17025:1999 was issued by the ISO in late 1999 and was internationally adopted in 2000. A second release- ISO/IEC 17025:2005 was made on May 12, 2005 after it was agreed that it needed to have its wording more closely aligned with the 2000 version of ISO 9001. The most significant changes introduced greater emphasis on the responsibilities of senior management, as well as explicit requirements for continual improvement of the management system itself, particularly communication with the customer. Finally upgraded to 2017 version (UNIDO, 2009).

2.1.2 The standard:

ISO has released the most recent version of the ISO/IEC 17025 standard- the 2017 edition. The development of this standard became necessary as it is geared towards achieving the goal and purpose of promoting confidence, accuracy and trustworthiness in the operation of testing and calibration laboratories. The ISO/IEC 17025 standard contains general requirements for the competence of testing and calibration laboratories, which help them, increase the effectiveness of their activities (ISO 17025, 2017). The ISO/IEC 17025 standard helps laboratories to provide reliable data and technically valid results to their customers, so as to be deemed competent. It is important to mention that this standard is also applicable to all organizations performing laboratory activities such as universities, research centers, and others, and can be used by inspection bodies and/or

other conformity assessment bodies. It also helps to promote continual improvement of data quality and laboratory effectiveness (ISO 17025, 2017). After the implementation of the revised international standard, the laboratory will be able to demonstrate that it operates within the new framework using the recent technology and information technology (IT) techniques. Furthermore, the format of this standard has been significantly changed to be more in line with new ISO formatting guidelines. The standard takes into consideration the latest version of the ISO 9001 standard, so as to facilitate the implementation of ISO/IEC 17025 in laboratories that have already met the requirements of ISO 9001 (ISO 17025, 2017). The scope of the ISO/IEC 17025 standard covers all the laboratory activities including testing, sampling, and calibration (ISO 17025, 2017). The new version of the ISO/IEC 17025 standard focuses more on information technology, which incorporates the use of computer systems, laboratory information management system software, and the provision of electronic test results. The standard also focuses on the concept of risk-based thinking, whereby the laboratory takes a proactive approach towards addressing risks that can prevent the laboratory from achieving its objectives (ISO 17025, 2017).

2.1.3 ISO/IEC 17025:1999 versus ISO/IEC 17025:2005:

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. Greater emphasis and more concentration of customers communications especially to actively evaluate, monitor asses and analyze customers feedback on service quality, and ensure the resulting information is used as the basis of decisions and actions to improve the management system.

2. Greater emphasis and more concentration of the need to use information from quality control data to evaluate the performance of the quality system and to identify opportunities for improvement.

3. Insistence on a demonstrated commitment to continually improve the quality management system and identified methodologies and mechanisms for achieving this (ISO 17025, 2005).

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 (ISO 17025, 2005). 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 (ISO 17025, 2005).

2.1.4 ISO/IEC 17025:2005 versus ISO/IEC 17025:2017:

To begin with, the 2005 version of ISO/IEC 17025 included the following: scope, normative references, terms and definitions, management requirements and technical requirements. Meanwhile, the 2017 version of ISO/IEC 17025 includes the following: scope, normative references, terms and definitions, general requirements, structural requirements, resource requirements, process requirements and management system requirements. When making comparisons between the scope of ISO/IEC 17025:2005 version and the scope of ISO/IEC 17025:2017 version, it is noted that the 2017 version of the ISO/IEC 17025 standard specifies the general requirements for the impartiality, and consistent operation of laboratories (ISO 17025, 2017). Additionally, in the normative reference section of ISO/IEC 17025:2017, ISO/IEC Guide 99 is listed as a reference which provides the basic and general

concepts, and associated terms. ISO/IEC 17000 is also listed as a reference, which specifies the vocabulary and the general principles for conformity assessment. The terminology has been updated as well, which means that the ISO/IEC 17025:2017 standards cover the newest ISO/IEC terminology and the changes that have been included in the international vocabulary of metrology (VIM). Under the section terms and definitions of the ISO/IEC 17025:2017 standard, the term "laboratory" has been added. This term refers to the bodies that perform one or more of the following activities such as calibration testing, and/or sampling, associated with subsequent testing or calibration. It is important to mention that the new version focuses more on information technology, mainly in the use of systems, the provision of electronic test results, and the provision of electronic records (ISO 17025, 2017).

2.1.5 Overview to main requirements of content of ISO/IEC 17025:2017:

2.1.5.1 General requirements:

This clause highlights two main elements: impartiality and confidentiality. This clause ensures that the laboratory is committed to impartiality and that the risks related to impartiality are identified on a continuous basis. Meanwhile, confidentiality ensures that prior to the release of the information into a public domain, customers are informed. Confidentiality also entails not releasing the information obtained from a source other than the customer, as well as the source of the information to the customer unless it has been authorized by the source. Additionally, this clause emphasizes the release of confidential information when required by law or authorized by contractual arrangements. The laboratory should commit to ensure information confidentiality during all processes, treatments and interactions (ISO 17025, 2017).

2.1.5.2 Structural requirements:

This clause emphasizes the legal status of the laboratory, the structure of the laboratory, the identification of the personnel and the management, as well as the availability of the personnel responsible for implementing and maintaining the integrity of the management system. It also emphasizes the documentation of procedures to the extent necessary to ensure consistency in the application of laboratory activities and the validity of the results (ISO 17025, 2017). The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis. Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility (ISO 17025, 2017).

2.1.5.3 Resource requirements:

This clause establishes the need for laboratories to ensure the availability of personnel, facilities, equipment, systems and support services required for the smooth performance/operations and management of all its activities. Calibration of equipment shall be done when measurement accuracy or measurement uncertainty affects the validity of reported results and this will further assist in establishing the metrological traceability of the reported results. The laboratory shall also ensure that it communicates to its customers on all externally provided products and services i.e. subcontracting activities, purchasing services and supplies with requirements and controls in place (ISO 17025, 2017).

2.1.5.3.1 Personnel:

All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system. The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience. The laboratory shall have procedure (s) and retain records for: determining the competence requirements, selection, training supervision, authorization and monitoring competence of personnel. The standard also indicated the laboratory shall authorize personnel to perform specific laboratory activities (ISO 17025, 2017).

2.1.5.3.2 Facilities and environmental conditions:

The requirements for facilities and environmental conditions suitable for the laboratory activities to be documented, including the conditions related to monitoring, controlling and recording environmental conditions. The standard sets requirements to those environmental conditions which can effect on the results of laboratory activities. Depending on the nature of laboratory activities the same parameter can be or cannot be important for the testing results. Measures to control facilities may include access to and use of areas affecting laboratory activities, prevention of contamination and effective area separation, including sites or facilities outside of laboratory’s permanent control (ISO 17025, 2017).

2.1.5.3.3 Equipment:

The laboratory shall have access to equipment including: measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus, that is required for the correct performance of laboratory activities and that can

influence the results. The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration. The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. The laboratory shall establish a calibration program to maintain confidence in the status of calibration. Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable: the identity of equipment, the manufacturer's name, type identification and serial number, evidence of verification that equipment conforms with specified requirements, the current location, calibration dates, results of calibrations and adjustments (ISO 17025, 2017).

2.1.5.3.4 Metrological traceability:

The standard is giving great attention to metrological traceability issues. The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference and ensure that measurement results are traceable to the international system of units (SI) (ISO 17025, 2017).

2.1.5.3.5 Externally provided products and services:

The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities. And a procedure and retain records for: defining, reviewing and approving the laboratory's requirements for externally provided products and services, defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers, ensuring that externally provided products and services conform to the laboratory's established requirements (ISO 17025, 2017).

2.1.5.4 Process requirements:

This clause represents the procedures and other methods for the review of requests, tenders, and contracts. The clause covers the requests of the customers, the decision rule and the differences between tenders and requests that should be applicable to customers before any other laboratory activity takes place. It also covers the selection, verification, and validation of methods. This ensures that the laboratory will use appropriate methods and procedures for its activities. Furthermore, the laboratory will ensure that it is using the most recent methods which cover the latest technological developments. Through the use of relevant or current technology or methodology, the laboratory will be able to develop a sampling plan when it intends to carry out sampling of substances, materials or products for subsequent testing or calibration. Other elements captured by the clause are: handling of test or calibration items, technical records, evaluation of measurement uncertainty, ensuring the validity of results, reporting of results, complaints, nonconforming work, control of data, and information management (ISO 17025, 2017).

2.1.5.4.1 Review of requests, tenders and contracts:

The laboratory shall have a procedure for the review of requests, tenders and contracts. The laboratory informs the customer when the method requested by the customer is considered to be inappropriate or out of date. When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined, Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer. Any differences between the request or tender and the contract shall be resolved before laboratory activities commence and informed the customer of any deviation from the contract. Records shall also be

retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities (ISO 17025, 2017).

2.1.5.4.2 Selection, verification and validation of methods:

The laboratory shall use appropriate methods and procedures for all laboratory activities, and ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application. International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented. When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed. The laboratory shall retain the following records of validation: the validation procedure used specification of the requirements, determination of the performance characteristics of the

method, results obtained and a statement on the validity of the method, detailing its fitness for the intended use (ISO 17025, 2017).

2.1.5.4.3 Sampling:

The requirements are applicable to the laboratories which perform just sampling activities as well as for testing and calibration laboratories which are responsible also for sampling. A sampling plan and a sampling method are expected to be available and implemented when the laboratory carries out sampling of substances, materials or products for subsequent testing or calibration. Records of sampling data should be retained per standard requirements (ISO 17025, 2017).

2.1.5.4.4 Handling of test or calibration items:

A procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items should be drafted including a system for the identification of test or calibration items. Deviations from specified conditions are expected to be recorded and the customer to be consulted for next steps. In the case that some items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded (ISO 17025, 2017).

2.1.5.4.5 Technical records:

The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task. And ensure

that amendments to technical records can be tracked to previous versions or to original observations (ISO 17025, 2017).

