Sudan University of Science and Technology

College of Graduate Studies

The Impact of Implementation of ISO 17025:2005 on Laboratories Performance .Case study of :Central Laboratory, Khartoum Refinery Company Ltd, Khartoum State- Sudan

أثر تطبيق المواصفة آيزو 17025:2005 على آداء المختبرات . دراسة حاله : المختبر المركزي، شركة مصفاة الخرطوم المحدودة، ولاية الخرطوم– السودان

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

By

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الآيـــــة

قال تعالى:

بسم الله الرحمن الرحيم

﴿فَتَعَالَى اللَّهُ الْمَلِكُ الْحَقُّ ۗ وَلَا تَعْجَلْ

بِالْقُرْآنِ مِن قَبْلِ أَن يُقْضَىٰ إِلَيْكَ وَحْيُهُ ۖ

وَقُل رَّبِّ زِدْنِي عِلْماً﴾

صدق الله العظيم

سورة طه: الآية 114

Dedication

To my home country "Sudan" which I hope to see it the best one over the world in quality field.

To the soul of my beloved mother.

To the soul of my beloved father.

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

To my extended family, my brothers and sisters.

To my friends and colleagues in Khartoum Refinery Company.

To my beloved wife for her moral support, her good wishes and invitations to me and success discrimination and hoping to see me the best in everything.

To my beloved son (Ahmed)

To my beloved daughter (Aryam)

I dedicate this work.

Acknowledgement

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Abstract

This descriptive case study was conducted in Central Laboratory, Khartoum Refinery Company Ltd, Khartoum State- Sudan to assess the impact of implementation of ISO 17025 on laboratories performance during the period from May 2019 to December 2019. A questionnaire was used as data collection tool to achieve the study objective. Seventy three questionnaires were distributed to all laboratory employees in Central Laboratory in Khartoum Refinery, 65 of the laboratory employees were responded with percentage of (89.0%), while (8) were not responded. The data were analyzed using Statistical Package for Social Sciences (SPSS); the test used was Chi-squre. The study showed that there was a relationship between the working environment conditions and laboratories performance in central laboratory at Khartoum Refinery Company. The study reflected that there was a relationship between implementing documentation and control system and laboratories performance in central laboratory at Khartoum Refinery Company. In addition to, there was a relationship between the continuous improvement and laboratories performance in central laboratory at Khartoum Refinery Company. The study revealed that there was a relationship between meeting the technical requirements of ISO 17025:2005 and laboratories performance in central laboratory at Khartoum Refinery Company. The study concluded that implementation of ISO 17025:2005 have improvd on laboratories performance in Central Laboratory, Khartoum Refinery Company Ltd, Khartoum State- Sudan.

مستخلص الدراسه

أجريت دراسة هذه الحاله الوصفيه في المختبر المركزي، شركة مصفاة الخرطوم المحدودة، ولاية الخرطوم– السودان لتقييم أثر تطبيق المواصفة آيزو 17025 على آداء المختبرات في الفترة من مايو 2019م إلى ديسمبر 2019م. استخدمت الإستبانة كآداة لجمع البيانات لتحقيق هدف الدراسة. ثلاث و سبعون استبانة وزعت على جميع العاملين في المختبر المركزي في شركة مصفاة الخرطوم, استجاب منهم 65 بنسبة (89.0%) ولم يستجب 8 منهم. حللت البيانات باستخدام الحزم الإحصائية للعلوم الاجتماعية (SPSS), المنهجية التي استخدمت كانت باستخدام مربع كاى. اظهرت الدراسة أن هناك علاقة بين ظروف بيئة العمل و آداء المختبرات في المختبر المركزي بشركة مصفاة الخرطوم. عكست الدراسة أن هناك علاقة بين تطبيق نظام الوثائق و التحكم و آداء المختبرات في المختبر المركزي بشركة مصفاة الخرطوم. بالاضافة إلى، أن هناك علاقة بين التطوير المستمر و آداء المختبرات في المختبر المركزي بشركة مصفاة الخرطوم. كشفت الدراسة أن هناك علاقة بين تلبية المتطلبات الفنية للمواصفة آيزو 17025 و آداء المختبرات في المختبر المركزي بشركة مصفاة الخرطوم. خلصت الدراسه إلى أن تطبيق المواصفة آيزو 17025 عمل على تطوير الآداء في المختبر المركزي، شركة مصفاة الخرطوم المحدودة، 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:

An ISO/IEC 17025 general requirement for the competence of testing and calibration laboratories is the main ISO standard used by testing and calibration laboratories. In most 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 a laboratory that is not accredited. Originally known as ISO/IEC Guide 25, ISO/IEC 17025 was initially issued by the International Organization for Standardization in 1999. There are many commonalities with the ISO 9000 standard, but ISO/IEC 17025 is more specific in requirements for competence and applies directly to those organizations that produce testing and calibration results and is based on somewhat more technical principles (CALA, 2018). Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results (Honsa and Deborah, 2003). It is also the basis for accreditation from an accreditation body. 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 2005 version of the standard comprises five elements; normative references, terms and definitions, 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 that

determine the correctness and reliability of the tests and calibrations performed in the laboratory. The version of ISO/IEC 17025 has modified this structure to be scope, normative references, terms and definitions, general requirements, structural requirements, resource requirements, process requirements and management system requirements. General requirements and structural requirements are related to the organization of the laboratory itself. Structure requirements cite those issues related to the people, plant, and other organizations used by the laboratory to produce its technically valid results. Process requirements are the heart of this version of the standard in describing the activities to ensure that results are based on accepted science and aimed at technical validity. Management system requirements are those steps taken by the organization to give itself quality management system tools to support the work of its people in the production of technically valid results (SAI GLOBAL, 2012).

1.2 Research problem:

The laboratory performance is always very critical to quality and also the importance of the laboratories services. The lack of completely implementing of the quality assurance and quality control systems in laboratories, the weakness management system, the poor quality in laboratories' services, poor competencies of staff, inadequate resources and bad environmental conditions are the important major factors that should lead to inaccurate and unreliable results, retesting, wasting time, wasting material and samples and failing to investigate products specifications status. So, this study tried to answer the following questions:

- What is the impact of implementation of ISO 17025 on the working environment conditions inside the central laboratory at Khartoum Refinery Company?
- What is the impact of implementation of ISO 17025 on implementation of documentation and control system in the central laboratory at Khartoum Refinery Company?
- What is the impact of implementation of ISO 17025 on continuous improvement in the central laboratory at Khartoum Refinery Company?
- What is the impact of implementation of ISO 17025 on meeting the technical requirements of ISO and improving the performance of central laboratory at Khartoum Refinery Company?

1.3 Rationale:

The laboratories performance in analyzing materials sector is one of the most important sectors in oil and gas industry. Recently many quality studies had been done in this sector in order to participate in improvement and develop the laboratories performance. As a sample for private and governmental sectors, Khartoum Refinery Company, Central Laboratory was chosen to be the case study of this research in a trying to understand the impact of implementation of ISO 17025 on improving the central laboratory performance, so that the study can participate in indirect way in warranty of analytical results accuracy. In addition to helpful to assess the views of employees involved in the management system based on ISO 17025. Therefore, findings are expected to contribute towards improving staff motivation and the management system.

1.4 Objectives of the study:

1.4.1General objective:

To assess the impact of implementation of ISO 17025 on laboratories performance in Central Laboratory, Khartoum Refinery Company Ltd, Khartoum State- Sudan

1.4.2 Specific objectives:

- To identify a relationship between the working environment conditions and laboratories performance in central laboratory at Khartoum Refinery Company.
- To identify a relationship between implementation of documentation and control system and laboratories performance in central laboratory at Khartoum Refinery Company.
- To identify a relationship between continuous improvement and laboratories performance in central laboratory at Khartoum Refinery Company.
- To identify a relationship between meeting the technical requirements of ISO 17025 and laboratories performance in central laboratory at Khartoum Refinery Company.

1.5 The hypotheses:

- There is a statistically significant relationship between the working environment conditions and laboratories performance in central laboratory at Khartoum Refinery Company.
- There is a statistically significant relationship between implementation of documentation and control system and laboratories performance in central laboratory at Khartoum Refinery Company.
- There is a statistically significant relationship between continuous improvement and laboratories performance in central laboratory at Khartoum Refinery Company.
- There is a statistically significant relationship between meeting the technical requirements of ISO 17025 and laboratories performance in central laboratory at Khartoum Refinery Company.

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. It covers almost every industry, from technology to food safety, to agriculture and healthcare (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. 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). 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:

The requirements of the 2017 version of the ISO/IEC 17025 standard are applicable to all organizations performing testing, calibration, and/or sampling (ISO 17025, 2017). The ISO/IEC 17025:2005 standard itself comprises five elements: scope, normative references, terms and definitions, management requirements and technical requirements. There are two main clauses management requirements and technical

requirements. Management requirements are related to the operation and effectiveness of the quality management system within the laboratory, and this clause has similar requirements to ISO 9001. Technical requirements address the competence of staff; testing methodology; equipment and quality; and reporting of test and calibration results (ISO 17025, 2005). The new standard provides an update in: terminology, process approach, whereby the standard is aligned with other recent standards such as: ISO 9001; scope; the usage of recent and updated information technology (IT) and the concept of risk-based thinking.

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.

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 of the content of ISO/IEC 17025:2005:

2.1.5.1 Management requirements:

These are mainly: the requirements for organization, management system, document control, review of request, tenders and contracts, subcontracting of test and calibration, purchasing service and supplies, service to customer, complaints, control of nonconforming testing and calibration work, improvement, corrective action, preventive action control of record and management reviews (ISO 17025, 2005).

2.1.5.1.1 Document control:

In general, the laboratory shall maintain and establish a procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals. In this context "document" could be, procedures policy statements, specifications, calibration tables, charts, text books, posters, notices, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written (ISO 17025, 2005).

2.1.5.1.2 Document approval and issue:

State that all documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and shall be readily available to preclude the use of invalid and/or obsolete documents (ISO 17025, 2005). Motioned that the procedures

adopted shall ensure that: the authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed, all documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements (ISO 17025, 2005). Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, and the total number of pages or a mark to signify the end of the document and the issuing authorities (ISO 17025, 2005).

