## Sudan University of Science and Technology College of graduate studies

## Impact of Implementation of ISO 17025 in Chemical laboratories- Case Study of Sudanese Standards & Metrology Organization- 2016

اثر تطبيق الايزو 17025 علي المعامل الكيميائية-دراسة حالة الهيئة السودانية للمواصفات والمقاييس-2016

# A dissertation submitted for partial fulfillment for M.Sc degree in Management Quality and Excellence

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## قال تعالى:

وَقُلِ اعمَلُوا فَسَيرَى اللَّهُ عَمَلَكُم وَرَسُولُهُ وَالمُؤمِنُونَ وَسَتُرَدُّونَ إِلَى عَالِمِ الغَيبِ وَالشَّهَادَةِ فَيُنَبِّئُكُم بِمَا كُنتُم تَعمَلُونَ ﴿١٠٥﴾

صدق الله العظيم

سورة التوبة الآية (105)

## DeDication

I dedicate this dissertation to my beloved sister

My husband

My kids

My friends

To The I oving my moTher

they have successfully made me the person lam becoming

## Acknowl edgment

I am highly grateful to God for his blessing, with great pleasure I would like to acknowledge the support, assistances and contribution made by individuals from the beginning of the field work, providing me access, data and information, to the writing process until the completion of this thesis.

First of all, I want to give thanks to Dr. Mohamed Siddig for the access and assistance in order to make my field work possible, thanks for your critical eye and constructive criticism and for your time to go through the whole chapters to 'polishing' the language, sentence by sentence in a short time.

I give my special appreciation for the manager of SSMO ALfatih Yaseen for his sincerity and willingness to participate and provide me rich and valuable data, and for being such a nice neighbor.

To my friends for their time, our discussions on the thesis, comments, ideas that contribute to improvement of the thesis.

At last but not least thanks to SSMO for the study opportunity, and for technical assistance during the last phase of finishing this thesis.

#### Abstract

This descriptive study was carried out in Sudanese Standards and Metrology Organization (SSMO), during the period from December 2015 to May 2016, to detect the impact of implementation of ISO 17025 on chemical laboratories of Sudandards standers and metrology organization, which contain two groups: management requirements and technical requirement laboratories.

Questionnaires was distributed to the six head departments of the laboratories that apply ISO 17025 and then collected and analyzed using SPSS program ,frequencies and percentages were calculated.

The study revealed the following results, in technical requirements which include the laboratories design before implementing of ISO was divided between good (67.7%) and fair (33.3%) but after implementation were improved to excellence (100%). Environment condition inside laboratories before very good (16.7%), good (33.3%) and fair (50%) but after implementing of ISO improved to very good (83.3%) and excellence (16.7%). Continuous improvement of devices before ISO were give good (83.3%), fair (16.7%) but after implementation were improved to very good (83.3%), good (16.7%). The efficiency of individual inside laboratory before implementing of ISO was good (66.7%), fair (33.3%) but after implementation was improved to excellence (33.3%), very good(66.7%) .The responsibilities and powers of the members of the laboratory to avoid inconsistencies before implementing ISO no (66.7%), sometime (33.3%) but after yes (100%). Accreditation system that includes description of all operation before implementing ISO no (66.7%), sometime (33.3%), but after implementation yes (100%). The setting of non matching process before implementation no (66.7%), sometime (33.3%) but after implementation yes (100%). The definition of responsibilities for dealing with non conforming work before yes (83.3%), sometime (16.7%), but after the implementation yes (100%). The records of members with competence before yes (83.3%), no (16.7%), but after yes (100%). Using of modern calibration in the laboratory the frequency before implement was no (83.3%), sometime (16.7%), but after yes (100%). Monitor of non matching process with possibility of providing opportunities for improvement before sometimes (50%), yes (33.3%) and no (16.7%), but after implementation

yes (100%). Specific laboratory method to validate test methods before implementing ISO no (83.3%), sometime (16.7%), but after yes (100%). The system to practice the process of withdrawal and sample processing before yes(100%) and after also yes by (100%). Specific way to insure the validity of the test results before no (100%) but after yes (100%). In management requirement there are also improvement as we can see from the results the legal status of lab established in quality manual before implementing ISO 17025 no (100%) but after implementation yes (100%). Purchase orders are available before implementation (66.7%) said that it is available by 30% but after implementation (83.3%) said available by 70%. Control and archiving of documents in laboratory before the frequency fair (83.3%) but after very good Illustrative description of the organizational structure before (100%).implementation no (100%) but after implementing yes (100%). Policies and objectives of the laboratory match in terms of quality with what stated in quality manual yes (66.7%) but after yes (100%). The list of all the laboratory methods used system before no (66.7%) but after implementing yes (66.7%). The internal and external documents alike which must be submitted for verification before no (66.7%) but after yes (100%). Involving of senior management in the review of the laboratory the frequency before no (66.7%) but after yes (100%). Agreement on the procedures carried out according to the time period specified before no (50%) but after yes (100%). Stop working to inform the client if necessary before implementing yes (83.3%) but after yes (100%). Taking immediate action if necessary before yes (100%) and also after implementation yes (100%). Corrective and preventive actions carried out and be verified before no (83.3%) but after implement yes (83.3%). Subcontracting and deal only with accredited laboratories before implement no (100%) but after implementing yes (33.3%). Description of quality manual laboratory to the formation and system documentation before no (100%) but after yes (100%). The system applied in laboratory allows the implementation of internal audits whenever necessary before no (100%) but after yes (100%). Follow up of the laboratory to customer survey procedures before no (100%) but after implementation yes (100%).