2.1.5.4.6 Evaluation of measurement uncertainty:

Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis. A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations. And laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method (ISO 17025, 2017).

2.1.5.4.7 Ensuring the validity of results:

A procedure and records are required for monitoring the validity of results, which can include, among others: use of reference materials or quality control (QC) materials, use of alternative traceable instrumentation, functional checks, use of standards with control charts, intermediate checks, replicate tests or calibrations, retesting or recalibration, correlation of results, review of reported results, intra laboratory comparisons and testing of blind samples. Participating in proficiency tests (PT's) and/or inter laboratory comparisons (ILC's) is expected where available and appropriate. Such activities, according to the standard, must be planned and reviewed (ISO 17025, 2017).

2.1.5.4.8 Reporting of results:

The results shall be reviewed and authorized prior to release and provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and

shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records. The common information required to be included the following: title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”), the name and address of the laboratory, the location of performance of the laboratory activities, the name and contact information of the customer, identification of the method used, a description, unambiguous identification, and when necessary, the condition of the item, the date of receipt of the test or calibration item (s), and the date of sampling, the date (s) of performance of the laboratory activity, the date of issue of the report, the results with, where appropriate, the units of measurement, additions to deviations or exclusions from the method, identification of the person (s) authorizing the report, clear identification when results are from external providers. In addition, the specific information for test reports, calibration certificates, reporting statements of conformity, reporting opinions and interpretations and amendments to reports (ISO 17025, 2017).

2.1.5.4.9 Complaints:

A documented process is required for receiving, evaluating and making decisions on complaints. This process is expected to be available to any interested party upon request. The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual (s) not involved in the original laboratory activities in question (ISO 17025, 2017).

2.1.5.4.10 Nonconforming work:

A nonconforming work procedure is expected to be in place ensuring that the responsibilities and authorities for the management of nonconforming work are defined, subsequent actions are taken considering the risk levels,

an evaluation is made of the significance of the nonconforming work, take a decision to accept the nonconforming work, the customer is notified, if possible, work is recalled, if needed, and the responsibility for authorizing the resumption of work is defined. Halting or repeating of work and withholding of reports, as necessary can be considered among the required actions. Records of nonconforming work and relative actions are expected to be retained (ISO 17025, 2017).

2.1.5.4.11 Control of data and information management:

The laboratory shall have access to the data and information needed to perform laboratory activities and the laboratory information management system (s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system (s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation. The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system (s) are made readily available to personnel (ISO 17025, 2017).

2.1.5.5 Management system requirements:

This clause states that the laboratory has two options to choose when implementing a management system, Option A or Option B.

Option A: This option lists the main requirements for implementing a laboratory management system. This means that the laboratory can implement directly a management system based on the requirements of ISO/IEC 17025. In addition, the laboratory can choose to incorporate the requirements of ISO 9001 that are relevant for performing laboratory activities (ISO 17025, 2017).

Option B: When a laboratory chooses to implement a management system through Option B, they have to operate in accordance with the requirements of ISO 9001, in a way that fulfills requirements 4 to 7 of the ISO/IEC 17025 standard (ISO 17025, 2017).

The laboratory management can choose between implementing a management system in accordance to lists the minimum requirements for implementation of a management system in a laboratory and establish and maintain a management system in accordance with the requirements of ISO 9001. The documentation requirements related to the operation of the management system are: management system policies and objectives, analysis of customer feedback, corrective actions, non-conformities related records, internal audit and results records and management review input and output record. By introducing the risk-based thinking in the standard some reduction in prescriptive requirements and their replacement by performance-based requirements was possible. Risks and opportunities associated with the laboratory activities are new elements added in the recent revision of the standard. These activities are described throughout the standard and include risks related to impartiality, statements of conformity, nonconforming work and corrective actions (ISO 17025, 2017).

2.2 Relationship to ISO 9001:

ISO 9001 is the general standard which specific the requirements for a quality management system. Laboratories which meet the requirements of ISO 17025 also operate in accordance with the requirements of ISO 9001 that are relevant to testing and calibration activities. Depending on the laboratory business, the laboratory could assess its quality management system according to ISO 9001 or ISO 17025 standard. According to the ISO 17025 standard, the conformity of the quality management system with the requirements of ISO 9001 does not prove, by itself the

competence of the laboratory to produce technically valid data and results. A laboratory that is accredited according to the ISO 17025 standard does not guarantee the fulfillment of all ISO 9001 requirements. By the other side, ISO 9001 certified laboratory could not have enough technical competence to assess conformity of certain equipment, products or services or people. ISO 9001 standards is concerned mainly with what the laboratory does to ensure the compliance of their products or services according to customer requirements (Pizzolato *et al*., 2008). There are some important differences between the two standards (ISO 9001 and ISO17025), because ISO 17025 does not meet all the ISO 9001 requirements, mainly those related to product requirements and implementation requirements for monitoring and evaluate processes. Those laboratories that are interested in demonstrate technical competence should adopt the ISO 17025 standard. Moreover, those laboratories that are already accredited by the ISO 17025 standard and that are embedded in organizations that also carry out activities such as accounting, marketing, consulting, training and other, should evolve to an ISO 9001 quality management system (Pizzolato *et al*., 2008).

2.3 Laboratory accreditation:

2.3.1 Definition of accreditation:

ISO/IEC 17000:2004 defines accreditation as the third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (ISO 17000, 2004).

2.3.2 The advantages of being an accredited laboratory (according to International Laboratory Accreditation Cooperation (ILAC)):

2.3.2.1 A recognition of testing competence:

Laboratory accreditation provides formal recognition to competent laboratories, thus providing a ready means for customers to identify and

select reliable testing, measurement and calibration services. To maintain this recognition, laboratories are re-evaluated regularly by the accreditation body to ensure their continued compliance with requirements, and to check that their standard of operation is being maintained (ILAC, 2008).

2.3.2.2 A marketing advantage:

Accreditation is an effective marketing tool for testing, calibration and measurement organizations, and a passport to submit tenders to contractors that require independently verified laboratories. Laboratory accreditation is highly regarded both nationally and internationally as a reliable indicator of technical competence. Many industries, such as the construction materials industry, routinely specify laboratory accreditation for suppliers of testing services. Many accreditation bodies also publish a directory of their accredited laboratories, which includes the laboratories' contact details plus information on their testing capabilities. This is another means of promoting a laboratory's accredited services to potential clients. Through a system of international agreements accredited laboratories receive a form of international recognition, which allows their data to be more readily accepted in overseas markets. This recognition helps to reduce 20 costs for manufacturers and exporters that have their products or materials tested in accredited laboratories, by reducing or eliminating the need for retesting in another country (ILAC, 2008).

2.3.2.3 A benchmark for performance:

Laboratory accreditation benefits laboratories by allowing them to determine whether they are performing their work correctly and to appropriate standards, and provides them with a benchmark for maintaining that competence. Many such laboratories operate in isolation to their peers, and rarely, if ever, receive any independent technical

evaluation as a measure of their performance. A regular assessment by an accreditation body checks all aspects of a facility's operations related to consistently producing accurate and dependable data. Areas for improvement are identified and discussed, and a detailed report provided at the end of each visit. Where necessary, follow-up action is monitored by the accreditation body so the facility is confident that it has taken the appropriate corrective action (ILAC, 2008).

2.3.2.4 Enhance customer confidence and satisfaction:

Confidence in a product is enhanced if customers know it has been thoroughly evaluated by an independent, competent testing facility that is an accredited laboratory. Increasingly, customers are relying on independent evidence, rather than simply accepting a supplier's word that the product is fit for purpose (ILAC, 2008).

2.3.2.5 Avoid retesting:

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 (ILAC, 2008).

2.3.2.6 International recognition:

Laboratory accreditation ensures international acceptability of test data and facilitates trade among countries. This reduces cost for exporters and duplication of test in the importing countries (ILAC, 2008).

2.3.3 The Accreditation process:

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: increase in public confidence, assurance that quality data is being used to establish baselines for key analyses and decisions, reduced uncertainties associated with decisions that affect the protection of human health and the environment and improved efficiency of assessment process (Abdulraheem and Bakheit, 2017). 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, 2008). 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 a responsible organization for assessing national accreditation bodies and Mauritius Accreditation Service (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 quality management system (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 and Bakheit, 2017).

2.3.4 The choice between laboratory accreditation and ISO 9001 certification:

Accreditation uses criteria and procedures specifically developed to determine technical competence. Specialist technical assessors conduct a thorough evaluation of all factors in a laboratory that affect the production of test or calibration data. The criteria are based on the international standards called ISO/IEC 17025 or ISO 15189 (refer to specific brochure covering medical testing laboratories), which are used for evaluating laboratories throughout the world. Laboratory accreditation bodies use ISO/IEC 17025 to specifically assess factors relevant to the laboratory's technical competence, including the: technical competence of staff, validity and appropriateness of test methods, traceability of measurements and calibrations to national standards, suitability, calibration and maintenance of test equipment, testing environment, sampling, handling and transportation of test items and quality assurance

of test and calibration data. By this process, accreditation aims at assuring you and your customers that your laboratory's test or calibration data are accurate and reliable. The ISO 9001 standard is widely used in manufacturing and service organizations to evaluate their system for managing the quality of their product or service. Certification of an organization's quality management system against ISO 9001 aims at confirming the compliance of the management system to this standard. Whilst laboratories may be certified to ISO 9001, such certification does not make any statement about the technical competence of a laboratory (ILAC, 2008).

2.3.5 How do laboratories become accredit?

Laboratories can have either all or part of their testing and calibration activities accredited. The accreditation process involves a thorough evaluation of all the elements of a laboratory that contribute to the production of accurate and reliable test data. The evaluation process can take one to several days, and involves the use of specialist technical assessors who evaluate the specific types of testing or measurement being performed. The assessment criteria are based on the international standard ISO/IEC 17025, which is used for evaluating laboratories throughout the world. Laboratory accreditation bodies use this standard specifically to assess the factors listed earlier and relevant to a laboratory's ability to produce precise, accurate test and calibration data. At the end of the assessment a detailed report on the evaluation is presented to the laboratory, highlighting any areas that require attention and corrective action prior to the laboratory being recommended for accreditation. Once accredited, the laboratory is re-evaluated periodically to ensure its continued compliance with requirements, and to check that its standard of operation is being maintained (ILAC, 2008).