2.1.5.1.3 Document changes:

Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval (ISO 17025, 2005). Where practicable, the altered or new text shall be identified in the document or the appropriate attachments (ISO 17025, 2005). If the laboratory's document control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable (ISO 17025, 2005). Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled (ISO 17025, 2005).

2.1.5.1.4 Improvement:

The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality

objectives, audit results, analysis of data, corrective and preventive actions and management review (ISO 17025, 2005).

2.1.5.1.5 Corrective action:

2.1.5.1.5.1 General:

The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified. A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, and feedback from customers and from staff observations (ISO 17025, 2005).

2.1.5.1.5.2 Causes analysis:

The procedure for corrective action shall start with an investigation to determine the root cause (s) of the problem. Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration (ISO 17025, 2005).

2.1.5.1.5.3 Selection and implementation of corrective actions:

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action (s) most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem. The laboratory shall document and implement any required

changes resulting from corrective action investigations (ISO 17025, 2005).

2.1.5.1.5.4 Monitoring of corrective actions:

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective (ISO 17025, 2005).

2.1.5.1.5.5 Additional audits:

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this international standard, the laboratory shall ensure that the appropriate areas of activity are audited as soon as possible. Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified (ISO 17025, 2005).

2.1.5.1.6 Preventive action:

Needed improvements and potential sources of nonconformities, either technical or concerning the management system shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement (ISO 17025, 2005). Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective. Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints (ISO 17025, 2005).

2.1.5.2 Technical requirements:

2.1.5.2.1 General:

Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from: human factors, accommodation and environmental conditions, test and calibration methods and method validation, equipment, measurement traceability, sampling and the handling of test and calibration items (ISO 17025, 2005). The extent to which the factors contribute to the total uncertainty of measurement differs considerably between tests and calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses (ISO 17025, 2005).

2.1.5.2.2 Personnel:

The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and demonstrated skills, as required. In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the customer. The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have: relevant

knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service and knowledge of the general requirements expressed in the legislation and standards and an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned (ISO 17025, 2005). The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated (ISO 17025, 2005). The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system (ISO 17025, 2005). The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests or calibrations. Job descriptions can be defined in many ways (ISO 17025, 2005). As a minimum, the following should be defined: the responsibilities with respect to performing tests or calibrations; the responsibilities with respect to the planning of tests or calibrations and evaluation of results; the responsibilities for reporting opinions and interpretations; the responsibilities with respect to method modification and development and validation of new methods; expertise and experience required; qualifications and training programs and managerial duties (ISO 17025, 2005). The management shall authorize specific personnel to perform particular types of sampling, test and/or

calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization (s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed (ISO 17025, 2005).

2.1.5.2.3 Accommodation and environmental conditions:

Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations. The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented (ISO 17025, 2005). The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations (ISO 17025, 2005). There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination (ISO 17025, 2005). Access to and use of areas affecting

the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances. Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary (ISO 17025, 2005).

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

2.1.6.1 General requirements:

Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality. The laboratory management shall be committed to impartiality. The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality. The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality. The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential (ISO 17025, 2017).

2.1.6.2 Structural requirements:

Main requirements are including: legal status of the laboratory, organization and management structure, identification of management,

range of laboratory activities, documenting its procedures, availability of personnel responsible for the implementation and maintaining the integrity of the management system. 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. This means that the laboratory is expected to be accredited, and include in the scope of accreditation only testing/calibration/sampling activities that is providing by utilizing its own resources (ISO 17025, 2017). In its 2005 version the standard allowed to subcontract tests and calibrations in the case that the laboratory was not in position to perform them. According to the new standard the laboratory can be accredited only for those laboratory activities, for which it is competent. Subcontracting is allowed only for outstanding situations, like overload of work, sickness of personnel, maintenance of equipment or other similar cases (ISO 17025, 2017).

2.1.6.3 Resource requirements:

The importance of the provision of the resources such as the personnel, facilities and environmental conditions, equipment, metrological traceability, and the externally provided products and services used to support the operation of the laboratory. Resource requirements are considered to include personnel, facilities, equipment, systems and support services necessary to manage and perform the laboratory activities. It is expected that all internal or external personnel of the laboratory shall be competent and act impartially. The standard doesn't refer to all personnel, but only to personnel who could influence on the results of laboratory activities. This is not only personnel who is directly involved in testing/calibration/sampling activities, but also personnel who is indirectly involved, like technical personnel. For example, it can be personnel that perform maintenance of the equipment, or management

system personnel, who evaluate suppliers and/or maintain the management system including internal auditing activities (ISO 17025, 2017). The competence requirements, which are expected to be documented, include education, qualification, training, technical knowledge, skills (like capacity to evaluate the significance of laboratory activities deviations) and experience. In addition, procedure and records are expected for selection, training, supervision, authorization and monitoring of competence of personnel. The standard also defines the cases where it is expected for the laboratory to authorize personnel to perform specific laboratory activities (ISO 17025, 2017). It is expected for 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). A procedure for handling, transport, storage, use and planned maintenance of equipment is required. Equipment requirements are applicable to hardware, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus, whatever is required for achieving correct results during laboratory activities. It is also expected that the equipment used for measurement should achieve the required measurement accuracy or measurement uncertainty (ISO 17025, 2017).

2.1.6.4 Process requirements:

2.1.6.4.1 Review of requests tenders and contracts:

A procedure is required to address issues such as the level of understanding of requirements; laboratory's capability and resources to meet the requirements; implementation of appropriate control over external providers used (if any), and selection of appropriate methods to meet the customers' requirements. It is expected that the laboratory shall inform the customer when the required testing/calibration/sampling method is considered to be inappropriate or out of date. When a statement of conformity to a specification or standard is required, the decision rule (which specifies pass/fail criteria) selected shall be communicated to, and agreed with, the customer. Contract review procedure shall be applied also for any changes in the contract/tender/request. Relative review records are required (ISO 17025, 2017).

2.1.6.4.2 Selection, verification and validation of methods:

The term "method" in the standard is used to identify calibration method, testing/measurement procedure, sampling procedure. The laboratory is expected to ensure that it uses the latest valid version of a method, unless it is not appropriate or possible to do so. Methods used can include methods published in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment or laboratory-developed or laboratory-modified methods. The laboratory shall verify that it can properly perform selected methods. Deviations from methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. Non-standard methods, laboratory-developed methods and modified standard methods are expected to be validated, and relevant records are expected to be kept (ISO 17025, 2017).

2.1.6.4.3 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).

2.1.6.4.4 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).

2.1.6.4.5 Technical records:

Requirements to retain technical records are in place to ensure the traceability of laboratory activities and to provide information for potential decision making. The technical records are expected to 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 if required, providing traceability to previous versions or to original observations if amended (ISO17025, 2017).

2.1.6.4.6 Evaluation of measurement uncertainty:

For testing laboratories it is expected to evaluate measurement uncertainty considering all contributions which are of significance,

including those accruing from sampling. It is noted in the standard that for a particular method, where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result, if the laboratory can demonstrate that the identified critical influencing factors are under control and monitoring. For calibration laboratories it is expected to evaluate the measurement uncertainty for all calibrations considering all contributions which are of significance, including those accruing from sampling (ISO 17025, 2017).

2.1.6.4.7 Reporting of results:

Laboratory activity results shall be reported. The standard sets requirements for results review and authorization as retained in the relative technical records. The common information required to be included in the test, calibration or sampling reports. 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).

2.1.6.4.8 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).

2.1.6.4.9 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).

2.1.6.4.10 Control of data information management:

Requirements for the laboratory information management system (s) used for the collection, processing, recording, reporting, storage or retrieval of data (ISO 17025, 2017).

2.1.6.5 Management system requirements:

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/IEC 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 Previous studies:

A 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 impact of implementation of ISO 17025 on Sudanese laboratories.
- Improvement of training process inside laboratory.
- Enhancing the service provided by laboratory to be in high quality.
- Establishing clear management system and clear responsibility inside laboratory.
- Adequate and suitable accommodation and environmental conditions inside laboratory lead to reliable testing results.

The current study is differs from the previous study in:

- Laboratory scope, because the oil and gas laboratories have additional risk and need more control when testing processes were running, so top management should fully committed to system of quality.

Another 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 impact of implementation of ISO 17025 on performance of Sudanese laboratories.
- Both of the studies were found a positive relationship between implementation of ISO 17025 and laboratories performance.

The current study is differs from the previous study in:

- Laboratory scope, current study was conduct in laboratory for testing materials in oil and gas industry while pervious study was conducted in laboratory for measurement and calibration.
- This study focused on the requirements of standard of ISO 17025:2005 and their applications while pervious study focused on ISO 17025:2017.

A study done by Fadul (2014) in impact of implementing ISO 17025 in the quality of Sudanese laboratories' service. The study found that the service provided by the national public health laboratory (NPHL) was in poor quality, lack of management system, lack of clarity of responsibilities inside NPHL, there was defect on the training process inside NPHL and working environment inside NPHL was not suitable and adequate to give correct reliable testing results.

The current study is similar with the previous study in:

- Both of studies focused on the impact of implementing ISO 17025 on the quality of Sudanese laboratories.
- Both of studies found that there was unclear training procedure, programs and plans, which will influence competency and technical requirements.

The current study is differs from the previous study in:

- The current study found that the responsibilities inside the central laboratory was clearly identified, while the previous study found un clarity of responsibilities inside (NPHL) laboratory.
- The current study found that the working environment condition in the central laboratory was suitable and adequate to get correct reliable testing results, while the previous study showed that the working environment condition inside (NPHL) laboratory was not suitable and un adequate to get correct reliable testing results.

A study done by Mohammed (2016) in the impact of implementation of ISO 17025 on chemical laboratories, the study aimed to detect the laboratories performance before and after implementation of ISO 17025. The study found that the impact of implementing ISO 17025 was clearly visible, the systems have been improved to the best and increasing the performance of the laboratory.