The study concludes that great and clear improvement in laboratories that implemented ISO and got accreditation certificate.

## المستخلص

أجريت هذه الدراسة الوصفية بالهيئة السودانية للمواصفات والمقاييس في الفترة من ديسمبر 2015الى مايو 2016, لتقييم المعامل الكيميائية قبل وبعد تطبيق المواصفه الدولية ISO 17025, والتي تحتوي علي مجموعتين من المواصفات متطلبات ادارية وفنية.

وزع الاستبيان على ستة أشخاص يراسون ادارات من التمرين المعملي تطبق ISO 17025 ثم جمع الاستبيان وحلل باستخدام برنامج SPSS.

كشفت الدراسة عن النتائج التالية التي تشمل المتطلبات الفنية لتصميم المعمل قبل تطبيق ISO مقسم بين جيد بنسبة (67%) ومقبول بنسبة (33.3%) ولكن بعد تطبيق الايزو تحسن للامتياز بنسبة (100%) حالة البيئة داخل المعمل قبل تطبيق الايزو كانت جيد جدا بنسبة (16.7%) جيد بنسبة (33.3%) ومقبول بنسبة (50%) ولكن بعد تطبيق الايزو تحسن الى جيد جدا بنسبة (83.3%) وممتازبنسبة (16.7%). التحسين المستمر للاجهزة قبل التطبيق كانت بين جيد بسبة (83.3%) ومقبول بنسبة (16.7%) لكن بعد التطبيق تحسنت الجودة الى جيد بنسبة (16.7%) وجيد جدا بنسبة (83.3%) . كفاءة الفرد داخل المختبر قبل التطبيق كانت جيد بنسبة (66.7%) ومقبول بنسبة (33.3%) ولكن بعد التطبيق تحسنت الى جيد جدا بنسبة (66.7%) وامتياز بنسبة (33.3%). النشاطات والمسؤوليات والصلاحيات لافراد المختبر لتفادي التضارب قبل التطبيق كانت مطبقة احيانا بنسبة (33.3%) والتوجد بنسبة (66.7%) ولكن بعد التطبيق تم تطبيقها بنسبة (100%) . نظام الاعتماد الذي يشمل جميع العمليات قبل التطبيق كان موجود احيانا بنسبة (33.3%) لا يوجد بنسبة (66.7%) لكن بعد التطبيق طبق بنسبة (100%). نظام تحديد ضبط العمليات الغير مطابقة قبل التطبيق كان معدوم بنسبة (66.7%) ومطبق احيانا بنسبة (33.3%) لكن بعد التطبيق طبق بنسبة (100%). تحديد المسؤوليات للتعامل مع العمل غير المطابق قبل التطبيق كان موجود بنسبة (83.3%) واحيانا بنسبة (16.6%) وبعد التطبيق طبق بنسبة (100%). احتفاظ المختبر بسجلات محدثة للأفراد ذوي الخبرة قبل التطبيق كان مطبق بنسبة (83.3%) لايطبق بنسبة (16.7%) وبعد التطبيق طبق بنسبة (100%). استخدام المختبر طرق الأختبار وعمليات المعايرة الحديثة قبل التطبيق لايوجد بنسبة (83.3%) واحيانا بنسبة (16.7%) ولكن بعد التطبيق طبق بنسبة (100%). رصد العمليات غير المطابقة مع امكانية توفير فرص التحسين لها قبل التطبيق كانت تطبق احيانا بنسبة (50%) نعم مطبقة بنسبة (33.3%) ولا تطبق بنسبة (16.7%) وبعد التطبيق طبقت بنسبة (100%). الطرق المحددة بالمختبر للتحقق من صحة طرق الأختبار قبل التطبيق كانت لا تطبق بنسبة (83.3%) واحيانا تطبق بنسبة (16.7) ولكن بعد التطبيق طبقت بنسبة (100%). لدى المختبر نظام متبع لعملية سحب وتجهيز العينات قبل التطبيق موجود بنسبة (100%) وبعد التطبيق أيضا موجود بنسبة (100%). المختبر يمتلك طرق محددة للتأكد من صحة نتائج الأختبار قبل التطبيق لاتوجد بنسبة (100%) وبعد التطبيق وجدت بنسبة .(%100) في المتطلبات الادارية يوجد أيضا تحسين وذلك من خلال النتائج, فالوضع القانوني للمختبر مبين في دليل الجودة قبل تطبيق الايزولايوجد بنسبة (100%) ولكن بعد التطبيق طبق بنسبة (100%). توفر طلبيات الشراء من أجهزة ومتطلبات عمل قبل التطبيق كانت غير متوفرة بنسبة (66.7%) وبعد التطبيق توفرت بنسبة ( 83.3%) . ضبط وحفظ السجلات والوثائق بالمختبر قبل التطبيق كانت مقبولة بنسبة (83.3%) ولكن بعد التطبيق تحسنت الى جيد جدا بنسبة (100%). وجود وصف توضيحي للهيكل التنظيمي للمختبر قبل التطبيق لايوجد بنسبة (100%) وبعد التطبيق نفذ بنسبة (100%). تطابق سياسات وأهداف المختبر من حيث الجودة مع ما ذكر في دليل الجودة قبل التطبيق كانت مطبقة بنسبة (66.7%) وبعد التطبيق تحسنت بنسبة (100%). وجود قائمة بالمختبر لجميع الوثائق المستخدمة بالنظام قبل التطبيق لاتوجد بنسبة (66.7) وبعد التطبيق طبقت بنسبة (66.7%). معرفة المختبر بالوثائق الداخلية والخارجية على السواء والتي يجب أن تقدم للتحقق قبل التطبيق لاتوجد بنسبة (66.7%) ولكن بعد التطبيق نفذت بنسبة (100%). مشاركة الادارة العليا في المراجعة للمختبر قبل التطبيق لا توجد بنسبة (66.7%) وبعد التطبيق طبقت بنسبة (100%). الاتفاق على الاجراءات التي نفذت وفقا للفترة الزمنية المحددة قبل التطبيق لاتطبق بنسبة (50%) وبعد التطبيق طبقت بنسبة (100%). وقف العمل وابلاغ العميل اذا لزم الأمر قبل التطبيق موجود بنسبة (83.3%) وبعد التطبيق تحسن بنسبة (100%). اتخاذ اجراءات فورية اذا لزم الأمر قبل موجودة بنسبة (100%) وبعد التطبيق ايضا بنسبة (100%). تنفيذ الاجراءات التصحيحية والوقائية اللازمة والتحقق منها قبل التطبيق التوجد بنسبة (83.3%) وبعد التطبيق تحسنت بنسبة (83.3%). التعاقد والتعامل مع مختبرات معتمدة قبل التطبيق لاتوجد بنسبة (100%) وبعد التطبيق تحسنت بنسبة (33.3%). تضمن دليل الجودة بالمختبر وصف تكوين وثائق النظام قبل التطبيق لاتوجد بنسبة (100%) وبعد التطبيق وجدت بنسبة (100%). النظام المطبق بالمختبر يسمح بتنفيذ مراجعات داخلية متى ما دعت الضرورة لذلك, قبل التطبيق لم تنفذ بنسبة (100%) وبعد التطبيق نفذت بنسبة (100%). للمختبر اجراءات متبعة لاستطلاع رأى العملاء قبل التطبيق لا توجد (100%) وبعد التطبيق طبقت بنسبة (100%).