2.4 Previous studies:

A study done by Ahmed (2018) in impact of implementation of ISO 17025 in laboratories performance (Case study of Nano for measurement and calibration center, Khartoum Bahri- Sudan). The study focused on the relationship between the implementation of ISO 17025 and management system, customer satisfaction, performance and competence of personnel, key strategic result and improves of working environment. The study found a positive relationship between the implementation of ISO 17025 and management system, customer satisfaction, performance and competence of personnel, key strategic result and improve of working environment.

The current study is similar with the previous study in:

- Both of the studies focused on the requirements of standard of ISO 17025.
- Laboratory scope, both of the studies were conducted in laboratory for measurement and calibration.

The current study is differs from the previous study in:

- This study focused on the impact of accreditation on laboratories performance regarding ISO/IEC 17025:2017 while pervious study focused on impact of implementation of ISO 17025 on laboratories performance.

Another study done by Abbas (2018) in impact of implementation of ISO 17025 in DNA laboratory in Sudanese forensic laboratories, the study found that the training method inside DNA laboratory needs an improvement process. The service provided by DNA laboratory is partially good and with high quality, but it needs improvement process. There is no clear management system with known responsibility inside DNA laboratory. Working environment inside DNA laboratory is suitable and helps in correct testing results. Top management partially committed

for improving the management and technical system in DNA laboratories by implementing ISO/IEC 17025 quality system.

The current study is similar with the previous study in:

- Both of the studies focused on the implementation of ISO 17025 on Sudanese laboratories.

The current study is differs from the previous study in:

- Laboratory scope, this study was conducted in laboratory for measurement and calibration while previous study was conducted in laboratory for testing.
- This study focused on the impact of accreditation on laboratories performance regarding ISO/IEC 17025:2017 while pervious study focused on the requirements of standard of ISO 17025:2005.

A study done by Hamza (2015) in the impact of implementing ISO 17025:2005 standards and its role in improving the performance of the laboratories of Sudanese standards and metrology organization (SSMO), the study found that the awareness and perception of top managers of ISO requirements support them in the evaluation and measuring the system leading to desired result, work environment inside the laboratory was suitable and adequate to get correct, reliable testing results, implementing ISO 17025 improve the performance of the laboratory of (SSMO), there was a procedure to identify training needs, and the research was convinced that the (SSMO) was working to educate all employees and their knowledge of procedures for the application of ISO 17025:2005, the (SSMO) was committed to meet its customers' needs in high quality, that was through maintaining improvement, measurement accuracy and ensuring the consistency of the results.

The current study is similar with the previous study in:

- Both of the studies focused on the impact of implementing ISO 17025 standards and its roles in performance of the laboratories in Sudan.

The current study is differs from the previous study in:

- The present study was conducted in laboratory for calibration while previous study was conducted in laboratory for testing and calibration.
- This study focused on the requirements of standard of ISO 17025:2017 while previous study focused on the requirements of standard of ISO 17025:2005.

A study done by Elhuni (2016) in quality management system audit and its impact on company's performance in Libyan Petroleum Institute, Tripoli-Libya. The study examined the effect of ISO 17025 accreditation on laboratory performance in Libya. The results showed statistically positive or significant effects on laboratory performance. When a laboratory adopts ISO 17025 accreditation for merely gaining a marketing advantage, this correct motivation brings the laboratory positive outcomes such as high satisfactory and suspicious laboratory measurements and low satisfactory laboratory measurements. On the other hand, the laboratory adopts ISO accreditation for such purposes of improving quality, reliability, accuracy and consistency of its products, services and processes, and customer satisfaction, the laboratory can improve its laboratory performance, customers' loyalty and competitiveness in the market.

The current study is similar with the previous study in:

- Both previous study and this study focused on the impact of accreditation on laboratories performance regarding ISO/IEC 17025.

The current study differs from the previous study in:

- The current study was conducted in Sudanese laboratory in Nano for Measurement and Calibration Center while the pervious study was conducted in the Libyan Petroleum Institute, Tripoli-Libya.
- The current study focused on requirements of /IEC 17025:2017 while previous study focused on requirements of /IEC 17025:2005.

Another study done by Andargie (2019) in Challenges and impact of ISO/IEC 17025 accreditation in Ethiopian Conformity Assessment and Ethiopian National Metrology Institute. The study showed all respondents valued accreditation since it helped them to improve their laboratory operations and fulfill their customers' expectations. The study revealed that accreditation has had a positive impact on laboratory processes and has improved the level of competitive advantage; prevent retesting problems, an effective marketing tool, market share, customer trust. Moreover, the majority agreed that there was a better communication from management and they were satisfied to work in an accredited laboratory.

The current study is similar with the previous study in:

- Both previous study and this study focused on the impact of accreditation on laboratories performance regarding ISO/IEC 17025.

The current study differs from the previous study in:

- The current study implemented in Sudanese accredited laboratory in Nano for Measurement and Calibration Center while the previous study implemented in governmental institutes in Ethiopian Conformity Assessment and Ethiopian National Metrology Institute.

CHAPTER THREE

Materials and Methods

Chapter 3

Materials and methods

3.1 Study design:

It is a descriptive case study.

3.2 Study area:

The study was conducted at Nano for Measurement and Calibration Center, Khartoum state, Sudan. All staff were participated in the study.

3.2.1 Nano for Measurement and Calibration Center:

Nano for Measurement and Calibration Center started with the purpose of providing measurement and calibration services in 2006. In the year 2017, 21 values (parameters) were accredited from among the activities of the center's laboratories on the basis of the requirements of the standard ISO17025:2005 from the National Council for Accreditation in Egypt (EGAC). The scope of accreditation was expanded to (40) values (parameters) in the various laboratories of the center in the year 2018. During the years 2018 and 2019, the management system was reestablished based on the requirements of the standard ISO 17025:2017. The center provides its services to all industrial, service and medical establishments operating in Sudan. The accredited laboratories in the Nano for Measurement and Calibration Center are: Temperature Laboratory, Medical Instruments Laboratory, Dimensions Laboratory, Radio Frequency and Electrical Laboratory, Pressure Laboratory, Force Laboratory and Mass and Balance Laboratory (NMCC, 2019).

3.3 Study period:

The study was conducted during the interval from November 2020 to March 2021.

3.4 Data collection tools:

Self-administrated questionnaire (appendix) was used as the basic tool in this study. The quantitative survey consisted of questionnaire contained

four hypotheses that covered the research questions which were distributed to all Nano for Measurement and Calibration Center staff. The study depends on the questionnaire as a key to offer gathering information from the study population.

3.5 Data analysis:

The data obtained were analyzed using the Statistical Package for Social Sciences (SPSS). To achieve the objectives of the study, statistical methods were used the frequency distribution of the answers, the percentages and Chi-square test for the significance of differences between the test results considering all other variables. Then data were presented in tables.

3.6 Ethical consideration:

Study permissions were obtained from College of Graduate Studies-Sudan University of Science and Technology, then from management of Nano for Measurement and Calibration Center. Also, permission was taken from all individuals before being included in the study. Each individual was informed about the nature of the study.

CHAPTER FOUR

Results

Chapter 4

Results

4.1 General characteristics of study population:

The study was conducted on 34 study subjects, 22 (64.7%) were males and 12 (35.3%) were females. The age ranged between 20-44 years old. Regarding the academic level of study subjects, 19 (55.9%) were having a bachelor degree. Regarding the years of experience, 14 (41.2%) were having experience less than 10 years. Regarding the job title, 12 (35.3%) were engineer. Regarding the level of training on ISO 17025:2017, 18 (52.9%) were very good.

4.2 Reliability and validity of questionnaire:

Reliability and validity of questionnaire were shown in table (4.1).

Table (4.1): Reliability and validity of questionnaire

No.	The hypotheses	Reliability	Validity
1	There is a statistically significant relationship between accreditation and validity of results issue by laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.	0.93	0.96
2	There is a statistically significant relationship between accreditation and the performance and efficiency of employees according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.	0.89	0.94
3	There is a statistically significant relationship between accreditation and customer satisfaction according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.	0.65	0.81
4	There is a statistically significant relationship between accreditation and financial returned to the laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.	0.87	0.93
Total		0.92	0.96

4.3 The results of the first hypothesis (There is a statistically significant relationship between accreditation and validity of results issue by laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center):

4.3.1 The frequency distribution for the respondents' answers about the questions of the first hypothesis:

Table (4.2) showed: The laboratory management committed to impartiality by the strongly agree (85.3%) and agree by (14.7%) and neutral by (0.0%) and disagree by (0.0%) and strongly disagree by (0.0%). The information about the customer confidential between customer and laboratory by the strongly agree (79.4%) and agree by (17.6%) and neutral by (2.9%) and disagree by (0.0%) and strongly disagree by (0.0%). The facilities and environmental condition suitable for the laboratory activities by the strongly agree (67.6%) and agree by (23.5%) and neutral by (8.8%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory monitor, control and record environ mental conditions by the strongly agree (73.5%) and agree by (23.5%) and neutral by (2.9%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory implements an intermediate examination program by the strongly agree (47.1%) and agree by (47.1%) and neutral by (5.9%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory ensures that measurement results are traceable to the international system of unit (SI) by the strongly agree (82.4%) and agree by (14.7%) and neutral by (2.9%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory has a procedure to ensure the suitable external provider products and services by the strongly agree (70.6%) and agree by (20.6%) and neutral by (8.8%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory uses appropriate methods and procedures for all laboratory activities by the strongly agree (67.6%) and

agree by (32.4%) and neutral by (0.0%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory uses the last valid version of standard methods by the strongly agree (82.4%) and agree by (14.7%) and neutral by (2.9%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory validates of non-standard methods by the strongly agree (67.6%) and agree by (26.5%) and neutral by (5.9%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory has a procedure to evaluation of the measurement uncertainty by the strongly agree (82.4%) and agree by (17.6%) and neutral by (0.0%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory has a procedure for monitoring validity of the results by the strongly agree (70.6%) and agree by (23.5%) and neutral by (5.9%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory has a program to participant of inter laboratory comparisons by the strongly agree (70.6%) and agree by (26.5%) and neutral by (2.9%) and disagree by (0.0%) and strongly disagree by (0.0%).