The current study is similar with the previous study in:

- Both of the studies focused on impact of implementation of ISO 17025:2005 in performance of Sudanese laboratories.
- The systems have been improved to the best and increasing the performance of the laboratory after implementation of ISO 17025:2005, same as my study which was concluded that the continuous improvement contribute positively in increasing performance of the laboratory.

The current study is differs from the previous study in:

- The current study aimed to detect the impact of implementing ISO17025:2005 on laboratories performance while pervious study aimed to detect the laboratories performance before and after implementation of ISO 17025:2005.

A study by Babiker (2019) in assessment of laboratory technicians awareness, qualifications and training regarding applying laboratories

equipments calibration in East Nile Hospital, Khartoum State- Sudan. The study concluded that there was statistically significant relationship between knowing the importance of laboratory calibration and its application. There was statistically significant relationship between the level of academic qualification for laboratory technicians and performing calibration. There was statistically significant relationship between training the technicians on the method of calibration application and performing it.

The current study is similar with the previous study in:

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

The current study is differs from the previous study in:

The current study was conducted in laboratory for testing materials in oil and gas industry, while the previous study conducted in laboratory for calibration activities.

Another study 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.
- Work environment inside the laboratory contribute positively in leading to get correct, reliable and valid testing results.
- There was a positive relationship between continues improvement and performance of laboratories.

The current study is differs from the previous study in:

- The present study was conduct in oil and gas industry laboratory for testing materials, while the previous study was conducted in Sudanese standards and metrology organization (SSMO) for testing and calibration activities.

A study done by Silva *et al.* (2013) in cause analysis for unsatisfactory results in proficiency testing activities, (case study of Brazilian calibration laboratories accredited under ISO 17025:2005), the study indicated that the main root causes observed by the laboratories were related to personnel, equipment, and calibration standards and methods. Some items that considered needing more investigation include controlling the process of calibration: responsibilities and authorization for equipment operation, protection of hardware and software, use of updated calibration correction factors, segregate and clearly signed equipment out of service, purchase of calibration services, and adequacy suitability of environmental conditions.

The current study is similar with the previous study in:

- Adequacy and suitability of environmental conditions and their contribution on getting reliable valid results.
- The importance of personnel, equipment, and calibration standards and methods and how they can affect the laboratory results, same as my study in the last hypothesis which illustrate that there was a positive

relationship between meeting technical requirements and increasing laboratories performance.

The current study is differs from the previous study in:

- The current study was conducted in laboratory for testing materials in oil and gas industry while the previous study was conducted in laboratory for calibration.
- The current study was conducted in Sudanese laboratory, while the pervious study was conducted in Brazilian calibration laboratories accredited under ISO 17025.

A study done by Shihub (2009) in an investigation of the attitudes of laboratory staff to the establishment of accredited laboratories (case study of the Libyan Chemical and Petrochemical Industries), the study explained the problems in quality management in the developing countries in term of: management, technical, training, culture, communication and accommodation and environmental condition factors that affect quality programs. The study aimed to find out the effect of management, technical, communication, accommodation and environmental condition quality and training factors, as establishment of accreditation of laboratories. The results of study indicated that there was a positive relation between laboratories accreditation and management factors, technical factors, communication, accommodation and environmental condition quality, cultural factors and training factors.

The current study is similar with the previous study in:

- Accommodation and environmental condition as factors that could affect quality programs.
- The results of previous study indicated that there was a positive relation between laboratories accreditation and management factors, technical factors, training factors and accommodation and environmental condition quality, as well as my study, also indicated that there was a positive

relationship between the working environment conditions and laboratories performance, there was a statistically significant relationship between implementing a documented controlled system and laboratories performance, continuous improvement contributes positively in laboratories performance and there was a statistically significant relationship between meeting the technical requirements of ISO 17025 and laboratories performance.

The current study differs from the previous study in:

- The current study was conducted in Sudanese laboratory in oil and gas industry, while the pervious study was conducted in the Libyan Chemical and Petrochemical Industries.
- The present study conducted in the impact of implementing ISO 17025 on laboratories performance in term of two clauses from management requirement and two clauses from technical requirement, while the previous study was investigated wide range of factors that could affect the implementation of ISO 17025 requirements, such as (management factors, technical factors, communication factors, accommodation and environmental condition quality, cultural factors and training factors).

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 Khartoum Refinery Company, Central Laboratory, Khartoum state, Sudan.

3.2.1 Khartoum Refinery Company and Central Laboratory:

Khartoum Refinery Company is a modern refinery of oil and Gas Industry, the main business of company is to refine the Crude oil. The company is a joint venture between Sudan and China, investment by china National Petroleum Corporation and Sudan Ministry of Petroleum on 50% basis. The refinery units consist of (Crude distillation Unit, Residue Catalytic Delayed Coking Unit, Continuous Catalytic Reforming Unit, Gasoline/ Diesel Hydro Treating Unit, storage tanks for crude oil, storage tanks for products, utilities such as water treatment, air separation, power station, steam production, industrial waste water treatment and central laboratory for hydrocarbon and water analysis. All the refinery units are controlled automatically by a very advance control system. The production capacity for Khartoum Refinery Company is (100.000bb/Day). The company structure consists of five divisions: administration, production, maintenance, technical and utilities). Every division consists of many departments. The central laboratory is a department in technical division. The central laboratory structure consists of five sections: quality, instrument, water analysis, classic chemistry and physical chemistry testing. The laboratory provides services of testing materials such as finish products, under process crude oil and refinery gases. Most of testing follows American Society for Testing Materials methods (ASTM). Also the Laboratory provide support service by

testing the oxygen and explosive gases level in confine spaces area as a safety issues during maintenance and overall period. The manpower of central laboratory is 73 employees, classified to: one department, five sections head, chemists and technicians. The central laboratory staff is mainly divided into two parts (Day time staff which working for 8 hours/ day and shift staff which working 12 hours/ day). The laboratory is certified in ISO 9001:2015 and ISO 17025:2005. The central laboratory ensures that policies, procedures and instructions are implemented to ensure the accuracy, reliability of the results (Khartoum Refinery Company, 2005).

3.3 Study population:

The study was conducted on all central laboratory staff, targeted to all staff (department manager, section heads, engineers, chemists and technicians) at Khartoum Refinery Company, Khartoum state, Sudan.

3.4 Sample size:

The targeted sample of this research was the total population of the laboratory staff (73) but the actual sample number was (65) who were responded to fulfill the questionnaire.

3.5 Study period:

The study was conducted during the interval from May 2019 to December 2019.

3.6 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 laboratory staff. The study depends on the questionnaire as a key to offer gathering information from the study population.

3.7 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.

3.8 Ethical consideration:

Study permissions were obtained from College of Graduate Studies-Sudan University of Science and Technology, then from management of Khartoum Refinery Company. Also, permission was taken from all individuals before being included in the study. Each individual was informed on the nature of the study.

CHAPTER FOUR

Results

Chapter 4

Results

4.1 General characteristics of study population:

The study was conducted on 65 study subjects, 61 (93.8%) were males and 4 (6.2%) were females. The age ranged between 20-60 years old. Regarding the academic level of study subjects, 39 (60.0%) were having a diploma degree. Regarding the years of experience, 18 (27.7%) were having experience less than 5 years. Regarding the job title, 54 (83.1%) were technician. Regarding the level of training on ISO 17025, 25 (38.5%) 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

The hypotheses	Reliability	Validity
The first hypothesis	0.90	0.95
The second hypothesis	0.87	0.93
The third hypothesis	0.94	0.97
The fourth hypothesis	0.94	0.97
Overall	0.97	0.98

4.3 The results of the first hypothesis (There is a statistically significant relationship between the working environment conditions and laboratories performance in central laboratory at Khartoum Refinery Company):

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

Table (4.2) showed: There are procedures to protect samples under testing from contaminated by surrounding environment or any other samples or solutions by the strongly agree (41.5%) and agree by (43.1%) and neutral by (9.2%) and disagree by (1.5%) and strongly disagree by

(4.6%). There are procedures to monitor the general environmental situation inside the laboratory by the strongly agree (38.5%) and agree by (36.9%) and neutral by (9.2%) and disagree by (9.2%) and strongly disagree by (6.2%). There are control procedures for the environmental condition such as humidity, radiation, dust, noise level, temperature and lighting intensity by the strongly agree (18.5%) and agree by (35.4%) and neutral by (27.7%) and disagree by (12.3%) and strongly disagree by (6.2%). Analysis and testing shall be discontinued if the laboratory's environmental condition does not match the environmental condition required by the ASTM standard by the strongly agree (12.3%) and agree by (32.3%) and neutral by (21.5%) and disagree by (23.1%) and strongly disagree by (10.8%). Employees perform analysis in an excellent environment in terms of lighting, ventilation, humidity and temperature by the strongly agree (16.9%) and agree by (55.4%) and neutral by (9.2%) and disagree by (9.2%) and strongly disagree by (9.2%). Laboratory management provides all analysis needs of materials, devices, calibration solutions and any resources for analysis in the analysis sites by the strongly agree (53.8%) and agree by (36.9%) and neutral by (1.5%) and disagree by (3.1%) and strongly disagree by (4.6%). Laboratory analysis equipment is calibrated periodically and continuously by external calibration bodies by the strongly agree (44.6%) and agree by (24.6%) and neutral by (10.8%) and disagree by (12.3%) and strongly disagree by (7.7%). The validity and efficiency of analytical instruments are tested with standard samples before the analysis begins by the strongly agree (49.2%) and agree by (36.9%) and neutral by (9.2%) and disagree by (3.1%) and strongly disagree by (1.5%).