وخلصت الدراسة الى وجود تحسين كبير في المعامل التي قامت بتطبيق ISO وتحصلت علي شهادة الاعتماد.

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# **Chapter One Introduction**

## **Chapter One**

## 1. Introduction

#### 1.1 Introduction:

Quality system is a set of interrelated or interacting elements that organizations use to formulate quality policies and quality objectives and to establish the processes that are needed to ensure that policies are followed and objectives are achieved. These elements include structures, programs, practices, roles, procedures, plans, rules, responsibilities, relationship, contracts, agreements, documents, records, methods, tools, techniques, technologies, and resources (Praxiom Research Group Limited, 2016).

International Organization for Standardization (ISO) is an independent, non governmental international organization with membership of 162 national standards bodies.ISO has published international standard and related documents, covering almost every industry, from technology, to food safety, to agriculture and health care (Hahn *et al*, 2016).

ISO/IEC 17025was first issued in 1999 by the International Organization for Standardization (ISO) and the International Electro technical Commission (IEC). It is the single most important standard for calibration and testing laboratories around the world. 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 (Ng Kim-soon, 2012).

The Sudanese standards and metrology organization (SSMO) is a governmental organization set up under the private law of SSMO, issued in 1993. The structure includes 15 laboratories in addition to those established at the SSMO branches, most important and well equipped ones are those in port Sudan branch (SSMO Report, 2010).

In this study is to identify the impact of the application of ISO/IEC 17025: 2005 for some laboratories in the Sudanese standards and metrology organization

(SSMO), which has implemented the specification and obtain a certificate of accreditation and the extent of the improvement that has occurred after the implementation.

## 1.2: Objectives:

## 1.2.1: General objective:

To study the impact of implementation of ISO 17025 in chemical laboratories of Sudanese standards and metrology organization.

## Chapter two Literature review

## **Chapter Two**

## 2. Literature review

## **2.1: Quality:**

Quality has a different means according to field of specification such as for individuals mean convinced the work, stimulate the performance of the work as proper and acceptable, cooperation within the team, awareness and self-discipline, commitment and pledge to fulfill the requirements. But for management, define as a clear vision for all departments and divisions, good working relationships, role models, meet obligations. While for customers means, access to high-quality commodity, and at a reasonable price at an appropriate time in a good way (Praxiom research group limited, 2014).

## 2.2: Quality system:

Quality system is a unified global system of quality standards universally agreed to be an international document to ensure the quality of management. It is a system of checking on what their work conform to procedures and policies that have written and adopted (Esin sadikoglu and talha temour, 2012).

## 2.3: International Organization for Standardization ISO:

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" (Hahn *et al*, 2016).

## 2.3.1: ISO 17025:

ISO/IEC 17025 is the general requirements for the competence of testing and calibration laboratories is the main ISO stander used by testing and calibration laboratories. 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 it applies directly to those organizations that produce testing and calibration on

results. 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 is not accredited. Originally known as ISO/IEC Guide 25. Since its initial release, a second release was made in 2005 after it was agreed that it needed to have its quality system words more closely aligned with the 2000 version of ISO 9001 (Honsa *et al*, 2012).

The standard was first published in 1999 and on 12 May 2005 the alignment work of the ISO/CASCO committee was completed with the issuance of the reviewed standard. The most significant changes introduced greater emphasis on the responsibilities of senior management, and explicit requirements for continual improvement of the management system itself, and particularly, communication with the customer (Hahn *et al*, 2016).

The two main sections in ISO/IEC 17025 are management requirements and technical requirements. Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements includes factors which determine the correctness and reliability of the tests and calibrations performed in laboratory (Honsa *et al*, 2012).

Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an accreditation body. Since the standard is about competence, accreditation is simply formal recognition of a demonstration of that competence. A prerequisite for a laboratory to become accredited is to have a documented quality management system. The usual contents of the quality manual follow the outline of the ISO/IEC 17025 standard (Honsa *et al*, 2012).

## 2.3.1.1: Management requirements:

## **2.3.1.1.1: Organization:**

It is legal identity that satisfies needs of the customer, protection of customer's information, electronic storage and transmission of data. Also responsibilities of key personnel of the parent organization that influence testing activities. In addition personnel awareness of their duties and contribution to achievement of management system objectives. Appropriate communication processes by top management regarding the effectiveness of the management system (QNI, 2014).

## 2.3.1.1.2: Management system:

In management system there should be quality manual: in policy, system, programmers, procedures and instructions communicated. The quality policy is issued by top management and includes defined objectives, commitment to comply with the standard and continual improvement (QNI, 2014).

#### 2.3.1.1.3: Document control:

Invalid or obsolete documents removed or assured against unintended use. The Periodic review, revision of procedures and changes should be reviewed and identified. Description of computerized system also for changes (EURACHEM/CITAC Guide, 2007).

## 2.3.1.1.4: Review of requests, tenders and contracts:

Procedures for review:

The requirements including the methods are defined and documented, capacity and resources to meet the requirements and appropriate test method is selected meeting the customer's requirements.

Customers and affected personnel are informed about any requirement or deviation (EURACHEM/CITAC Guide, 2007).

## 2.3.1.1.5: Subcontracting of tests and calibration:

Laboratory subcontracts work for reasons such as work load, the lab is responsible except when customer or authority specifies subcontractor. There is register of subcontractors (ONI, 2014).

## 2.3.1.1.6: Purchasing services and supplies:

Procedure for selection and purchasing of services and supplies that affect the quality of tests/ calibration, supplies that affect the quality of tests/ calibration are not used until inspected or verified to standard specifications, data on services and supplies, reviewed and approved technical contend (QNI, 2014).

#### 2.3.1.1.7: Service to customer:

Co-operation to clarify requests and the performance in relation to the work performed\_ ensure confidentiality to other customer, reasonable access for witnessing, preparation of items needed for verification purposes, information of delay or deviations in test/ calibration performance, positive and negative feedback from customer for system improvement (EURACHEM/CITAC Guide, 2007).

## **2.3.1.1.8:** Complaints:

Records for all complaints, procedure for resolution of complaints investigation of corrective actions (QNI, 2014).

## 2.3.1.1.9: Control of nonconforming testing and/or calibration work:

Procedure what to do if an aspect of the test/ calibration or result does not conform with the procedure, the responsibilities for management of nonconforming work including halting of work, withholding of test report/ calibration, if this non conforming work could reoccur: corrective action procedure shall be followed (QNI, 2014).

## **2.3.1.1.10: Improvement:**

Analysis of data, corrective and preventive action, management review (QNI, 2014)

#### **2.3.1.1.11:** Corrective action:

Procedure for corrective actions when nonconforming work or deviations have been identified, corrective action to prevent recurrence, monitor result of CA's: are they effective (ISO Guide 98-3, 2008).

## **2.3.1.1.12: Preventive action:**

Preventive actions are opportunities for needed improvement and to reduce the likelihood of occurrence of potential sources of non compliances. Preventive action is proactive process to identify opportunities for improvement rather than a reaction to problems or complaints (ISO Guide 98-3, 2008).

#### **2.3.1.1.13:** Control of records:

This clause tells about establish and mention procedures to control of records through identification, collection, indexing, access, filling, storage, maintenance and disposal of quality and technical records (NQI, 2014).

## 2.3.1.1.14: Internal auditing:

Guides on policy and procedure of internal quality audit and implementation and effectiveness (ILAC, 2002).

## 2.3.1.1.15: Management review:

Periodic review for effectiveness of Management system. Suitability of policy and procedures, reports of managerial personnel and outcome of audits (international and external), recommendations for improvement (ILAC, 2002).

## 2.3.1.2: Technical Requirements:

## 2.3.1.2.1: General:

Many factor impact correctness and reliability of tests and calibration. Factors affect uncertainty shall be taken into account in: test procedure, training/qualification of equipment, selection and calibration of equipment

(Thompson *et al*, 2006).

#### 2.3.1.2.2: Personnel:

Uses competent staff including contracted employees, supervise as necessary, document qualifications and training, job description for managerial and technical personnel, special authorization for sampling, tests/ calibrations, issuing test reports/ certificates, giving opinions (Thompson *et al*, 2006).

## 2.3.1.2.3: Accommodation and environmental conditions:

Accommodation and environment to suit testing / calibration control and record environmental conditions, effective separation between incompatible activities – prevent cross contaminations, good housekeeping (NQI, 2014).

## 2.3.1.2.4: Test and calibration methods and method validation:

Uses appropriate methods to meet customer needs, Prefer standard methods, validate any non –standard methods, various ways to validate: calibration using ref std or CRM –comparison with other methods –ILC –assessment of uncertainty of results, control of data, appropriate check for calculations and data transfer (NQI, 2014).

## **2.3.1.2.5: Equipment:**

Equipment and its software are capable of achieving accuracy required. Operated by authorized personnel and user- instructions available. Procedures for safe handling, transport, maintenance, equipment outside control of the laboratories are checked before returned to service, intermediate checks and adjustments (Bedson and Sargent, 1996).