Table (4.2): The frequency distribution for the respondents' answers about the questions of the first hypothesis

No.	Phrases	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	The laboratory management committed to impartiality.	29	5	0	0	0
		85.3%	14.7%	0.0%	0.0%	0.0%
2	The information about the customer confidential between customer and laboratory.	27	6	1	0	0
		79.4%	17.6%	2.9%	0.0%	0.0%
3	The facilities and environmental condition suitable for the laboratory activities.	23	8	3	0	0
		67.6%	23.5%	8.8%	0.0%	0.0%
4	The laboratory monitor, control and	25	8	1	0	0
		73.5%	23.5%	2.9%	0.0%	0.0%

	record environ mental conditions.					
5	The laboratory implements an intermediate examination program.	16	16	2	0	0
		47.1%	47.1%	5.9%	0.0%	0.0%
6	The laboratory ensures that measurement results are traceable to the international system of unit (SI).	28	5	1	0	0
		82.4%	14.7%	2.9%	0.0%	0.0%
7	The laboratory has a procedure to ensure the suitable external provider products and services.	24	7	3	0	0
		70.6%	20.6%	8.8%	0.0%	0.0%
8	The laboratory uses appropriate methods and procedures for all laboratory activities.	23	11	0	0	0
		67.6%	32.4%	0.0%	0.0%	0.0%
9	The laboratory uses the last valid version of standard methods.	28	5	1	0	0
		82.4%	14.7%	2.9%	0.0%	0.0%
10	The laboratory validates of non-standard methods.	23	9	2	0	0
		67.6%	26.5%	5.9%	0.0%	0.0%
11	The laboratory has a procedure to evaluation of the measurement uncertainty.	28	6	0	0	0
		82.4%	17.6%	0.0%	0.0%	0.0%
12	The laboratory has a procedure for monitoring validity of the results.	24	8	2	0	0
		70.6%	23.5%	5.9%	0.0%	0.0%
13	The laboratory has a program to participant of inter laboratory comparisons.	24	9	1	0	0
		70.6%	26.5%	2.9%	0.0%	0.0%

4.3.2 Chi-square test results for respondents' answers regarding the questions of the first hypothesis:

The results of table (4.3) interpreted as follows: the value of Chi-square calculated to signify the differences between "The laboratory management committed to impartiality" was (16.94) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The information about the customer confidential between customer and laboratory" was (33.58) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The facilities and environmental condition suitable for the laboratory activities" was (19.11) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory monitor, control and record environ mental conditions" was (26.88) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory implements an intermediate examination program" was (11.52) with p-value (0.003) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory ensures that measurement results are traceable to the international system of unit (SI)" was (37.47) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory has a procedure to

ensure the suitable external provider products and services" was (21.94) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory uses appropriate methods and procedures for all laboratory activities" was (4.23) with p-value (0.040) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory uses the last valid version of standard methods" was (37.47) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory validates of non-standard methods" was (20.17) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory has a procedure to evaluation of the measurement uncertainty" was (14.23) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory has a procedure for monitoring validity of the results" was (22.82) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory has a program to participant of inter laboratory comparisons" was (24.05) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences.

Table (4.3): Chi-square test results for respondents' answers regarding the questions of the first hypothesis

No.	Phrases	Chi-square value	Df	Sig.	Median	Interpretation
1	The laboratory management committed to impartiality.	16.94	1	0.000	5.00	Strongly agree
2	The information about the customer confidential between customer and laboratory.	33.58	2	0.000	5.00	Strongly agree
3	The facilities and environmental condition suitable for the laboratory activities.	19.11	2	0.000	5.00	Strongly agree
4	The laboratory monitor, control and record environ mental conditions.	26.88	2	0.000	5.00	Strongly agree
5	The laboratory implements an intermediate examination program.	11.52	2	0.003	5.00	Strongly agree
6	The laboratory ensures that measurement results are traceable to the international system of unit (SI).	37.47	2	0.000	5.00	Strongly agree
7	The laboratory has a procedure to ensure the suitable external provider products and services.	21.94	2	0.000	5.00	Strongly agree
8	The laboratory uses appropriate methods and procedures for all laboratory activities.	4.23	1	0.040	5.00	Strongly agree
9	The laboratory uses the last valid version of standard methods.	37.47	2	0.000	5.00	Strongly agree
10	The laboratory validates of non-standard methods.	20.17	2	0.000	5.00	Strongly agree
11	The laboratory has a procedure to evaluation of the measurement uncertainty.	14.23	1	0.000	5.00	Strongly agree
12	The laboratory has a procedure for monitoring validity of the results.	22.82	2	0.000	5.00	Strongly agree
13	The laboratory has a program to participant of inter laboratory comparisons.	24.05	2	0.000	5.00	Strongly agree

4.4 The results of the second hypothesis (There is a statistically significant relationship between accreditation and the performance and efficiency of employees according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center):

4.4.1 The frequency distribution for the respondents' answers about the questions of the second hypothesis:

Table (4.4) showed: All laboratory employees have a clear job description that defines responsibilities and authorities by the strongly agree (58.8%) and agree by (29.4%) and neutral by (8.8%) and disagree by (2.9%) and strongly disagree by (0.0%). The laboratory trains employees according to a procedure that determines the training need by the strongly agree (26.5%) and agree by (29.4%) and neutral by (35.3%) and disagree by (5.9%) and strongly disagree by (2.9%). The laboratory supports the training program and the development of personal skills by the strongly agree (38.2%) and agree by (32.4%) and neutral by (26.5%) and disagree by (2.9%) and strongly disagree by (0.0%). The laboratory measures the effectiveness training program by the strongly agree (29.4%) and agree by (29.4%) and neutral by (32.4%) and disagree by (5.9%) and strongly disagree by (2.9%). The laboratory measures the returner of training by the strongly agree (35.3%) and agree by (32.4%) and neutral by (26.5%) and disagree by (2.9%) and strongly disagree by (2.9%). The laboratory has a procedure for monitoring and evaluation of personnel performance by the strongly agree (67.6%) and agree by (17.6%) and neutral by (8.8%) and disagree by (2.9%) and strongly disagree by (2.9%). Accreditation according to ISO/ IEC 17025 requirements increases employees' confidence in doing their jobs by the strongly agree (73.5%) and agree by (23.5%) and neutral by (2.9%) and disagree by (0.0%) and strongly disagree by (0.0%).

Table (4.4): The frequency distribution for the respondents' answers about the questions of the second hypothesis

No.	Phrases	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	All laboratory employees have a clear job description that defines responsibilities and authorities.	20	10	3	1	0
		58.8%	29.4%	8.8%	2.9%	0.0%
2	The laboratory trains employees according to a procedure that determines the training need.	9	10	12	2	1
		26.5%	29.4%	35.3%	5.9%	2.9%
3	The laboratory supports the training program and the development of personal skills.	13	11	9	1	0
		38.2%	32.4%	26.5%	2.9%	0.0%
4	The laboratory measures the effectiveness training program.	10	10	11	2	1
		29.4%	29.4%	32.4%	5.9%	2.9%
5	The laboratory measures the returner of training.	12	11	9	1	1
		35.3%	32.4%	26.5%	2.9%	2.9%
6	The laboratory has a procedure for monitoring and evaluation of personnel performance.	23	6	3	1	1
		67.6%	17.6%	8.8%	2.9%	2.9%
7	Accreditation according to ISO/ IEC 17025 requirements increases employees' confidence in doing their jobs.	25	8	1	0	0
		73.5%	23.5%	2.9%	0.0%	0.0%

4.4.2 Chi-square test results for respondents' answers regarding the questions of the second hypothesis:

The results of table (4.5) interpreted as follows: The value of Chi-square calculated to signify the differences between "All laboratory employees have a clear job description that defines responsibilities and authorities" was (26.00) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory trains employees according to a procedure that determines the training need" was (14.52) with p-value (0.006) which

was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between “The laboratory supports the training program and the development of personal skills” was (9.76) with p-value (0.021) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between “The laboratory measures the effectiveness training program” was (13.94) with p-value (0.007) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between “The laboratory measures the returner of training” was (17.17) with p-value (0.002) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between “The laboratory has a procedure for monitoring and evaluation of personnel performance” was (50.70) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between “Accreditation according to ISO/ IEC 17025 requirements increases employees' confidence in doing their jobs” was (26.88) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences.

Table (4.5): Chi-square test results for respondents' answers regarding the questions of the second hypothesis

No.	Phrases	Chi-square value	Df	Sig.	Median	Interpretation
1	All laboratory employees have a clear job description that defines responsibilities and authorities.	26.00	3	0.000	5.00	Strongly agree
2	The laboratory trains employees according to a procedure that determines the training need.	14.52	4	0.006	4.00	Agree
3	The laboratory supports the training program and the development of personal skills.	9.76	3	0.021	4.00	Agree
4	The laboratory measures the effectiveness training program.	13.94	4	0.007	4.00	Agree
5	The laboratory measures the returner of training.	17.17	4	0.002	4.00	Agree
6	The laboratory has a procedure for monitoring and evaluation of personnel performance.	50.70	4	0.000	5.00	Strongly agree
7	Accreditation according to ISO/ IEC 17025 requirements increases employees' confidence in doing their jobs.	26.88	2	0.000	5.00	Strongly agree

4.5 The results of the third hypothesis (There is a statistically significant relationship between accreditation and customer satisfaction according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center):

4.5.1 The frequency distribution for the respondents' answers about the questions of the third hypothesis:

Table (4.6) showed: The laboratory has the resources and capability to meet customer request by the strongly agree (38.2%) and agree by (50.0%) and neutral by (11.8%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory has a clear contract with the customer before beginning the calibration process by the strongly agree (64.7%) and agree by (32.4%) and neutral by (2.9%) and disagree by (0.0%) and

strongly disagree by (0.0%). The laboratory informs the customer of any deviation from contract by the strongly agree (64.7%) and agree by (35.3%) and neutral by (0.0%) and disagree by (0.0%) and strongly disagree by (0.0%). The laboratory commits with the agreed delivery time by the strongly agree (8.8%) and agree by (47.1%) and neutral by (26.5%) and disagree by (17.6%) and strongly disagree by (0.0%). The laboratory provides the calibration service at an appropriate cost compared to accredited laboratories by the strongly agree (38.2%) and agree by (41.2%) and neutral by (14.7%) and disagree by (5.9%) and strongly disagree by (0.0%). The laboratory responds to comments, complaints and suggestions and is handled with caution by the strongly agree (26.5%) and agree by (67.6%) and neutral by (5.9%) and disagree by (0.0%) and strongly disagree by (0.0%).