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

No.	Phrases	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	There are procedures to protect samples under testing from contaminated by surrounding environment or any other samples or solutions	27	28	6	1	3
		41.5%	43.1%	9.2%	1.5%	4.6%
2	There are procedures to monitor the general environmental situation inside the laboratory	25	24	6	6	4
		38.5%	36.9%	9.2%	9.2%	6.2%
3	There are control procedures for the environmental condition such as humidity, radiation, dust, noise level, temperature and lighting intensity	12	23	18	8	4
		18.5%	35.4%	27.7%	12.3%	6.2%
4	Analysis and testing shall be discontinued if the laboratory's environmental condition does not match the environmental condition required by the ASTM standard	8	21	14	15	7
		12.3%	32.3%	21.5%	23.1%	10.8%
5	Employees perform analysis in an excellent environment in terms of lighting, ventilation,	11	36	6	6	6
		6.9%	55.4%	9.2%	9.2%	9.2%

	humidity and temperature					
6	Laboratory management provides all analysis needs of materials, devices, calibration solutions and any resources for analysis in the analysis sites	35	24	1	2	3
		52.3%	36.9%	1.5%	3.1%	4.6%
7	Laboratory analysis equipment is calibrated periodically and continuously by external calibration bodies	29	16	7	8	5
		44.6%	24.6%	10.8%	12.3%	7.7%
8	The validity and efficiency of analytical instruments are tested with standard samples before the analysis begins	32	24	6	2	1
		49.2%	36.9%	9.2%	3.1%	1.5%

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 "There are procedures to protect samples under testing from contaminated by surrounding environment or any other samples or solutions" was (54.92) 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 "There are procedures to monitor the general environmental situation inside the laboratory" was (34.15) 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 “There are control procedures for the environmental condition such as humidity, radiation, dust, noise level, temperature and lighting intensity” was (17.84) 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 “Analysis and testing shall be discontinued if the laboratory's environmental condition does not match the environmental condition required by the ASTM standard” was (10.00) 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 “Employees perform analysis in an excellent environment in terms of lighting, ventilation, humidity and temperature” was (52.30) 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 “Laboratory management provides all analysis needs of materials, devices, calibration solutions and any resources for analysis in the analysis sites” was (74.61) 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 “Laboratory analysis equipment is calibrated periodically and continuously by external calibration bodies” was (30.00) 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 “Validity and efficiency of analytical instruments are tested with standard samples before the analysis begins” was (61.23) 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	There are procedures to protect samples under testing from contaminated by surrounding environment or any other samples or solutions.	54.92	4	0.000	4.00	Agree
2	There are procedures to monitor the general environmental situation inside the laboratory.	34.15	4	0.000	4.00	Agree
3	There are control procedures for the environmental condition such as humidity, radiation, dust, noise level, temperature and lighting intensity.	17.84	4	0.000	4.00	Agree
4	Analysis and testing shall be discontinued if the laboratory's environmental condition does not match the environmental condition required by the ASTM standard.	10.00	4	0.000	3.00	Neutral
5	Employees perform analysis in an excellent environment in terms of lighting, ventilation, humidity and temperature.	52.30	4	0.000	4.00	Agree
6	Laboratory management provides all analysis needs of materials, devices, calibration solutions and any resources for analysis in the analysis sites.	74.61	4	0.000	5.00	Strongly agree
7	Laboratory analysis equipment is calibrated periodically and continuously by external	30.00	4	0.000	4.00	Agree

	calibration bodies.					
8	The validity and efficiency of analytical instruments are tested with standard samples before the analysis begins.	61.23	4	0.000	4.00	Agree

4.4 The results of the second hypothesis (There is a statistically significant relationship between implementation of documentation and control system and laboratories performance in central laboratory at Khartoum Refinery Company):

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

Table (4.4) showed: The document control system clearly identify the difficulty of implementing some of the procedures described in the document by the strongly agree (43.1%) and agree by (24.6%) and neutral by (27.7%) and disagree by (3.1%) and strongly disagree by (1.5%). The application of documentation and control system helps to facilitate and understand the work instructions by the strongly agree (52.3%) and agree by (33.8%) and neutral by (6.2%) and disagree by (6.2%) and strongly disagree by (1.5%). The application of the documentation system sometimes complicates work procedures by the strongly agree (4.6%) and agree by (15.4%) and neutral by (29.2%) and disagree by (32.3%) and strongly disagree by (18.5%). Controlling the procedures and instructions of the work through documentation reduces the work pressure through the clarity of responsibilities and authorities for employees by the strongly agree (60.0%) and agree by (21.5%) and neutral by (12.3%) and disagree by (3.1%) and strongly disagree by (3.1%). All procedures related to laboratory activities are available, understood and clearly documented to the employees by the strongly agree (40.0%) and agree by (26.2%) and neutral by (16.9%) and disagree by (15.4%) and strongly disagree by (1.5%). Documents are reviewed,

updated and controlled periodically by the strongly agree (52.3%) and agree by (18.5%) and neutral by (20.0%) and disagree by (6.2%) and strongly disagree by (3.1%). There is documentation and archiving of external source documents and procedures (such as calibration procedures, standard samples, maintenance procedures and spare parts for devices) by the strongly agree (49.2%) and agree by (27.7%) and neutral by (18.5%) and disagree by (%3.1) and strongly disagree by (1.5%). When the document expires, it is canceled immediately and another replacement document is issued by the strongly agree (50.8%) and agree by (23.1%) and neutral by (23.1%) and disagree by (3.1%) and strongly disagree by (0.0%). The laboratory management maintains all documents related to all devices in addition to the procedures of the periodic maintenance plan by the strongly agree (53.8%) and agree by (18.5%) and neutral by (23.1%) and disagree by (3.1%) and strongly disagree by (1.5%).

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

No.	Phrases	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	The document control system clearly identify the difficulty of implementing some of the procedures described in the document	28	16	18	2	1
		43.1%	24.6%	27.7%	3.1%	1.5%
2	The application of documentation and control system helps to facilitate and understand the work instructions	34	22	4	4	1
		52.3%	33.8%	6.2%	6.2%	1.5%
3	The application of the documentation system sometimes complicates work procedures	3	10	19	21	12
		4.6%	15.4%	29.2%	32.3%	18.5%
4	Controlling the	39	14	8	2	2

	procedures and instructions of the work through documentation reduces the work pressure through the clarity of responsibilities and authorities for employees	60.0%	21.5%	12.3%	3.1%	3.1%
5	All procedures related to laboratory activities are available, understood and clearly documented to the employees	26	17	11	10	1
		40.0%	26.2%	16.9%	15.4%	1.5%
6	Documents are reviewed, updated and controlled periodically	34	12	13	4	2
		52.3%	18.5%	20.0%	6.2%	3.1%
7	There is documentation and archiving of external source documents and procedures (such as calibration procedures, standard samples, maintenance procedures and spare parts for devices)	32	18	12	2	1
		49.2%	27.7%	18.5%	3.1%	1.5%
8	When the document expires, it is cancelled immediately and another replacement document is issued	33	15	15	2	0
		50.8%	23.1%	23.1%	3.1%	0.0%
9	The laboratory management maintains all documents related to all devices in addition to the procedures of the periodic maintenance plan	35	12	15	2	1
		53.8%	18.5%	23.1%	3.1%	1.5%

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 "The document control system clearly identify the difficulty of implementing some of the

procedures described in the document" was (40.30) 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 application of documentation and control system helps to facilitate and understand the work instructions" was (63.69) 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 application of the documentation system sometimes complicates work procedures" was (16.15) 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 Controlling the procedures and instructions of the work through documentation reduces the work pressure through the clarity of responsibilities and authorities for employees" was (72.61) 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 all procedures related to laboratory activities are available, understood and clearly documented to the employees" was (26.30) 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 Documents are reviewed, updated and controlled periodically" was (49.53) 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 "There is documentation and archiving of external source documents and procedures (such as calibration procedures, standard

samples, maintenance procedures and spare parts for devices)“ was (50.15) 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 “When the document expires, it is canceled immediately and another replacement document is issued” was (29.95) 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 management maintains all documents related to all devices in addition to the procedures of the periodic maintenance plan” was (58.00) 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	The document control system clearly identifies the difficulty of implementing some of the procedures described in the document.	40.30	4	0.000	4.00	Agree
2	The application of documentation and control system helps to facilitate and understand the work instructions.	63.69	4	0.000	5.00	Strongly agree
3	The application of the documentation system sometimes complicates work procedures.	16.15	4	0.000	2.00	Disagree
4	Controlling the procedures and instructions of the work through documentation	72.61	4	0.000	5.00	Strongly agree

	reduces the work pressure through the clarity of responsibilities and authorities for employees.					
5	All procedures related to laboratory activities are available, understood and clearly documented to the employees.	26.30	4	0.000	4.00	Agree
6	Documents are reviewed, updated and controlled periodically.	49.53	4	0.000	5.00	Strongly agree
7	There is documentation and archiving of external source documents and procedures (such as calibration procedures, standard samples, maintenance procedures and spare parts for devices).	50.15	4	0.000	4.00	Agree
8	When the document expires, it is canceled immediately and another replacement document is issued.	29.95	3	0.000	5.00	Strongly agree
9	The laboratory management maintains all documents related to all devices in addition to the procedures of the periodic maintenance plan.	58.00	4	0.000	5.00	Strongly agree

4.5 The results of the third hypothesis (There is a statistically significant relationship between continuous improvement and laboratories performance in central laboratory at Khartoum Refinery Company):

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

Table (4.6) showed: The laboratory management maintains clear and effective policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives by the strongly agree (15.4%) and agree by (44.6%) and neutral by (9.2%) and disagree by (23.1%) and strongly disagree by (7.7%). There are a certain procedures and effective decision making to corrective actions in cases of errors in the analysis by the strongly agree (32.3%) and agree by (41.5%) and neutral by (9.2%) and disagree by (13.8%) and strongly disagree by (3.1%). When an error occurs in the analysis, there is a procedures lead to the root causes of the error by the strongly agree (27.7%) and agree by (38.5%) and neutral by (16.9%) and disagree by (15.4%) and strongly disagree by (1.5%). There is a clear methodology to monitor the effectiveness of the corrective action to ensure that errors are fundamentally resolved at the planned time by the strongly agree (29.2%) and agree by (29.2%) and neutral by (29.2%) and disagree by (10.8%) and strongly disagree by (1.5%). Laboratory management takes a series of preventive actions to ensure that there are no errors during the analysis process, through analysis and assessment of the risks that may accompany the analysis by the strongly agree (32.3%) and agree by (30.8%) and neutral by (15.4%) and disagree by (18.5%) and strongly disagree by (3.1%). Laboratory management conducts an assessment of preventive and corrective actions to ensure their effectiveness in preventing future errors by the strongly agree (35.4%)

and agree by (26.2%) and neutral by (21.5%) and disagree by (13.8%) and strongly disagree by (3.1%). Proactive preventive procedures and measures are in place to discover opportunities for continuous improvement by the strongly agree (21.5%) and agree by (32.3%) and neutral by (20.0%) and disagree by (20.0%) and strongly disagree by (6.2%).