## **2.3.1.2.6:** Traceability:

#### Calibration labs:

Traceable to SI: primary standards, secondary standards calibrated by metrology institute, external calibration by laboratories having ISO 17025, If not available: CRM, inter laboratories.

Testing labs: If calibration is dominant factor in uncertainty apply same as cal (Bedson and Sargent, 1996).

## 2.3.1.2.7: Sampling:

Sampling plan and procedures if customer deviations from sampling plan: recorded included in all documents and communicated, Records of all relevant data (NQI, 2014).

## 2.3.1.2.8: Handling of test and calibration items:

Procedure for transport, receipt, handling, protection, storage, retention, and disposal, facilities for avoiding loss or damage to test / calibration item (NQI, 2014).

## 2.3.1.2.9: Assuring the quality of test and calibration results:

Procedures for QC for monitoring validity of result are statistical techniques. Replicate tests/ calibration using the same or different methods, retesting/recalibration of retained items (Hullihen *et al*, 2009).

## 2.3.1.2.10: Reporting the results:

Reports with all info as requested by the customer and method used, test report includes information at least about the laboratory, customer, test/calibration item, dates, method used, sampling, results and authorization, test report include in

addition: statement of compliance, environmental conditions, additional requirements by specific method. No recommendation for the calibration interval in calibration certificate except when agreed with the customer, opinions and interpretations shall be clearly marked (Hullihen *et al*, 2009).

## 2.4: Main benefits of correctly implements ISO/IEC 17025:

Implementing ISO/IEC 17025 as part of laboratory quality initiatives provides both laboratory and business benefits such as: having access to more contracts for testing and/or calibration. Some public and private organizations only give contracts to accredited laboratories. Accreditation will also help to get more contracts from organizations that don't mandate accreditation, but do give preference to accredited laboratories in competitive situations, improved national and global reputation and image of the laboratory, continually improving data quality and laboratory effectiveness, having a basis for most other quality systems related to laboratories, such as good manufacturing practices and good laboratory practices. Analytical testing laboratories seeking ISO/IEC 17025 will be impacted in multiple areas, the main difference between good analytical practices and formal accreditation is the amount of documentation to be developed. There is no doubt that any good analytical laboratory uses qualified analysts, checks the performance of equipment used for testing, and validates analytical methods. However, many times the outcome of the tests is not fully documented. ISO/IEC 17025 accreditation requires formal documentation for nearly everything. It is similar to operating in a regulated environment – 'what is not documented is a rumor,' and is viewed by assessors as 'not being done (Huber L, 2009)

## 2.5 Sudanese standards and metrology organization (SSMO):

## 2.5.1 History of SSMO:

Standardization in Sudan goes back to year 1889 when first order of weights and measures was issued in 1955 witnessed the release of first detailed Sudanese law of weights and measures and foundation the history of concerned department. The law was meant to facilitate mode and means of trade among citizens. In 1972 the

law of weights and measures was amended. Second amendment was aimed to meet the needs of commerce and industry. In 1972 the act of quality control of agricultural products was issued to monitor quality of exports of cereals and oil seeds. During the period 1968-1975, quality control laboratories at Khartoum, Port Sudan and ELObaid were established under the umbrella of ministry of trade. Department of gold testing and Hall-marking was performing certification of gold in accordance with the law of 1972. In1968 department of standards was formed within the framework of ministry of industry. First law of standards was issued in 1990. In 1992-1993 Sudanese standards and metrology organization (SSMO)law was approved, to avoid duplication and enhance an efficient start-up, in october 1994 a ministerial resolution has shifted department of weights and measures, gold testing and hall-marking and quality control to SSMO, In 2007 the foundation order of the Sudanese standards and metrology organization (SSMO) and law was approved, In 2008 the new law of standards and specification was approved and came into enforcement by the approval of the executive regulations in 2009, In 2009 the law of import and export inspection for the services, products conformities and the marketing of products and service was approved and came into enforcement by the SSMO board, according to all the above mention regulation and lows, the laboratories have entity that can be held legally responsible and the laboratories have been formally established, the SSMO is the sole autonomous authority for all standardization activities in the Sudan (SSMO report, 2010).

## 2.5.2: SSMO main and subsidiary branches:

Khartoum head quarter, Red sea, Khartoum Airport, Suba, Elgadarif, Elobaid, Wadi Halfa, Kassala, Abeedya, Neyala, Wad Madani, Dongla, Shellateen, Qary, Alfasher and ElGenena (SSMO report, 2010).

## 2.5.3 Means and Tools:

Provision of national standards and technical regulations with regional and international standards, training of personnel, laboratory analysis and inspection, inspection and qualification and accreditation of service laboratories, release of

quality manuals and procedures, issuing of quality and compliance certificate, granting quality mark, monitor and supervise proper implementation of standards and technical regulations (SSMO report, 2010).



**SSMO (2016)** 

## 2.5.4: Main objectives of SSMO and SSMO testing laboratories:

Protection & awareness of consumers, Strengthening national economy, Improve of national products & services, Adoption of philosophy of quality assurance and enforce implementation, Standardization of commodities, Monitoring quality of imports & exports, Satisfaction of customers, who are concerned with laboratories testing, and or SSMO services, Achievement of quality work within testing

laboratories, Awareness, training, seminars, and workshops activities parties (SSMO report, 2010).

#### 2.5.5: SSMO customers:

Is product suppliers including producers, importers and exporters; and the interested parties, particularly, those concerned with laboratories testing works (SSMO report, 2010).

#### **2.5.6: SSMO future vision:**

Is to see all of its activities are certified and accredited according to the international standards. Therefore, it is strongly committed to launch with its testing laboratories as a threshold point.