Table (4.6): The frequency distribution for the respondents' answers about the questions of the third hypothesis

No.	Phrases	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	The laboratory has the resources and capability to meet customer request.	31	17	4	0	0
		38.2%	50.0%	11.8%	0.0%	0.0%
2	The laboratory has a clear contract with the customer before beginning the calibration process.	22	11	1	0	0
		64.7%	32.4%	2.9%	0.0%	0.0%
3	The laboratory informs the customer of any deviation from contract.	22	12	0	0	0
		64.7%	35.3%	0.0%	0.0%	0.0%
4	The laboratory commits with the agreed delivery time.	3	16	9	6	0
		8.8%	47.1%	26.5%	17.6%	0.0%
5	The laboratory provides the calibration service at an appropriate cost compared to accredited laboratories.	13	14	5	2	0
		38.2%	41.2%	14.7%	5.9%	0.0%
6	The laboratory responds to comments, complaints and suggestions and is handled with caution.	9	23	2	0	0
		26.5%	67.6%	5.9%	0.0%	0.0%

4.5.2 Chi-square test results for respondents' answers regarding the questions of the third hypothesis:

The results of table (4.7) interpreted as follows: The value of Chi-square calculated to signify the differences between "The laboratory has the resources and capability to meet customer request" was (7.82) with p-value (0.020) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory has a clear contract with the customer before beginning the calibration process" was (19.47) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory informs the customer of any deviation from contract" was (12.94) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory commits with the agreed delivery time" was (10.94) with p-value (0.012) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory provides the calibration service at an appropriate cost compared to accredited laboratories" was (12.35) with p-value (0.006) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory responds to comments, complaints and suggestions and is handled with caution" was (20.17) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences.

Table (4.7): Chi-square test results for respondents' answers regarding the questions of the third hypothesis

No.	Phrases	Chi-square value	Df	Sig.	Median	Interpretation
1	The laboratory has the resources and capability to meet customer request.	7.82	2	0.020	4.00	Agree
2	The laboratory has a clear contract with the customer before beginning the calibration process.	19.47	2	0.000	5.00	Strongly agree
3	The laboratory informs the customer of any deviation from contract.	12.94	1	0.000	5.00	Strongly agree
4	The laboratory commits with the agreed delivery time.	10.94	3	0.012	4.00	Agree
5	The laboratory provides the calibration service at an appropriate cost compared to accredited laboratories.	12.35	3	0.006	4.00	Agree
6	The laboratory responds to comments, complaints and suggestions and is handled with caution.	20.17	2	0.000	4.00	Agree

4.6 The results of the fourth hypothesis (There is a statistically significant relationship between accreditation and financial returned to the laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center):

4.6.1 The frequency distribution for the respondents' answers about the questions of the fourth hypothesis:

Table (4.8) showed: Accreditation of laboratory according to ISO/IEC17025:2017 helps in achievement of the planned strategic objectives by the strongly agree (58.8%) and agree by (32.4%) and neutral by (8.8%) and disagree by (0.0%) and strongly disagree by (0.0%). Accreditation of laboratory according to ISO/IEC 17025:2017 helps in controlling and reduces undesired activities by the strongly agree (70.6%) and agree by (26.5%) and neutral by (2.9%) and disagree by (0.0%) and strongly disagree by (0.0%). Accreditation of laboratory according to ISO /IEC 17025:2017 increases the market share by the

strongly agree (67.6%) and agree by (26.5%) and neutral by (5.9%) and disagree by (0.0%) and strongly disagree by (0.0%). Accreditation of laboratory according to ISO/IEC 17025:2017 increases the value of revenue by the strongly agree (50.0%) and agree by (41.2%) and neutral by (8.8%) and disagree by (0.0%) and strongly disagree by (0.0%). Accreditation of laboratory according to ISO/IEC 17025:2017 helps in customer loyalty by the strongly agree (67.6%) and agree by (32.4%) and neutral by (0.0%) and disagree by (0.0%) and strongly disagree by (0.0%). Accreditation of laboratory according to ISO/IEC 17025:2017 consider the advantage in the market competition by the strongly agree (67.6%) and agree by (29.4%) and neutral by (2.9%) and disagree by (0.0%) and strongly disagree by (0.0%). Accreditation of laboratory according to ISO/IEC 17025:2017 helps the laboratory to accept the results nationality an abroad by the strongly agree (76.5%) and agree by (23.5%) and neutral by (0.0%) and disagree by (0.0%) and strongly disagree by (0.0%).

Table (4.8): The frequency distribution for the respondents' answers about the questions of the fourth hypothesis

No.	Phrases	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	Accreditation of laboratory according to ISO/IEC17025:2017 helps in achievement of the planned strategic objectives.	20	1	3	0	0
		58.8%	32.4%	8.8%	0.0%	0.0%
2	Accreditation of laboratory according to ISO/IEC 17025:2017 helps in controlling and reduces undesired activities.	24	9	1	0	0
		70.6%	26.5%	2.9%	0.0%	0.0%
3	Accreditation of laboratory according to ISO /IEC 17025:2017 increases the market share.	23	9	2	0	0
		67.6%	26.5%	5.9%	0.0%	0.0%
4	Accreditation of laboratory according to ISO/IEC	17	14	3	0	0
		50.0%	41.2%	8.8%	0.0%	0.0%

	17025:2017 increases the value of revenue.					
5	Accreditation of laboratory according to ISO/IEC 17025:2017 helps in customer loyalty.	23	11	0	0	0
		67.6%	32.4%	0.0%	0.0%	0.0%
6	Accreditation of laboratory according to ISO/IEC 17025:2017 considers the advantage in the market competition.	23	10	1	0	0
		67.6%	29.4%	2.9%	0.0%	0.0%
7	Accreditation of laboratory according to ISO/IEC 17025:2017 helps the laboratory to accept the results nationality an abroad.	26	8	0	0	0
		76.5%	23.5%	0.0%	0.0%	0.0%

4.6.2 Chi-square test results for respondents' answers regarding the questions of the fourth hypothesis:

The results of table (4.9) interpreted as follows: The value of Chi-square calculated to signify the differences between "Accreditation of laboratory according to ISO/IEC17025:2017 helps in achievement of the planned strategic objectives" was (12.76) with p-value (0.002) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Accreditation of laboratory according to ISO/IEC 17025:2017 helps in controlling and reduces undesired activities" was (24.05) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Accreditation of laboratory according to ISO /IEC 17025:2017 increases the market share" was (20.17) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Accreditation of laboratory according to ISO/IEC

17025:2017 increases the value of revenue" was (9.58) with p-value (0.008) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Accreditation of laboratory according to ISO/IEC 17025:2017 helps in customer loyalty" was (4.23) with p-value (0.040) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Accreditation of laboratory according to ISO/IEC 17025:2017 considers the advantage in the market competition" was (21.58) with p-value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Accreditation of laboratory according to ISO/IEC 17025:2017 helps the laboratory to accept the results nationality an abroad" was (9.52) with p-value (0.002) which was lower than the level of significant value (5%), these refer to the existence of statistically differences.

Table (4.9): Chi-square test results for respondents' answers regarding the questions of the fourth hypothesis

No.	Phrases	Chi-square value	Df	Sig.	Median	Interpretation
1	Accreditation of laboratory according to ISO/IEC17025:2017 helps in achievement of the planned strategic objectives.	12.76	2	0.002	5.00	Strongly agree
2	Accreditation of laboratory according to ISO/IEC 17025:2017 helps in controlling and reduces undesired activities.	24.05	2	0.000	5.00	Strongly agree

3	Accreditation of laboratory according to ISO /IEC 17025:2017 increases the market share.	20.17	2	0.000	5.00	Strongly agree
4	Accreditation of laboratory according to ISO/IEC 17025:2017 increases the value of revenue.	9.58	2	0.000	4.50	Strongly agree
5	Accreditation of laboratory according to ISO/IEC 17025:2017 helps in customer loyalty.	4.23	1	0.040	5.00	Strongly agree
6	Accreditation of laboratory according to ISO/IEC 17025:2017 considers the advantage in the market competition.	21.58	2	0.000	5.00	Strongly agree
7	Accreditation of laboratory according to ISO/IEC 17025:2017 helps the laboratory to accept the results nationality an abroad.	9.52	1	0.002	5.00	Strongly agree

4.7 Result of hypotheses of the study:

4.7.1 Result of the first hypothesis (There is a statistically significant relationship between accreditation and validity of results issue by laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center):

Table (4.10) showed that the value of the Chi-square test (29.52) by significant value (0.00) it was less than the probability value (0.05) and coefficient correlation (0.67), this means that there was a statistically significant relationship between accreditation and validity of results issue

by laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center**.**

Table (4.10): Result of first hypothesis (There is a statistically significant relationship between accreditation and validity of results issue by laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center)

No.	Coefficient correlation	Chi-square	Df	Sig.	Median	Scale	Statistical significant
34	0.67	29.52	3	0.000	5.00	Strongly agree	Significant

4.7.2 Result of the second hypothesis (There is a statistically significant relationship between accreditation and the performance and efficiency of employees according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center):

Table (4.11) showed that the value of the Chi-square test (14.70) by significant value (0.00) it was less than the probability value (0.05) and coefficient correlation (0.51), this means that there was a statistically significant relationship between accreditation and the performance and efficiency of employees according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.