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

No.	Phrases	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	The laboratory management maintains clear and effective policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives	10	29	6	15	5
		15.4%	44.6%	9.2%	23.1%	7.7%
2	There are a certain procedures and effective decision making to corrective actions in cases of errors in the analysis	21	27	6	9	2
		32.3%	41.5%	9.2%	13.8%	3.1%
3	When an error occurs in the analysis, there is a procedures lead to the root causes of the error	18	25	11	10	1
		27.7%	38.5%	16.9%	15.4%	1.5%
4	There is a clear methodology to monitor the effectiveness of the corrective action to ensure that errors are fundamentally resolved at the planned time	19	19	19	7	1
		29.2%	29.2%	29.2%	10.8%	1.5%
5	Laboratory management takes a series of preventive actions to ensure that there are no errors during the analysis process, through analysis and assessment of the risks that may accompany the analysis	21	20	10	12	2
		32.3%	30.8%	15.4%	18.5%	3.1%
6	Laboratory management conducts an assessment of preventive and corrective actions to ensure their effectiveness in preventing future errors	23	7	14	9	2
		35.4%	6.2%	1.5%	13.8%	3.1%
7	Proactive preventive procedures and measures are in place to discover opportunities for continuous improvement	14	21	13	13	4
		21.5%	32.3%	0.0%	20.0%	6.2%

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 management maintains clear and effective policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives" was (29.38) 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 "There are a certain procedures and effective decision making to corrective actions in cases of errors in the analysis" was (34.30) 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 "When an error occurs in the analysis, there is a procedures lead to the root causes of the error" was (25.07) 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 "There is a clear methodology to monitor the effectiveness of the corrective action to ensure that errors are fundamentally resolved at the planned time" was (22.15) 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 management takes a series of preventive actions to ensure that there are no errors during the analysis process, through analysis and assessment of the risks that may accompany the analysis" was (18.76) 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 management conducts an assessment of preventive and corrective actions to ensure their effectiveness in preventing future errors" was (19.53) 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 proactive preventive procedures and measures are in place to discover opportunities for continuous improvement" was (11.23) 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 management maintains clear and effective policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives.	29.38	4	0.000	4.00	Agree
2	There are a certain procedures and effective decision making to corrective actions in cases of errors in the analysis.	34.30	4	0.000	4.00	Agree
3	When an error occurs in the analysis, there is a procedures lead to the root causes of the error.	25.07	4	0.000	4.00	Agree
4	There is a clear methodology to monitor the effectiveness of the corrective action to ensure that errors are fundamentally resolved at the planned time.	22.15	4	0.000	4.00	Agree
5	Laboratory management takes a series of preventive	18.76	4	0.000	4.00	Agree

	actions to ensure that there are no errors during the analysis process, through analysis and assessment of the risks that may accompany the analysis.					
6	Laboratory management conducts an assessment of preventive and corrective actions to ensure their effectiveness in preventing future errors.	19.53	4	0.000	4.00	Agree
7	Proactive preventive procedures and measures are in place to discover opportunities for continuous improvement	11.23	4	0.000	4.00	Agree

4.6 The results of the fourth hypothesis (There is a statistically significant relationship between meeting the technical requirement of ISO 17025 and laboratories performance in central laboratory at Khartoum Refinery Company):

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

Table (4.8) showed: Laboratory management provides all conditions that lead to accurate and reliable results by the strongly agree (38.5%) and agree by (33.8%) and neutral by (20.0%) and disagree by (4.6%) and strongly disagree by (3.1%). The laboratory management monitors and controls the working conditions and provide suitable environment for the employees, samples and devices by the strongly agree (%29.2) and agree by (33.8%) and neutral by (20.0%) and disagree by (12.3%) and strongly disagree by (4.6%). Every individual working in the lab knows his/ her duties (responsibilities and authorities) by obtaining a copy of the job description by the strongly agree (44.6%) and agree by (27.7%) and neutral by (18.5%) and disagree by (4.6%) and strongly disagree by (4.6%). The job description clearly describes the responsibilities and

authorities powers by the strongly agree (44.6%) and agree by (18.5%) and neutral by (23.1%) and disagree by (7.7%) and strongly disagree by (6.2%). There is a procedure in the laboratory to determine the training needs of all employees by the strongly agree (15.4%) and agree by (16.9%) and neutral by (19.6%) and disagree by (27.7%) and strongly disagree by (23.1%). The laboratory has a clear training plan to raise the technical capabilities of workers by the strongly agree (13.8%) and agree by (15.4%) and neutral by (24.6%) and disagree by (21.5%) and strongly disagree by (24.6%). The laboratory management supports the training program and the development of personal skills of the laboratories and provide them to staff by the strongly agree (13.8%) and agree by (30.8%) and neutral by (10.8%) and disagree by (18.5%) and strongly disagree by (26.2%). Laboratory management determines mechanisms to evaluate factors that affect the validity of the results, for example, calibration of instruments, the samples, the experience of the analyst person, the environmental conditions … (etc.) by the strongly agree (43.1%) and agree by (21.5%) and neutral by (24.6%) and disagree by (6.2%) and strongly disagree by (4.6%). The laboratory management controls all data related to the analysis (results- calibration data- and others) by the strongly agree (49.2%) and agree by (29.2%) and neutral by (20.0%) and disagree by (1.5%) and strongly disagree by (0.0%). Instruments are calibrated on both (Software and Hardware) and completely isolated so that the settings are not changed by unauthorized person the one by the strongly agree (29.2%) and agree by (33.8%) and neutral by (27.7%) and disagree by (7.7%) and strongly disagree by (1.5%).

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

No.	Phrases	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	Laboratory management provides all conditions that lead to accurate and reliable results	25	22	13	3	2
		38.5%	33.8%	20.0%	4.6%	3.1%
2	The laboratory management monitors and controls the working conditions and provide suitable environment for the employees, samples and devices	19	22	13	8	3
		29.2%	33.8%	20.0%	12.3%	4.6%
3	Every individual working in the lab knows his / her duties (responsibilities and authorities) by obtaining a copy of the job description	29	18	12	3	3
		44.6%	27.7%	18.5%	4.6%	4.6%
4	The job description clearly describes the responsibilities and authorities powers	29	12	15	5	4
		44.6%	18.5%	23.1%	7.7%	6.2%
5	There is a procedure in the laboratory to determine the training needs of all employees	10	11	11	18	15
		15.4%	16.9%	16.9%	27.7%	23.1%
6	The laboratory has a clear training plan to raise the technical capabilities of workers	9	10	16	14	16
		13.8%	15.4%	24.6%	21.5%	24.6%
7	The laboratory management supports the training program and the development of personal skills of the laboratories and provide them to staff	9	20	7	12	17
		13.8%	30.8%	10.8%	18.5%	26.2%
8	Laboratory management determines mechanisms to evaluate factors that affect the validity of the results, for example, calibration of	28	14	16	4	3
		43.1%	21.5%	24.6%	6.2%	4.6%

	instruments, the samples, the experience of the analyst person, the environmental conditions … (etc.)					
9	The laboratory management controls all data related to the analysis (results-calibration data- and others)	32	19	13	1	0
		49.2%	29.2%	20.0%	1.5%	0.0%
10	Instruments are calibrated on both (Software and Hardware) and completely isolated so that the settings are not changed by unauthorized person the one	19	22	18	5	1
		29.2%	33.8%	27.7%	7.7%	1.5%

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 "The laboratory management provides all conditions that lead to accurate and reliable results" was (34.30) 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 management monitors and controls the working conditions and provide suitable environment for the employees, samples and devices" was (18.61) 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 "Every individual working in the lab knows his/ her duties (responsibilities and authorities) by obtaining a copy of the job description" was (37.07) 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 job description clearly describes the responsibilities and authorities powers” was (31.23) 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 “There is a procedure in the laboratory to determine the training needs of all employees” was (23.53) 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 clear training plan to raise the technical capabilities of workers” was (23.38) 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 management supports the training program and the development of personal skills of the laboratories and provide them to staff” was (28.18) 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 “Laboratory management determines mechanisms to evaluate factors that affect the validity of the results, for example, calibration of instruments, the samples, the experience of the analyst person, the environmental conditions … (etc.)” was (32.00) 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 management controls all data related to the analysis (results- calibration data- and others)”was (30.69) 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 "Instruments are calibrated on both (Software and Hardware) and completely isolated so that the settings are not changed by unauthorized person the one" was (26.92) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences.

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

No.	Phrases	Chi-square value	Df	Sig.	Median	Interpretation
1	Laboratory management provides all conditions that lead to accurate and reliable results.	34.30	4	0.000	4.00	Agree
2	The laboratory management monitors and controls the working conditions and provide suitable environment for the employees, samples and devices.	18.61	4	0.000	4.00	Agree
3	Every individual working in the lab knows his / her duties (responsibilities and authorities) by obtaining a copy of the job description.	37.07	4	0.000	4.00	Agree
4	The job description clearly describes the responsibilities and authorities powers.	31.23	4	0.000	4.00	Agree
5	There is a procedure in the laboratory to determine the training needs of all employees.	23.53	4	0.000	2.00	Disagree
6	The laboratory has a clear training plan to raise the technical capabilities of workers.	23.38	4	0.000	3.00	Neutral
7	The laboratory management supports the training program and the development of personal skills of the laboratories and provide them	28.18	4	0.000	3.00	Neutral

	to staff.					
8	Laboratory management determines mechanisms to evaluate factors that affect the validity of the results, for example, calibration of instruments, the samples, the experience of the analyst person, the environmental conditions … (etc.)	32.00	4	0.000	4.00	Agree
9	The laboratory management controls all data related to the analysis (results - calibration data - and others).	30.69	3	0.000	4.00	Agree
10	Instruments are calibrated on both (Software and Hardware) and completely isolated so that the settings are not changed by unauthorized person the one.	26.92	4	0.000	4.00	Agree

4.7 Result of hypotheses of the study:

4.7.1 Result of the first hypothesis (There is a statistically significant relationship between the working environment conditions and laboratories performance in central laboratory at Khartoum Refinery Company):

Table (4.10) showed that the value of the Chi-square test (15.67) by significant value (0.000) it is less than the probability value (0.05), this means that there was a relationship between the working environment conditions and laboratories performance in central laboratory at Khartoum Refinery Company.