Thus, this quality manual is an evidence for documenting this commitment in an approved management system according to ISO/IEC 17025:2005 international standard (SSMO report, 2010).

## 2.5.7: The stage of ISO-17025 for the Sudanese standards and metrology organization:

The Sudanese standards and metrology organization (SSMO) scheme for its laboratories accreditation has been started since 2008 with the first authorized committee with specific schedule include implementation of the parameter and requirements of ISO / IEC 17025:2005 on the testing scope in its different laboratories for head quarter and port Sudan branch, the committee prepared the quality manual and work procedures (managerial, technology), work instructions, standard operating procedure (SOP), standard methods for testing, quality policy. The committee was held its continuous meeting to reach the stage of hiring a consultant, presented bids, got tender quality advisory center in Egypt, after selecting the consultant contract for a specific period during which was every 6 months to review all the documentation to the office of quality as well as candidates for accreditation the laboratories technical activities, And exceed the time limit for action to counsel problem of calibration, there for the work of

bidding for a recognized calibration body a recognized Egypt body (national institute of standardization (NIS) which is recognize as (SI unit), accreditation program, internal audit and training of internal auditors by the chancellor, the simulation of the accreditation operation process is done as a final step of the constant schedule, after completing all the steps accreditation body was inform to start accreditation procedures according to ISO/ICE 17025.

## 2.5.8: Accreditation body (International, Regional, Local):

Top adaptation is the international laboratories accreditation council "ILAC".



**ILAC (2008)** 

Depending on the sequence above is the selection of the Egyptian accreditation council (EGAC), because they are closest geographically to Egyptian organization rely, then the accreditation body sends a team or taking the documents to be review and reply or send a report before them after three months, the accreditation process of the SSMO laboratories has been completed by the year 2011. The equipment and instrument calibration and participation the proficiency testing schedule program was the main factors that lead to this latency, and then check the date of the receipt of the certificate of the accreditation body for 4 years then visit another assessment.

## 2.5.8.1: SSMO labs before accreditation:

The system was not far from implementing of ISO/IEC 17025, all documentation system operation was done according to particular system such as quality terms, reports of tests results, but not detailed in clear way similar to that ISO/IEC 17025 system, Follow up system in the laboratories was well known by staff but not documented as in ISO/IEC 17025 system, internal quality control system of laboratories was done but not as that stated in ISO/IEC 17025 system, filling system of all laboratories personal was found only in SSOM human factor section and was not detailed as that of 17025 systems, recording of laboratories environmental condition system was not documented, equipment calibration operation, intermediate calibration check of laboratories equipment and instrument was not done and documented similar to that of 17025 systems, participation of proficiency tests program was not regular as it was not required, internal audit program was not performed regularly as stated in 17025 systems, analytical methods procedures and standards were not well controlled, customer complains system was not clearly defined.

## 2.5.8.2: Advantages of implementing ISO/ IEC 17025:2005 system in the SSMO laboratories:

Documentation of all the processes performed in the laboratories selection of specialist competent personnel, using of corrected calibration and precisely equipment, connection to other laboratories over the world for mutual information and participation in P.T. schedule (proficiently test), testing report issued by the

laboratory will gain sufficient confidentiality, increasing personnel experiences and skills, upgrading confidentiality level of the laboratory, control of non conforming work (corrective and preventive) action, performing internal audit to keep the continuous improvement.

# **Chapter Three Materials and Methods**

## **Chapter Three**

#### 3. Materials and Methods

## 3.1 Study design:

This is a descriptive study, aimed to study the impact of implementation of ISo17025 in chemical laboratories of Sudanese standards and metrology organization.

## 3.2 Study area:

Study was conducted in Sudanese Standards and Metrology Organization (SSMO) in Khartoum.

## 3.3 Study subjects:

The questionnaire was distributed to six of senior laboratory technicians of cement, chromatography, microbiology, spectrophotometer, general chemistry, laboratory yields.

## 3.4 data collection:

Data was collected through questionnaires that distributed to the six head departments of the laboratory that apply ISO 17025 and then collected and analyzed using SPSS program

## See appendix (1).

## 3.5 Statistical analysis:

Data was analyzed using SPSS program, frequency and percent were calculated for the data.

#### 3.6 Ethical consideration:

Questionnaire was filled by head technicians after taking written permission from SSMO administration.

# **Chapter Four Results**

## **Chapter Four**

## 4. Results:

Table 4.1: Frequency of technical requirements: pre and poet implementing of ISO 17025:

Variable		Pre		Post	
variable		Frequency	%	Frequency	%
	Ex	0	0.0	0	0.0
The general design in the	Very good	0	0.0	6	100
laboratory	Good	4	66.7	0	0.0
	Fair	2	33.3	0	0.0
	Ex	0	0.0	1	16.7
The environment inside the	Very good	1	16.7	5	83.3
laboratory	Good	2	33.3	0	0.0
	Fair	3	50.0	0	0.0
Devices (preservation	Ex	0	0.0	0	0.0
conditions, operating, periodic	v.good	0	0.0	5	83.3
maintenance, and calibration)	Good	5	83.3	1	16.7
are it in the case of continuous improvement is	Fair	1	16.7	0	0.0
The appropriateness and	Ex	0	0.0	2	33.3
The appropriateness and efficiency of individual inside	v.good	0	0.0	4	66.7
laboratory	Good	4	66.7	0	0.0
laborator y	Fair	2	33.3	0	0.0
Activities, responsibilities and	Yes	0	0.0	6	100
powers of the members of the	No	4	66.7	0	0.0
laboratory have been identified in order to avoid inconsistencies and overlap	Sometimes	2	33.3	0	0.0
Do accreditation system	Yes	0	0.0	6	100
includes a description of all	No	4	66.7	0	0.0
operations and activities technical laboratory	Sometimes	2	33.3	0	0.0
II 1.C 1.1 44 C	Yes	0	0.0	6	100
Has defined the settings for non-matching system process	No	4	66.7	0	0.0
non-matching system process	Sometimes	2	33.3	0	0.0
Is it the definition of	Yes	5	83.3	6	100
responsibilities for dealing	No	0	0.0	0	0.0
with non-conforming work, as	Sometimes	1	16.7	0	0.0