Table (4.11): Result of the second hypothesis (There is a statistically significant relationship between accreditation and the performance and efficiency of employees according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center)

No.	Coefficient correlation	Chi-square	Df	Sig.	Median	Scale	Statistical significant
34	0.51	14.70	3	0.000	4.00	Agree	Significant

4.7.3 Result of the third hypothesis (There is a statistically significant relationship between accreditation and customer satisfaction according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center):

Table (4.12) showed that the value of the Chi-square test (21.88) by significant value (0.00) it was less than the probability value (0.05) and coefficient correlation (0.66), this means that there was a statistically significant relationship between accreditation and customer satisfaction according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.

Table (4.12): Result of the third hypothesis (There is a statistically significant relationship between accreditation and customer satisfaction according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center)

No.	coefficient correlation	Chi-square	Df	Sig.	Median	Scale	Statistical significant
34	0.66	21.88	3	0.000	4.00	Agree	Significant

4.7.4 Result of the fourth hypothesis (There is a statistically significant relationship between accreditation and financial returned to the laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center):

Table (4.13) showed that the value of the Chi-square test (24.05) by significant value (0.00) it was less than the probability value (0.05) and coefficient correlation (0.63), this means that there was a statistically significant relationship between accreditation and financial returned to the laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.

Table (4.13): Result of the fourth hypothesis (There is a statistically significant relationship between accreditation and financial returned to the laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center)

No.	Coefficient correlation	Chi-square	Df	Sig.	Median	Scale	Statistical significant
34	0.63	24.05	3	0.000	5.00	Strongly agree	Significant

CHAPTER FIVE

Discussion, Conclusion and Recommendations

Chapter 5

Discussion, conclusion and recommendations

5.1 Discussion

The current study showed that the most frequency distribution for the respondents' answers regarding the questions of the first hypothesis was strongly agree for the statement (The laboratory management committed to impartiality), in general, means that most of the respondents have strongly agreed with all what mentioned about the first hypothesis. Regarding the first hypothesis, the results showed that the value of the Chi-square test by significant value it was less than the probability value and coefficient correlation, this means that there was a statistically significant relationship between accreditation and validity of results issue by laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center. The results reflected that the most frequency distribution for the respondents' answers regarding the questions of the second hypothesis was agree for the statement (The laboratory supports the training program and the development of personal skills), in general, means that most of the respondents have agreed with all what mentioned about the second hypothesis. The results of second hypothesis showed that the value of the Chi-square test by significant it was less than the probability value and coefficient correlation, this means that there was a statistically significant relationship between accreditation and the performance and efficiency of employees according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center. The present study showed that the most frequency distribution for the respondents' answers regarding the questions of the third hypothesis was agree for the statement (The laboratory responds to comments, complaints and suggestions and is handled with caution), means that most of the respondents have agreed with all what mentioned

about the third hypothesis. The results of third hypothesis showed that the value of the Chi-square test by significant value it was less than the probability value and coefficient correlation, this means that there was a statistically significant relationship between accreditation and customer satisfaction according to requirement of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center. The present study illustrated that the most frequency distribution for the respondents' answers regarding the questions of the fourth hypothesis was strongly agree for the statement (Accreditation of laboratory according to ISO/IEC 17025:2017 helps in controlling and reduces undesired activities), means that most of the respondents have strongly agreed with all what mentioned about the fourth hypothesis. The results of fourth hypothesis showed that the value of the Chi-square test by significant value it was less than the probability value and coefficient correlation, this means that there was a statistically significant relationship between accreditation and financial returned to the laboratory according to requirement of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center. The findings of the present study were in agreement with the findings of Ahmed (2018) who found that there was a positive relationship between implementing of ISO/IEC17025 standard and increase customers satisfaction. Also, the findings of the present study were in agreement with the findings of Abbas (2018) who found that the work environment inside the laboratory was suitable and helped in correct results and provided implementing ISO system enhanced the performance and the quality of the laboratory. The findings from the present study were in agreement with findings of Hamza (2015) who found that the awareness and perception of top managers of ISO helped them in the process of evaluation and measuring the system as well achieving intended results, work environment inside the laboratory was suitable and helped in correct testing results and

provided implementing ISO system enhanced the performance and the quality of the laboratory. The results obtained from the current study were in agreement with the results obtained by Elhuni (2016) who found that there was a statistically positive or significant effect of accreditation on laboratory performance. The findings obtained from the current study were in agreement with the findings obtained by Andargie (2019) who found that the accreditation have a positive impact on laboratory processes and have improved the level of competitive advantage; prevent retesting problems, an effective marketing tool, market share, customer trust. Moreover, the majority agreed that there was a better communication from management and they were satisfied to work in an accredited laboratory. The current study and previous showed that there was a significant effect of accreditation on the whole system in the laboratory. This effect appears through the performance of personnel in the laboratory so that accreditation ensures that personnel receive appropriate training to perform the required tasks and this has a positive effect on the validity of the results issued by the laboratory. Accreditation is considered a competitive advantage and an effective marketing performance for the laboratory, as the accreditation has a great impact in developing the infrastructure for quality and facilitating the movement of trade exchange between countries. The lack of accreditation leads to a major defect in the system within the laboratory.

5.2 Conclusion:

The study concluded that accreditation have a positive impact on validity of results issue by laboratory, the performance and efficiency of employees, customer satisfaction and financial returned to the laboratory in Nano for Measurement and Calibration Center.

5.3 Recommendations:

Based on the results of the study, recommended that the laboratory management should:

- Train employees according to a procedure that determines the training need, measure the effectiveness training program and measure the returner of training.
- Have a procedure for monitoring and evaluation of personnel performance.
- Commit with the agreed delivery time.
- Provide the calibration service at an appropriate cost compared to accredited laboratories.

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APPENDICES

Appendix (1)

جامعة السودان للعلوم والتكنولوجيا

كلية الدراسات العليا

الاخ/ الاخت .....المحترم/المحترمة

السلام عليكم ورحمة الله تعالى وبركاته

الموضـــــوع/ إستبيـــــــــــان

بالإشارة إلى الموضوع أعلاه أرجو شاكراً ملء إستمارة الإستبيان بغرض إستكمال متطلبات الحصول على درجة الماجستير من جامعة السودان للعلوم والتكنولوجيا فى تخصص إدارة الجودة الشاملة والإمتياز. إذ أننى أُجرى بحث بعنوان:

أثر الإعتماد على آداء المختبرات فيما يتعلق بالآيزو 2017:17025 (دراسة حالة: مركز نانو للقياس و المعايرة، ولاية الخرطوم– السودان)

أرجو شاكراً المشاركة والإجابة على هذا الإستبيان علماً بأن إجابتكم ستعامل باقصى درجات السرية ولن يتم استخدامها الاّ لأغراض هذا البحث العلمي فقط وبالطبع تعتمد عليها دقة وصحة النتائج التى سيخرج بها هذا البحث.

ولكم جزيل الشكر لحسن تعاونكم ،،،

الباحث:

شريف محمود حسن محمد

اولاً: البيانات الشخصية:

الرجاء وضع علامة (√) أمام الإجابة التي تختارها:

أ/النوع:

١. ذكر ☐ ٢. أنثى ☐

ب/ العمـــــــر:

١. أقل من ٢٥ سنة ☐ ٢. ٢٥ سنة وأقل من ٣٥ سنة ☐

٣. ٣٥ سنة وأقل من ٤٥ سنة ☐ ٤. ٤٥ سنة وأقل من ٥٥ سنة ☐

٥. أكثر من ٥٥ سنة ☐

ج/ المستوى التعليمي:

١. ثانوي ☐ ٢. دبلوم ☐

٣. بكالريوس ☐ ٤. ماجستير ☐

٥. دكتوراه ☐

د/ مدة شغل الوظيفة:

١. أقل من ٥ سنة ☐ ٢. ٥ سنة وأقل من ١٠ سنة ☐

٣. ١٠ سنة وأقل من ١٥ سنة ☐ ٤. ١٥ سنة وأقل من ٢٠ سنة ☐

٥. ٢٠ سنة فأكثر ☐

هـ/ المسمى الوظيفي:

١. تقني ☐ ٢. كيميائي ☐

٣. مهندس ☐ ٤. رئيس قسم ☐

٥. مدير إدارة ☐

و/ مستوى تدريبك على المواصفة القياسية ISO/IEC17025:2017:

١. ضعيف ☐ ٢. متوسط ☐

٣. جيد ☐ ٤. جيد جداً ☐

٥. ممتاز ☐

ثانياً: قياس متغيرات الدراسة:-

الرجاء وضع علامة (√) امام مستوى الموافقة المناسب:

الفرضية الأولى: هناك علاقة ذات دلالة إحصائية بين الإعتماد وصحة النتائج الصادرة من المختبر وفقاً لمتطلبات ISO/IEC17025:2017 بمركز نانو للقياس والمعايرة .

العبـــــــــــارة	أوافق بشدة	أوافق	محايد	لا أوافق	لا أوافـــق بشدة
١- تلتزم إدارة المختبر بالحياد.					
٢- المعلومـــات الخاصـــة بالعميـــل ســـرية بـــين العميـــل والمختبر.					
٣- المرافق والظروف البيئية مناسبة لأنشطة المختبر.					
٤- يقوم المختبر برصد ومراقبة وتسجيل الظروف البيئية.					
٥- ينفذ المختبر برنامج الفحص المتوسط.					
٦- يضمن المختبر إمكانية تتبع نتائج القياس في النظام الدولي للوحدة (SI).					
٧- لدى المختبر إجراء لضمان منتجات وخدمات المزود الخارجي المناسب.					
٨- يستخدم المختبر الأساليب والإجراءات المناسبة لجميع أنشطة المختبر.					
٩- يستخدم المختبر آخر نسخة صالحة للطرق القياسية.					
١٠- يتحقق المختبر من الأساليب غير القياسية.					
١١- المختبر لديه إجراء لتقييم الارتياب في القياس.					
١٢- المختبر لديه إجراء لرصد صحة النتائج.					
١٣- يحتوي المختبر على برنامج للمشاركة في المقارنات بين المختبرات.					