Table (4.10): Result of first hypothesis (There is a statistically significant relationship between the working environment conditions and laboratories performance in central laboratory at Khartoum Refinery Company)

No.	Chi-square	Df	Sig.	Median	Scale	Statistical significant
65	15.67	3.0	0.000	4.00	Agree	Significant

4.7.2 Result of the second hypothesis (There is a statistically significant relationship between implementation of documentation and control system and laboratories performance in central laboratory at Khartoum Refinery Company):

Table (4.11) showed that the value of the Chi-square test (39.84) by significant value (0.000) it is less than the probability value (0.05), this means that there was a relationship between implementation of documentation and control system and laboratories performance in central laboratory at Khartoum Refinery Company.

Table (4.11): Result of the second hypothesis (There is a statistically significant relationship between implementation of documentation and control system and laboratories performance in central laboratory at Khartoum Refinery Company)

No.	Chi-square	Df	Sig.	Median	Scale	Statistical significant
65	39.84	4	0.000	4.00	Agree	Significant

4.7.3 Result of the third hypothesis)There is a statistically significant relationship between continuous improvement and laboratories performance in central laboratory at Khartoum Refinery Company):

Table (4.12) showed that the value of the Chi-square test (19.53) by significant value (0.000) it is less than the probability value (0.05), this means that there was a relationship between continuous improvement and laboratories performance in central laboratory at Khartoum Refinery Company.

Table (4.12): Result of the third hypothesis)There is a statistically significant relationship between continuous improvement and laboratories performance in central laboratory at Khartoum Refinery Company)

No.	Chi-square	Df	Sig.	Median	Scale	Statistical significant
65	19.53	4	0.000	4.00	Agree	Significant

4.7.4 Result of the fourth hypothesis (There is a statistically significant relationship between meeting the technical requirement of ISO 17025 and laboratories performance in central laboratory at Khartoum Refinery Company):

Table (4.13) showed that the value of the Chi-square test (61.46) by significant value (0.000) it is less than the probability value (0.05) and Pearson's R (0.75), this means that there was a relationship between meeting the technical requirement of ISO 17025 and laboratories performance in central laboratory at Khartoum Refinery Company.

Table (4.13): Result of the fourth hypothesis (There is a statistically significant relationship between meeting the technical requirement of ISO 17025 and laboratories performance in central laboratory at Khartoum Refinery Company)

No.	Chi-square	Df	Sig.	Pearson's R	Scale	Statistical significant
65	61.46	9	0.000	0.75	Agree	Significant

CHAPTER FIVE

Discussion, Conclusion and Recommendations

Chapter 5

Discussion, conclusion and recommendations

5.1 Discussion

The present study showed that the most frequency distribution for the respondents' answers regarding the questions of the first hypothesis was 35 (52.3%) for strongly agree for the statement (Laboratory management provides all analysis needs of materials, devices, calibration solutions and any resources for analysis in the analysis sites), 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 (15.67) by significant value (0.000) it is less than the probability value (0.05); this means that there was a relationship between the working environment conditions and laboratories performance at Khartoum Refinery Company. The results reflected that the most frequency distribution for the respondents' answers regarding the questions of the second hypothesis was 39 (60.0%) for strongly agree for the statement (Controlling the procedures and instructions of the work through documentation reduces the work pressure through the clarity of responsibilities and authorities for employees), in general, means that most of the respondents have strongly agreed with all what mentioned about the second hypothesis. The results of second hypothesis showed that the value of the Chi-square test (39.84) by significant value (0.000) it is less than the probability value (0.05), this means that there was a relationship between the implementation of documentation and control system and laboratories performance at Khartoum Refinery Company. The present study showed that the most frequency distribution for the respondents' answers regarding the questions of the third hypothesis was 29 (44.6%) for agree for the statement (The laboratory management maintains clear and effective

policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives), 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 (19.53) by significant value (0.000) it is less than the probability value (0.05), this means that there was a relationship between the continuous improvement and laboratories performance at Khartoum Refinery Company. The present study illustrated that the most frequency distribution for the respondents' answers regarding the questions of the fourth hypothesis was 32 (49.2%) for strongly agree for the statement (The laboratory management controls all data related to the analysis (results- calibration data- and others)), 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 (61.46) by significant value (0.000) it is less than the probability value (0.05) and Pearson's R (0.75), this means that there was a relationship between meeting the technical requirements of ISO 17025 and laboratories performance. The findings from the present study were in disagreement with findings obtained by Fadul (2014) who found that the services provided by national public health laboratory (NPHL) was low quality; there was no clear management system with unknown responsibilities inside NPHL, but the findings of the present study were in agreement with the 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. Also, the results obtained from the present study

were in agreement with results obtained by Mohamed (2016) who found that the effect of the ISO 17025 was clearly visible; the systems have been improved to the best. 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 improvement of work environment and with findings of Abbas (2018) who found that the working accommodation and environment inside DNA laboratory is suitable and helps in correct testing results.

5.2 Conclusion:

The study concluded that implementation of ISO17025 have impact on working environment conditions inside the laboratory, implementation of documentation and control system and the continuous improvement in the central laboratory at Khartoum Refinery Company.

5.3 Recommendations:

Based on the results of the study recommended that:

- The laboratory management should commit and give strong instruction to the staff to discontinued testing immediately if the laboratory's environmental condition does not match the environmental condition.
- The laboratory management should simply, clearly identify the procedures of processes related to laboratory activities to allow all staff to easy understanding them.
- The laboratory management should maintain a clear and effective policy and plan for continuous improvement and upgrading of laboratory performance.
- The laboratory management should conducts analysis and assessment of the risks that may accompany the analysis, and take a series of preventive actions to ensure that there are no errors during the analysis process.
- The laboratory management should have a procedure to determine the training needs for all employees, and establish a training plan to raise the technical capabilities of all employees.

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APPENDICES

Appendix (1)

جامعة السودان للعلوم والتكنولوجيا

كلية الدراسات العليا

الاخ/ الاخت .....المحترم/المحترمة

السلام عليكم ورحمة الله تعالى وبركاته

الموضـــــــوع/ إستبيـــــــــــــان

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 تطبيق المواصفة آيزو 17025 على آداء المختبرات في المختبر المركزي، شركة مصفاة الخرطوم المحدودة، 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:

عبدالمنعم عبدالدائم علي محمد

اولاً: البيانات الشخصية:

الرجاء وضع علامة (√) امام الإجابة التي تختارها:

أ/النوع:

1. ذكر ☐ 2. أنثى ☐

ب/ العمـــــــر:

1. أقل من 25 سنة ☐ 2. 25 سنة وأقل من 35 سنة ☐
3. 35 سنه وأقل من 45 سنة ☐ 4. 45 سنه وأقل من 55 سنة ☐
5. أكثر من 55 سنة ☐

ج/ المستوى التعليمي:

1. ثانوي ☐ 2. دبلوم ☐
3. بكالريوس ☐ 4. ماجستير ☐
5. دكتوراه ☐

د/ مدة شغل الوظيفة:

1. أقل من 5 سنة ☐ 2. 5 سنة وأقل من 10 سنة ☐
3. 10 سنة وأقل من 15 سنة ☐ 4. 15 سنة وأقل من 20 سنة ☐
5. 20 سنة فأكثر ☐

هـ/ المسمى الوظيفي:

1. تقني ☐ 2. كيميائي ☐
3. مهندس ☐ 4. رئيس قسم ☐
5. مدير إدارة ☐

و/ مستوى تدريبك على المواصفة القياسية لكفاءة آداء نظام المعامل:

1. ضعيف ☐ 2. متوسط ☐
3. جيد ☐ 4. جيد جداً ☐
5. ممتاز ☐

ثانياً: قياس متغيرات الدراسة:-

الرجاء وضع علامة (√) امام مستوى الموافقة المناسب:

الفرضية الأولى: هناك علاقة ذات دلالة إحصائية بين ظروف بيئة العمل و آداء المختبرات في المختبر المركزي بشركة مصفاة الخرطوم.

العبـــــــــــــــارة	أوافق بشدة	أوافق	محايد	لا أوافق	لا أوافـق بشدة
1/ تقوم إدارة المختبر بوضع اجراءات تضمن عدم تلوث العينات تحت التحليل او الإختبار بالبيئة المحيطة او بأى عينات أو محاليل أخرى.					
2/ توجد اجراءات لمراقبة الوضع البيئي العام داخل المختبر.					
3/ توجد اجراءات مراقبة وتحكم للحالة البيئية مثل الرطوبة والاشعاعات والغبار ومستوى الضوضاء ودرجة الحراره وشدة الاضاءة.					
4/ يتم ايقاف عمليات التحليل والإختبار في حال عدم تطابق الحالة البيئية بالمختبر مع الحالة البيئية المطلوبة بمواصفات الاستاندرد ASTM.					
5/ يمارس العاملين عمليات التحليل في بيئة ممتازة من ناحية الاضاءة والتهوية والرطوبة ودرجة الحرارة.					
6/ توفر إدارة المختبر كل إحتياجات التحاليل من مواد واجهزة ومحاليل معايرة واى موارد للتحليل في اماكن التحليل.					
7/ تتم معايرة اجهزة التحليل بالمختبر دورياً وباستمرار من قبل جهات معايرة خارجية.					
8/ يتم اختبار صلاحية وكفاءة اجهزة التحليل بعينات قياسية قبل بدء عمليات التحليل.					