well as with regard to the work					
	Yes	1	83.3	6	100
Is the lab keeps up to date records of members with competence and experience	No	5	16.7	0	0.0
Is it laboratory used	Yes	0	0.0	6	100
procedures and test methods	No	5	83.3	0	0.0
and processes of modern calibration	Sometimes	1	16.7	0	0.0
Is the laboratory monitors non	Yes	2	33.3	6	100
matching processes with	No	1	16.7	0	0.0
possibility of providing opportunities for improvement it	Sometimes	3	50.0	0	0.0
Is there a specific laboratory	Yes	0	0.0	6	100
method to validate test	No	5	83.3	0	0.0
methods	Sometimes	1	16.7	0	0.0
Is the laboratory has system to	Yes	6	100	6	100
practice the process of	No	0	0.0	0	0.0
withdrawal and sample processing	Sometimes	0	0.0	0	0.0
Is the laboratory has a specific	Yes	0	0.0	6	100
way to make sure of the validity of the test results	No	6	100	0	0.0

## In table (4.1) of technical requirement shown:

the lab design before implementing ISO 17025 there are 4 person said good (66.7%) and 2 person said fair by percentage (33.3%) but after implementing there is improvement (100%) because the sixth person said excellence, environment condition inside lab before the frequency one very good(16.7%) two good(33.3%) three fair (50%) but after one excellence(16.7%) five very good (83.3%), continuous improvement of devices the frequency five good(83.3%) one fair(16.7%) but after implementing there are five very good(83.3%) one good(16.7%), the efficiency of individual inside lab before implementing ISO there are four person said good(66.7%) and two said fair(33.3%) but after

implementation two person said excellence(33.3%) and four said very good(66.7%), the responsibilities and powers of the members of the lab to avoid inconsistencies before implementing the frequency four no(66.7%) two sometimes (33.3%) but after the six person said yes (100%), accreditation system that includes description of all operation before implementing two people said sometimes it include(33.3%) and four people said no(66.7%) but after implementation six people said yes it include(100%), the setting of non matching process before implementation there are two person said sometimes (33.3%) and four said no(66.7%), but after implementation six people said yes(100%), the definition of responsibilities for dealing with non conforming work before the frequency five yes(83.3%) and one sometimes(16.7%) but after six said yes(100%), the records of members with competence before five people said that there are no(16.7%) and one said yes(83.3%) but after six people said yes(100%), using of modern calibration in the lab the frequency before one sometime(16.7%) and five no(83.3%) but after six(100%), monitor of non matching process with possibility of providing opportunities for improvement before the frequency three sometimes (50%) and one no (16.7%) two yes (33.3%) but after six persons said yes(100%), specific lab method to validate test methods the frequency before one sometimes (16.7%) and five no (83.3%) but after the frequency all the six person said yes(100%), the system to practice the process of withdrawal and sample processing before the frequency six yes(100%) and after also yes (100%), specific way to insure the validity of the test results before six no(100%) but after six yes(100%).

Table 4.2: Frequency of management requirements: pre and post implementing of ISO17025

*7 • 11		Pre		Post	Post	
Variable		Frequency	%	Frequency	%	
is the legal status of the	Yes	0	0.0	6	100	
laboratory established in a quality manual	No	6	100	0	0.0	
purchase orders of	%100	0	0.0	0	0.0	
equipment, consumables,	%70	0	0.0	5	83.3	
and work requirement	%50	2	33.3	1	16.7	
are available by percentage	%30	4	66.7	0	0.0	
	Ex	0	0.0	0	0.0	
Control and archiving of	v.good	0	0.0	6	100	
documents and records	Good	1	16.7	0	0.0	
in a laboratory are	Fair	5	83.3	0	0.0	
Is there an illustrative	Yes	0	0.0	6	100	
description of the organizational structure of the lab-quality evidence shows various administrative positions for individuals and is being updated	No	6	100	0	0.0	
Are the policies and	Yes	4	66.7	6	100	
objectives of the lab match in terms of quality with what stated in the quality manual	No	2	33.3	0	0.0	
Is there a list of all the	Yes	0	0.0	4	66.7	
laboratory methods used	No	4	66.7	2	33.3	
System	Sometimes	2	33.3	0	0.0	
Is the laboratory known	Yes	0	0.0	6	100	
in the internal and	No	4	66.7	0	0.0	
external documents alike, which must be submitted for verification, including documents relating to computer programs	Sometimes	2	33.3	0	0.0	