الفرضية الثانية: هنالك علاقة ذات دلالة إحصائية بين الإعتماد و آداء و كفاءة العاملين وفقاً لمتطلبات ISO/IEC17025:2017 بمركز نانو للقياس والمعايرة .

العبـــــــــــــارة	أوافق بشدة	أوافق	محايد	لا أوافق	لا أوافـــق بشدة
١- لـدى جميـع العـاملين بـالمختبر وصـف وظيفـي واضـح يحدد المسؤوليات و الصلاحيات.					
٢- يقوم المختبر بتدريب العاملين وفق إجراء يحدد الحاجة التدريبية.					
٣- يـدعم المختبـر برنـامج التـدريب وتنميـة المهـارات الشخصية.					
٤- يقيس المختبر برنامج التدريب الفعال.					
٥- يقيس المختبر العائد من التدريب.					
٦- لدى المختبر إجراء لرصد وتقييم أداء الموظفين.					
٧- الإعتماد وفقاً لمتطلبات الآيزو ١٧٠٢٥ يزيد من ثقة العاملين في آداء أعمالهم.					

الفرضية الثالثة: هنالك علاقة ذات دلالة إحصائية بين الإعتماد و رضا العملاء وفقاً لمتطلبات ISO/IEC17025:2017 بمركز نانو للقياس والمعايرة .

العبـــــــــــــارة	أوافق بشدة	أوافق	محايد	لا أوافق	لا أوافـــق بشدة
١- يمتلك المختبر الموارد والقدرة على تلبية طلبات العملاء.					
٢- المختبر لديه عقد واضح مع العميل قبل البدء في عملية المعايرة.					
٣- يقوم المختبر بإبلاغ العميل بأي انحراف عن العقد					
٤- يلتزم المختبر بوقت التسليم المتفق عليه.					
٥- يقدم المختبر خدمة المعايرة بتكلفة مناسبة مقارنة بالمختبرات المعتمدة.					
٦- يستجيب المختبر للتعليقات والشكاوى والاقتراحات ويتم التعامل معها بحذر.					

الفرضية الرابعة: هنالك علاقة ذات دلالة إحصائية بين الإعتماد و العائد المادي للمختبر وفقاً لمتطلبات ISO/IEC17025:2017 بمركز نانو للقياس والمعايرة .

العبـــــــــــــارة	أوافق بشدة	أوافق	محايد	لا أوافق	لا أوافـــق بشدة
١- يساعد اعتماد المختبر وفقاً لمتطلبات الآيزو 17025 في تحقيق الأهداف الإستراتيجية المخطط لها.					
٢- يساعد اعتماد المختبر وفقاً لمتطلبات الآيزو 17025 في التحكم و تقليل الأنشطة غير المرغوب فيها.					
٣- اعتماد المختبر وفقاً لمتطلبات الآيزو 17025 يزيد من الحصة السوقية.					
٤ اعتماد المختبر وفقاً لمتطلبات الآيزو 17025 يزيد من قيمة الإيرادات.					
٥- يساعد اعتماد المختبر وفقاً لمتطلبات الآيزو 17025 في ولاء العملاء.					
٦ اعتماد المختبر وفقاً لمتطلبات الآيزو 17025 يراعي الميزة في المنافسة في السوق.					
٧- اعتماد المختبر وفقاً لمتطلبات الآيزو 17025 يساعد المختبر على قبول نتائج الجنسية بالخارج.					

Appendix (2)

Sudan University of Science and Technology

College of Graduate Studies

Mr./Mrs.……

Peace, mercy and blessings of God

The subject: Questionnaire

With reference to the above, I would like to thank you for completing the questionnaire in order to complete the requirements for obtaining a master's degree in Sudan University of Science and Technology in the field of Total Quality Management and Excellence entitled:

The Impact of Accreditation on Laboratories Performance Regarding ISO/IEC 17025:2017 (A Case Study: Nano for Measurement and Calibration Center, Khartoum State- Sudan)

Please note that the data obtained will be used for the purpose of scientific research only and will be treated with strict confidentiality.

Thank you very much for your cooperation

Researcher:

Shareef Mahmoud Hassan Mohamed

Firstly: Personal information:

Please put (√) in the appropriate answer square which suit for you:

A. Sex:

1. Male ☐ 2. Female ☐

B. Age (years):

1. Less than 25 ☐ 2. 25 to 34 ☐

3. 35 to 44 ☐ 4. 45 to 54 ☐

5. More than 54 ☐

C. Academic level:

1. Secondary school ☐ 2. Diploma ☐

3. Bachelors ☐ 4. Master ☐

5. Doctorate ☐

D. Years of experience (years):

1. Less than 5 ☐ 2. 5 and less than 10 ☐

3. 10 and less than 15 ☐ 4. 15 and less than 20 ☐

5. More than 20 ☐

E. Job Title:

1. Technician ☐ 2. Chemist ☐

3. Engineer ☐ 4. Section head ☐

5. Department manager ☐

F. Level of training on ISO 17025:2017:

1. Poor ☐ 2. Moderate ☐

3. Good ☐ 4. Very good ☐

5. Excellent ☐

Secondly: Measuring the study variables

Please put (√) mark in the answer square that suits your opinion:

The first hypothesis:

There is a statistically significant relationship between accreditation and validity of results issue by laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.

The phrase	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1- The laboratory management committed to impartiality.					
2- The information about the customer confidential between customer and laboratory.					
3- The facilities and environmental condition suitable for the laboratory activities.					
4- The laboratory monitor, control and record environ mental conditions.					
5- The laboratory implements an intermediate examination program.					
6- The laboratory ensures that measurement results are traceable to the international system of unit (SI).					
7- The laboratory has a procedure to ensure the suitable external provider products and services.					
8- The laboratory uses appropriate methods and procedures for all laboratory activities.					
9- The laboratory uses the last valid version of standard methods.					
10- The laboratory validates of non-standard methods.					
11- The laboratory has a procedure to evaluation of the measurement uncertainty.					
12- The laboratory has a procedure for monitoring validity of the results.					
13- The laboratory has a program to participant of inter laboratory comparisons.					

The second hypothesis:

There is a statistically significant relationship between accreditation and the performance and efficiency of employees according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.

The phrase	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1- All laboratory employees have a clear job description that defines responsibilities and authorities.					
2- The laboratory trains employees according to a procedure that determines the training need.					
3- The laboratory supports the training program and the development of personal skills.					
4- The laboratory measures the effectiveness training program.					
5- The laboratory measures the returner of training.					
6- The laboratory has a procedure for monitoring and evaluation of personnel performance.					
7- Accreditation according to ISO/ IEC 17025 requirements increases employees' confidence in doing their jobs.					

The third hypothesis:

There is a statistically significant relationship between accreditation and customer satisfaction according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.

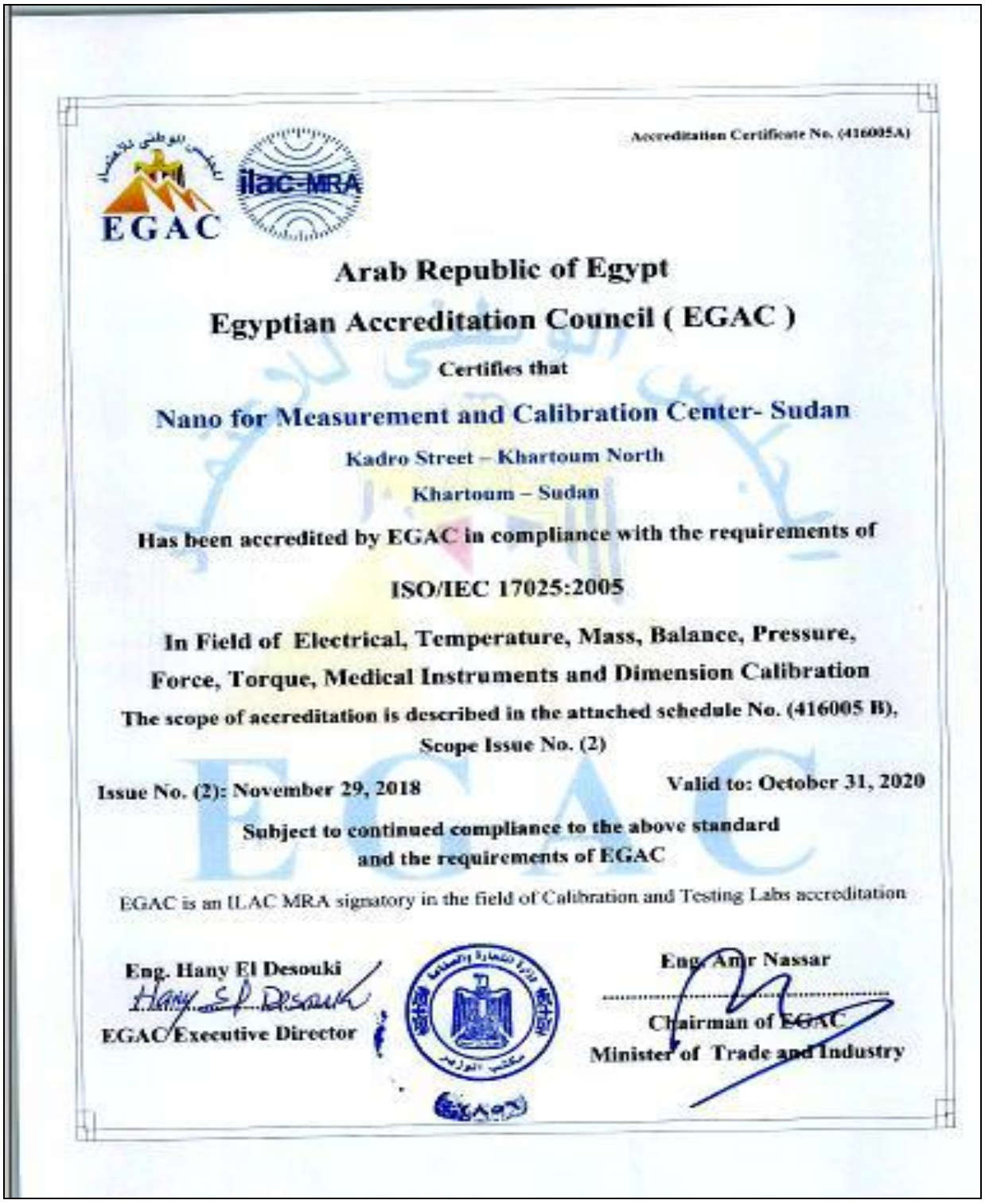
The phrase	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1- The laboratory has the resources and capability to meet customer request.					
2- The laboratory has a clear contract with the customer before beginning the calibration process.					
3- The laboratory informs the customer of any deviation from contract.					
4- The laboratory commits with the agreed delivery time.					
5- The laboratory provides the calibration service at an appropriate cost compared to accredited laboratories.					
6- The laboratory responds to comments, complaints and suggestions and is handled with caution.					