الفرضية الثانية: هناك علاقة ذات دلالة إحصائية بين تطبيق نظام الوثائق والتحكم و آداء المختبرات قي المختبر المركزي بشركة مصفاة الخرطوم.

العبـــــــــــــــارة	أوافـــق بشدة	أوافق	محايد	لا أوافق	لا أوافـق بشدة
1/ يساهم نظام التحكم في الوثائق في توضيح تطبيق الإجراءات.					
2/ تطبيق نظام التوثيق والتحكم بالوثائق يساعد على سهولة وفهم تطبيق تعليمات العمل.					
3/ تطبيق نظام التوثيق يؤدى إلى تعقيد اجراءات العمل احياناً.					
4/ التحكم فى إجراءات وتعليمات العمل من خلال التوثيق يقلل من ضغط العمل من خلال وضـــوح المســـئوليات والصـــلاحيات بالنســـبة للعاملين.					
5/ كل الإجراءات التي تخص سير العمليات في المختبر متاحة للعاملين ومفهومة وواضحة وموثقة					
6/ تتم مراجعة الوثائق وتحديثها والتحكم بها بصورة دورية.					
7/ يوجد توثيق وحفظ للوثائق والإجراءات خارجية المصدر مثل (إجراءات المعايرة والعينات القياسية وإجراءات الصيانة وقطع الغيار بالنسبة للأجهزة).					
8/ في حالة إنتهاء صلاحية الوثيقة يتم سحبها فوراً من أماكن العمل واصدار الوثيقة البديلة.					
9/ تحتفظ ادارة المختبر بكل الوثائق الخاصة بجميع الأجهزة بالاضافة إلى إجراءات خطة الصيانة الدورية.					

الفرضية الثالثة: هناك علاقة ذات دلالة إحصائية بين التحسين المستمر و آداء المختبرات في المختبر المركزي بشركة مصفاة الخرطوم.

العبـــــــــــــــارة	أوافـــق بشدة	أوافق	محايد	لا أوافق	لا أوافـق بشدة
1/ توجد سياسة واضحة وفعالة للتحسين المستمر ورفع مستوى الآداء في المختبر المركزي من خلال سياسة وأهداف الجودة.					
2/ تتبع إدارة المختبر إجراءات معينة وفعالة لإتخاذ قرار الإجراءات التصحيحية في حالات حدوث أخطاء في التحاليل.					
3/ تؤدي الإجراءات المتبعة عند حدوث خطأ في التحليل إلى الوصول إلى الأسباب الجذرية التي أدت لحدوث الخطأ.					
4/ توجد منهجية واضحة لمراقبة فعالية الإجراء التصحيحي لضمان حل الأخطاء بصورة جذرية فى الزمن المخطط له.					
5/ تتخذ إدارة المختبر جملة من الأفعال الوقائية لضمان عدم وقوع أخطاء أثناء عمليات التحليل وذلك من خلال التحليل والتقييم للمخاطر التي قد تصاحب عمليات التحليل.					
6/ تقوم إدارة المختبر باجراء تقييم للأفعال الوقائية والتصحيحية لضمان فعاليتها في منع وقوع الاخطاء مستقبلاً.					
7/ توجد اجراءات وقائية استباقية لاكتشاف فرص التحسين المستمر.					

الفرضية الرابعة: هناك علاقة ذات دلالة احصائية بين تلبية المتطلبات الفنية للمواصفة آيزو 17025 و آداء المختبرات في المختبر المركزي بشركة مصفاة الخرطوم.

العبـــــــــــــــارة	أوافـــق بشدة	أوافق	محايد	لا أوافق	لا أوافـــق بشدة
1/ توفر إدارة المختبر كل الظروف التي تؤدى للحصول على نتائج صحيحة ودقيقة وموثوق بها.					
2/ تراقب إدارة المختبر ظروف العمل والبيئة المناسبة للعاملين والظروف البيئية للعينات والأجهزة وتتحكم بها.					
3/ كل فرد من الأفراد العاملين بالمختبر يعرف تماماًمهامه وصلاحياته من خلال حصوله على نسخة من الوصف الوظيفي التي تليه.					
4/ يوضح الوصف الوظيفي المسئوليات والصلاحيات تماماً.					
5/ يوجد إجراء بالمختبر لتحديد الإحتياج التدريبى لكل العاملين.					
6/ توجد بالمختبر خطة تدريبية واضحة لرفع قدرات العاملين الفنية.					
7/ تدعم إدارة المختبر برنامج التدريب وتنمية المهارات الشخصية الخاصة بالمعامل وتوفرها للعاملين لتطويرهم.					
8/ تحدد إدارة المختبر آليات لتقييم العوامل التي تؤثر على صحة النتائج مثلاً معايرة الأجهزة – العينة – خبرة الشخص المحلل– الظروف البيئية المحيطة....(الخ).					
9/ تتحكم إدارة المختبر في جميع البيانات الخاصة بالتحليل (نتائج– بيانات معايرة– وغيرها).					
10/ تتم معايرة الأجهزة على الشقين (Software و Hardware) ويتم عزلها تماماً حتى لايتم تغيير ضبط الجهاز بشخص اخر غير مسؤول عن المعايرة.					

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 Implementation of ISO 17025 on Laboratories Performance in Central Laboratory, Khartoum Refinery Company Ltd, 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:

Abd Almoniem Abd Aldaim Ali 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 17025:2005:

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 the working environment conditions and laboratories performance in central laboratory at Khartoum Refinery Company.

The phrase	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1- There are procedures to protect samples under testing from contaminated by surrounding environment or any other samples or solutions.					
2-There are procedures to monitor the general environmental situation inside the laboratory.					
3-There are controlled procedures for the environmental condition such as humidity, radiation, dust, noise level, temperature and lighting intensity.					
4-Analysis and testing shall be discontinued if the laboratory's environmental condition does not match the environmental condition required by the ASTM standard.					
5-Employees perform analysis in an excellent environment in terms of lighting, ventilation, humidity and temperature.					
6-Laboratory management provides all analysis needs of materials, devices, calibration solutions and any resources for analysis in the analysis sites.					
7-Laboratory analysis equipment is calibrated periodically and continuously by external calibration bodies.					
8-The validity and efficiency of analytical instruments are tested with standard samples before the analysis begins.					

The second hypothesis

There is a statistically significant relationship between implementing documentation and control system and laboratories performance in central laboratory at Khartoum Refinery Company.

The phrase	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1-The document control system clearly identify the implementing of procedures.					
2-The application of documentation and control system helps to facilitate and understand the work instructions.					
3- The application of the documentation system sometimes complicates work procedures.					
4-Controlling the procedures and instructions of the work through documentation reduces the work pressure through the clarity of responsibilities and authorities for employees.					
5-All procedures related to laboratory activities are available, understood and clearly documented to the employees.					

6- Documents are reviewed, updated and controlled periodically.					
7- There is documentation and archiving of external source documents and procedures (such as calibration procedures, standard samples, maintenance procedures and spare parts for devices).					
8- When the document expires, it is canceled immediately and another replacement document is issued.					
9-The laboratory management maintains all documents related to all devices in addition to the procedures of the periodic maintenance plan.					

The third hypothesis

There is a statistically significant relationship between continuous improvement and performance laboratories in central laboratory at Khartoum Refinery Company.

The phrase	Strongly Agree	Agree	Neutral	Disagree	Strongly disagree
1-The laboratory management maintains clear and effective policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives.					
2-There are a certain procedures and effective decision making to corrective actions in cases of errors in the analysis					
3-When an error occurs in the analysis, there is a procedures lead to the root causes of the error.					
4-There is a clear methodology to monitor the effectiveness of the corrective action to ensure that errors are fundamentally resolved at					

the planned time.					
5-Laboratory management takes a series of preventive actions to ensure that there are no errors during the analysis process, through analysis and assessment of the risks that may accompany the analysis.					
6-Laboratory management conducts an assessment of preventive and corrective actions to ensure their effectiveness in preventing future errors.					
7-Proactive preventive procedures and measures are in place to discover opportunities for continuous improvement					