The fourth hypothesis:

There is a statistically significant relationship between accreditation and financial returned to the laboratory according to requirements of ISO/IEC17025:2017 in Nano for Measurement and Calibration Center.

The phrase	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1- Accreditation of laboratory according to ISO/IEC17025:2017 helps in achievement of the planned strategic objectives.					
2- Accreditation of laboratory according to ISO/IEC 17025:2017 helps in controlling and reduces undesired activities.					
3- Accreditation of laboratory according to ISO /IEC 17025:2017 increases the market share.					
4- Accreditation of laboratory according to ISO/IEC 17025:2017 increases the value of revenue.					
5- Accreditation of laboratory according to ISO/IEC 17025:2017 helps in customer loyalty.					
6- Accreditation of laboratory according to ISO/IEC 17025:2017 consider the advantage in the market competition.					
7- Accreditation of laboratory according to ISO/IEC 17025:2017 helps the laboratory to accept the results nationality an abroad.					

Appendix (3):



Accreditation Certificate No. (416005A)

EGAC

ilac-MRA

Arab Republic of Egypt

Egyptian Accreditation Council (EGAC)

Certifies that

Nano for Measurement and Calibration Center- Sudan

Kadro Street – Khartoum North

Khartoum – Sudan

Has been accredited by EGAC in compliance with the requirements of

ISO/IEC 17025:2005

In Field of Electrical, Temperature, Mass, Balance, Pressure, Force, Torque, Medical Instruments and Dimension Calibration

The scope of accreditation is described in the attached schedule No. (416005 B), Scope Issue No. (2)

Issue No. (2): November 29, 2018 **Valid to: October 31, 2020**

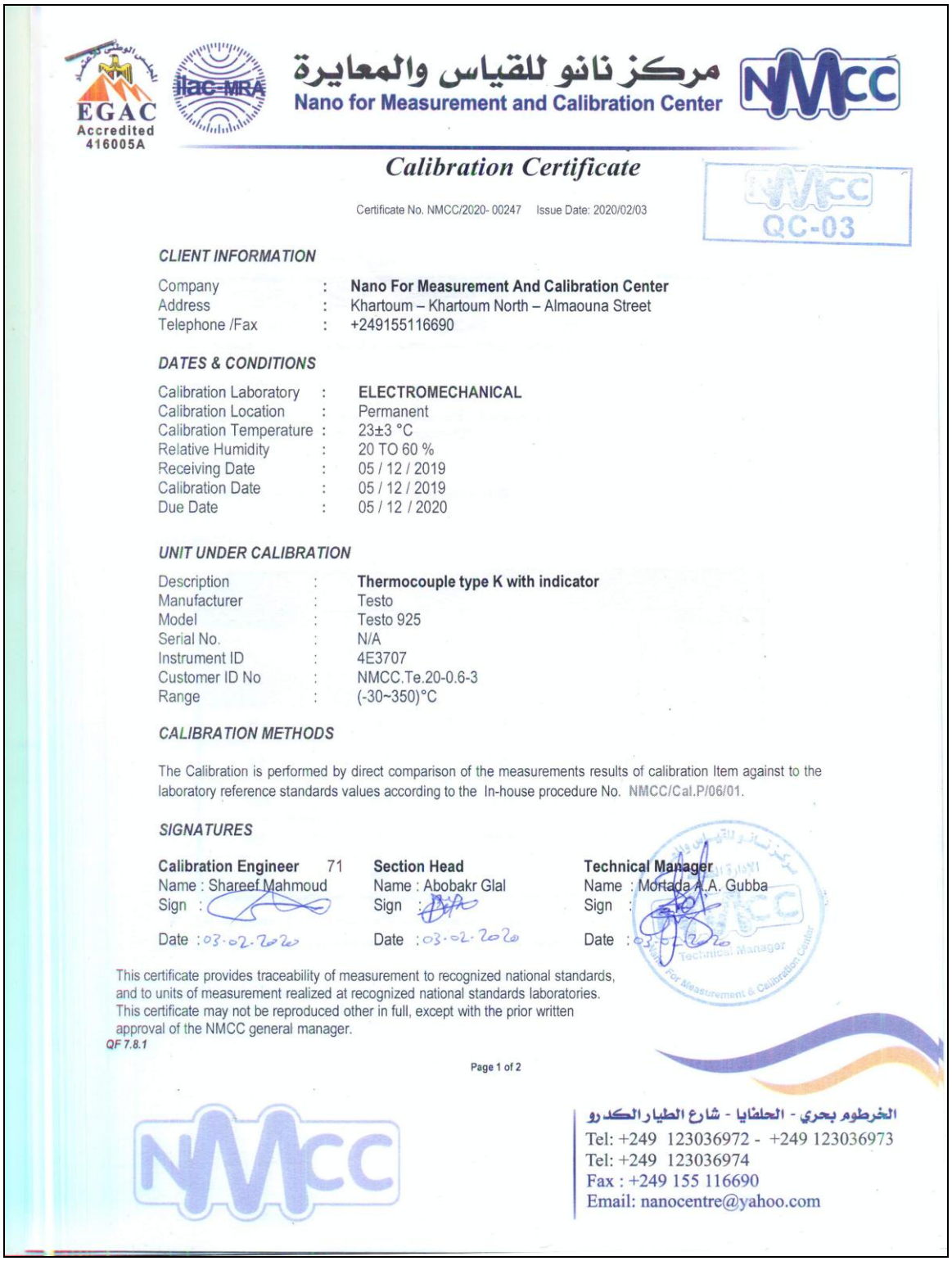
Subject to continued compliance to the above standard and the requirements of EGAC

EGAC is an ILAC MRA signatory in the field of Calibration and Testing Labs accreditation

Eng. Hany El Desouki
Hany El Desouki
EGAC Executive Director

Eng. Amr Nassar
Chairman of EGAC
Minister of Trade and Industry

Appendix (4):



مركز نانو للقياس والمعايرة
Nano for Measurement and Calibration Center

EGAC Accredited 416005A

ilac-MRA

NMCC

Calibration Certificate

Certificate No. NMCC/2020- 00247 Issue Date: 2020/02/03

NMCC QC-03

CLIENT INFORMATION

Company	:	**Nano For Measurement And Calibration Center**
Address	:	Khartoum – Khartoum North – Almaouna Street
Telephone /Fax	:	+249155116690

DATES & CONDITIONS

Calibration Laboratory	:	**ELECTROMECHANICAL**
Calibration Location	:	Permanent
Calibration Temperature	:	23±3 °C
Relative Humidity	:	20 TO 60 %
Receiving Date	:	05 / 12 / 2019
Calibration Date	:	05 / 12 / 2019
Due Date	:	05 / 12 / 2020

UNIT UNDER CALIBRATION

Description	:	**Thermocouple type K with indicator**
Manufacturer	:	Testo
Model	:	Testo 925
Serial No.	:	N/A
Instrument ID	:	4E3707
Customer ID No	:	NMCC.Te.20-0.6-3
Range	:	(-30~350)°C

CALIBRATION METHODS

The Calibration is performed by direct comparison of the measurements results of calibration Item against to the laboratory reference standards values according to the In-house procedure No. NMCC/Cal.P/06/01.

SIGNATURES

Calibration Engineer 71	Section Head	Technical Manager
Name : Shareef Mahmoud	Name : Abobakr Glal	Name : Mortada A.A. Gubba
Sign :	Sign :	Sign :
Date : 03-02-2020	Date : 03-02-2020	Date : 03-02-2020

Technical Manager For Measurement & Calibration Center

QF 7.8.1

NMCC

الخرطوم بحري - الحلفايا - شارع الطيار الكدرو
Tel: +249 123036972 - +249 123036973
Tel: +249 123036974
Fax : +249 155 116690
Email: nanocentre@yahoo.com

Appendix (5):

بسم الله الرحمن الرحيم

السيد / مدير مجمع نانو للقياس والمعايرة

السلام عليكم ورحمة الله وبركاته

الموضوع : بحث علمي لنيل درجة الماجستير في ادرة الجودة الشامة والامتياز

(جامعة السودان للعلوم والتكنولوجيا)

بالاشارة للموضوع اعلاه، وفي إطار الدراسة ارجو من سيادتكم التكرم بتوفير بعض المعلومات الخاصة بالمركز لغرض البحث العلمي والذي يختص باثر الاعتماد علي اداء معامل المركز وفق متطلبات المواصفة القياسية ISO17025:2017.

ولكم جزيل الشكر والاحترام

مقدم الطلب

شريف محمود حسن