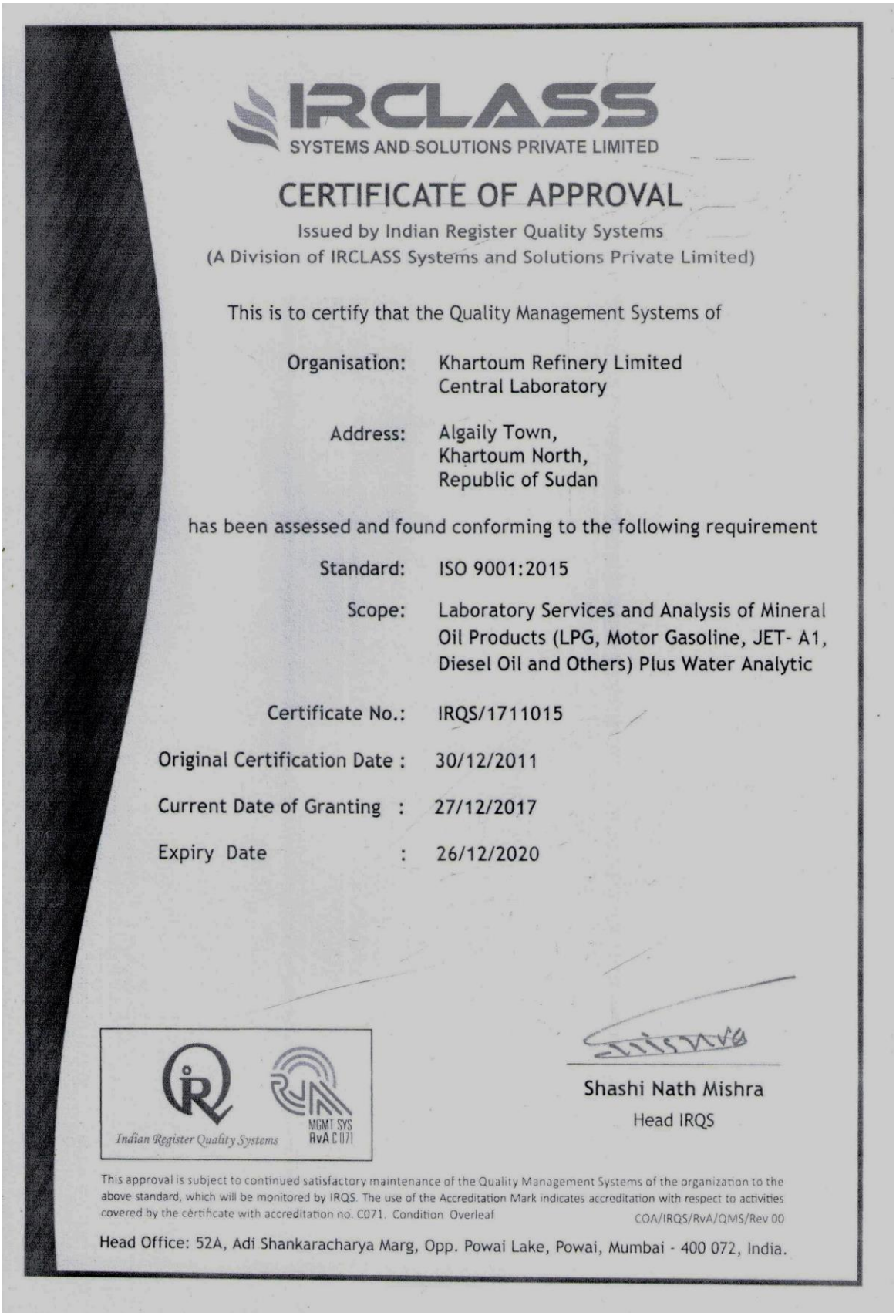
The fourth hypothesis

There is a statistically significant relationship between meeting the technical requirement of ISO 17025 and laboratories performance in central laboratory at Khartoum Refinery Company.

The phrase	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1-Laboratory management provides all conditions that lead to accurate and reliable results.					
2-The laboratory management monitors and controls the working conditions and provide suitable environment for the employees, samples and devices.					
3-Every individual working in the lab knows his / her duties (responsibilities and authorities) by obtaining a copy of the job description.					
4- The job description clearly describes the responsibilities and authorities powers.					
5-There is a procedure in the laboratory to determine the training needs of all employees.					
6-The laboratory has a clear training plan to raise the technical capabilities of workers.					
7-The laboratory management supports the training program and the development of personal skills of the laboratories and provide them to staff.					
8-Laboratory management determines mechanisms to evaluate factors that affect the validity of the results, for					

example, calibration of instruments ,the samples, the experience of the analyst person, the environmental conditions … (etc.)					
9-The laboratory management controls all data related to the analysis (results - calibration data - and others).					
10-Instrumens are calibrated on both (Software and Hardware) and completely isolated so that the settings are not changed by unauthorized person the one.					

Appendix (3):



IRCLASS
SYSTEMS AND SOLUTIONS PRIVATE LIMITED

CERTIFICATE OF APPROVAL

Issued by Indian Register Quality Systems
(A Division of IRCLASS Systems and Solutions Private Limited)

This is to certify that the Quality Management Systems of

Organisation: Khartoum Refinery Limited
Central Laboratory

Address: Algaily Town,
Khartoum North,
Republic of Sudan

has been assessed and found conforming to the following requirement

Standard: ISO 9001:2015

Scope: Laboratory Services and Analysis of Mineral Oil Products (LPG, Motor Gasoline, JET- A1, Diesel Oil and Others) Plus Water Analytic

Certificate No.: IRQS/1711015

Original Certification Date : 30/12/2011

Current Date of Granting : 27/12/2017

Expiry Date : 26/12/2020

Indian Register Quality Systems
MGMT SYS
RvA C 071

Shashi Nath Mishra
Head IRQS

This approval is subject to continued satisfactory maintenance of the Quality Management Systems of the organization to the above standard, which will be monitored by IRQS. The use of the Accreditation Mark indicates accreditation with respect to activities covered by the certificate with accreditation no. C071. Condition Overleaf

COA/IRQS/RvA/QMS/Rev 00

Head Office: 52A, Adi Shankaracharya Marg, Opp. Powai Lake, Powai, Mumbai - 400 072, India.

Appendix (4):

Certificate No. TL/41

KENYA ACCREDITATION SERVICE

KENAS

Accreditation Certificate

This is to certify that

KHARTOUM REFINERY COMPANY (KRC)
(CENTRAL LABORATORY)

is accredited as a Testing Laboratory
upon satisfying the requirements of

ISO/IEC 17025: 2005

General requirements for the competence of testing and calibration laboratories in respect of the attached schedule

Effective from: **01st December 2017**

Expiry on: **30th November 2020**

KENYA ACCREDITATION SERVICE

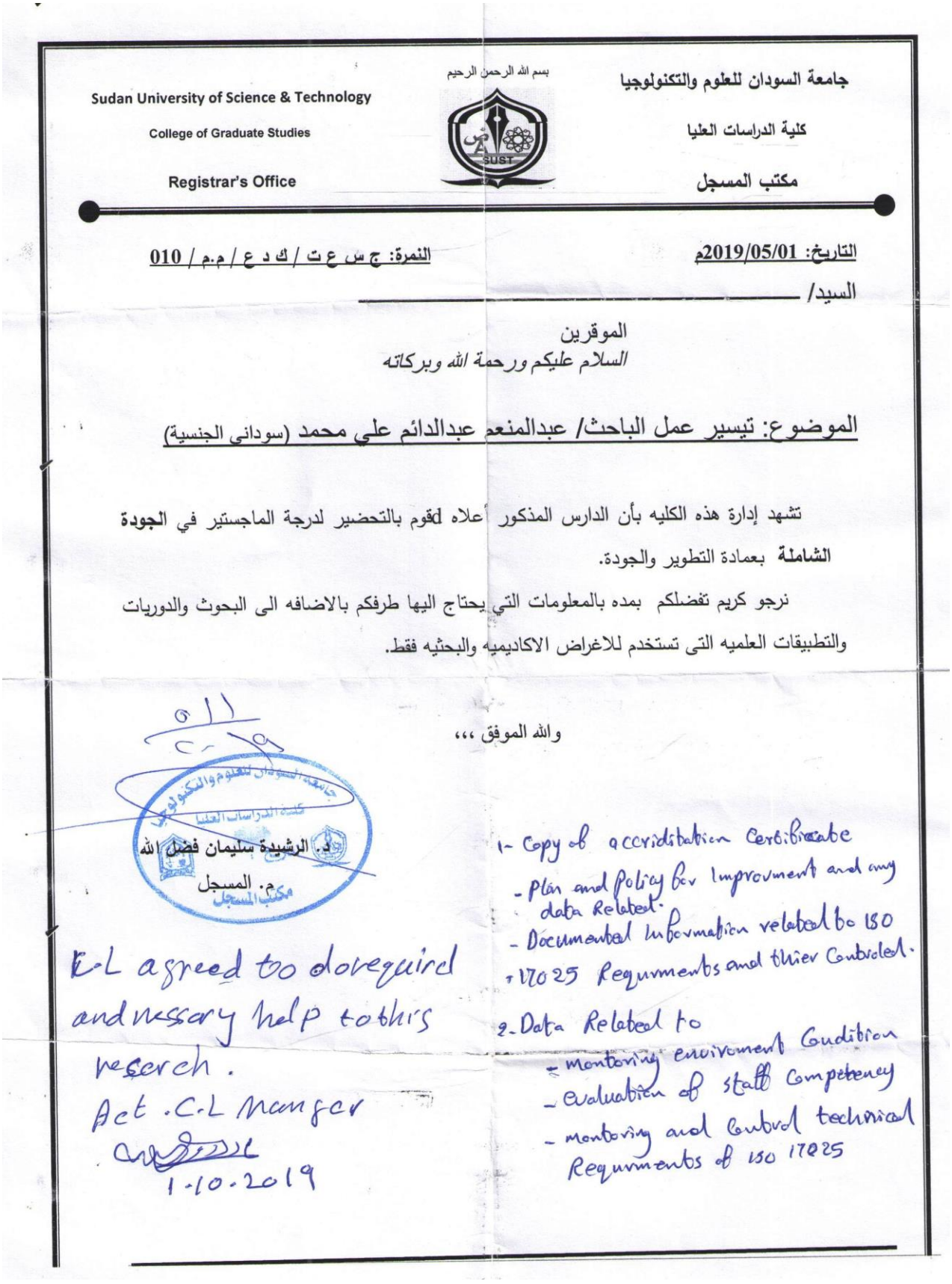
KENAS

ilac-MRA

Martin Chege

Chief Executive Officer / Authorised Officer
Kenya Accreditation Service

Appendix (5):



بسم الله الرحمن الرحيم

جامعة السودان للعلوم والتكنولوجيا
كلية الدراسات العليا
مكتب المسجل

Sudan University of Science & Technology
College of Graduate Studies
Registrar's Office

التاريخ: 2019/05/01م
النمرة: ج س ع ت / ك د ع / م.م / 010

السيد/ _____

الموقرين
السلام عليكم ورحمة الله وبركاته

الموضوع: تيسير عمل الباحث/ عبدالمنعم عبدالدائم علي محمد (سوداني الجنسية)

تشهد إدارة هذه الكليه بأن الدارس المذكور أعلاه يقوم بالتحضير لدرجة الماجستير في **الجودة الشاملة** بعمادة التطوير والجودة.

نرجو كريم تفضلكم بمده بالمعلومات التي يحتاج اليها طرفكم بالاضافه الى البحوث والدوريات والتطبيقات العلميه التى تستخدم للاغراض الاكاديميه والبحثيه فقط.

والله الموفق ،،،

د. الرشيدة سليمان فضل الله
م. المسجل
مكتب المسجل

1- Copy of accreditation Certificate
- Plan and Policy for Improvment and any data Related.
- Documented Information related to ISO 17025 Requirments and thier Controled.

2- Data Related to
- monitoring environment Condition
- Evaluation of staff Competency
- monitoring and Control technical Requirments of ISO 17025

E-L agreed to do required and nessary help to this research.
Act. C-L Manger
1-10-2019