	Yes	1	16.7	6	100
	No	4	66.7	0	0.0
Is senior management involved in the review of the laboratory	Sometimes	1	16.7	0	0.0
Is the agreement on the	Yes	2	33.3	6	100
procedures carried out	No	3	50.0	0	0.0
according to the time period specified	Sometimes	1	1.67	0	0.0
Did they stop working to	Yes	5	83.3	6	100
inform the client if necessary	No	1	16.7	0	0.0
Did they take immediate	Yes	6	100	6	100
action if necessary	No	0	0.0	0	0.0
Are corrective and	Yes	0	0.0	5	83.3
preventive actions	No	5	83.3	1	16.7
carried out the necessary and be verified	Sometimes	1	16.7	0	0.0
Does the lab have clear	Yes	0	0.0	2	33.3
conditions for subcontracting and deal only with accredited laboratories	No	6	100	4	66.7
Does the quality manual	Yes	0	0.0	6	100
laboratory describe the formation and system documentation	No	6	100	0	0.0
Is the system applied in	Yes	0	0.0	6	100
the laboratory allows the implementation of internal audits whenever necessary for that	No	6	100	0	0.0
Does the lab follow up to	Yes	0	0.0	6	100
a customer survey procedures	No	6	100	0	0.0

#### From table (4.2) frequency of management requirement:

The legal status of lab established in quality manual before implementing ISO 17025 six people said no(100%) but after implementation the six persons said yes(100%), purchase orders are available before implementation two person (33.3%) said that it is available by 50% and four persons(66.7%) said that it is available by 30% but after implementation five persons(83.3%) said available by 70% and one person(16.7%) said available by 50%, control and archiving of documents in lab before the frequency one good(16.7%) and five fair(83.3%) but after six people said it is very good(100%), illustrative description of the organizational structure before implementation the six people said there is no(100%) but after implementing the six said yes(100%), policies and objectives of the lab match in terms of quality with what stated in quality manual before there are four people said yes(66.7%) and two said no(33.3%) but after the all six said yes(100%), the list of all the lab methods used system before two person said sometimes(33.3%) and four persons said no(66.7%) but after implementing the frequency four yes(66.7%) and two no(33.3%), the internal and external documents alike which must be submitted for verification before four persons said there is no(66.7%) and two persons said sometimes(33.3%) but after the six persons said yes(100%), involving of senior management in the review of the lab the frequency before four no(66.7%) one yes(16.7%) and one sometimes(16.7%) but after six yes(100%), agreement on the procedures carried out according to the time period specified before one person said sometimes (1.67%) three said no (50%) two said yes(33.3%) but after the six yes(100%), stop working to inform the client if necessary before implementing the frequency five person yes(83.3%) and one no(16.7%) but after six person said yes(100%), taking immediate action if necessary before six yes(100%) and also after implement the six said yes(100%), corrective and preventive actions carried out and be verified before one sometimes(16.7%) five persons said no(83.3%) but after implement one said no(16.7%) and five yes(83.3%), subcontracting and deal only with accredited labs before implement the six people said there is no(100%) but after implementing two said yes(33.3%) and four said no(66.7%), description of quality manual laboratory to the formation and system documentation before the six people said there is no(100%) but after all the six said yes(100%), the system applied in lab allows the implementation of internal audits whenever necessary before the frequency six no(100%) but after six yes(100%), follow up of the lab to customer survey procedures before six persons said no(100%) but after implementation the six said yes(100%).

# **Chapter Five Discussion**

#### **Chapter Five**

#### 5. Discussion

According to the results there are differences in the performance of the laboratory after implementing ISO, in technical requirement it is seen from the results described above these is a clear improvement in the technical requirement stipulated by laboratories specifications, and it appears in the periodic maintenance of the equipment and calibration laboratory and the method of conservation has become a regular and permanent basis, which showed improvement in laboratory results, as defined responsibilities and bower of the members of the laboratory, each according to his experience and specialization on, it was introduced accreditation system description of all operation and activities technical laboratory, there are also becoming updated records of individuals qualified and experienced and had previously been nonexistent, and the laboratories become uses modern methods of testing and calibration, it has also been monitoring the non matching processes have been improved, there became the possibility to validate the results of laboratory tests, there became a documentation work of the receipt of the sample for the test to where they leave each end by testing stages as shown in appendices 2,3,4.

Improvement also in management requirement from the above results show the significant improvement that has occurred for the management requirement for laboratories after implementation, this is evident for the legal status of the laboratory, which was not shown in the final quality manual and applied 100%, and also it was seized documents and records in the laboratory where it was non-existent, senior management has also become involved in the review of the laboratory and will be agreed upon procedures carried out in accordance with the time period specified and were previously, the system was created to determine the process control non-conforming and takes it to stop the work if necessary and to inform the customer and take corrective and preventive actions are necessary and verified as shown in appendix 5, there also become followed procedures to solicit customer complaints and opinion.

According to study we found that there are significant variations between pre &post implementing of ISO 17025; there are improvement of the entire management and technical elements after implementing of ISO 17025.

Previous study done by Esin Sadikoglu ana Talha Temur their study examined the effects of ISO17025 accreditation on laboratory performance in Turkey. The result shows that when laboratory adopts ISO accreditation the laboratory can improve its performance.

# Chapter Six Conclusion and Recommendations

#### **Chapter Six**

#### **6: Conclusion and Recommendations**

#### **6.1 Conclusion:**

On the bases of the study we conclude that the effect of the ISO 17025 are clearly visible, the systems have been improved to the best.

#### **6.2 Recommendations:**

On the bases of the study we recommend that - further studies should be done by expansion the area of study to include not just the head technician but all the workers in technical and management area.

ISO 17025 should be implemented to other laboratories of SSMO.

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# Appendix

## **Appendix 1: Questionnaire**

-is the legal status of the laborate	ory established in a quality manual?
Yes ( )	No ( )
-The general design in the labora	atory:-
Excellence ( )	very good ( )
Good ( )	fair ( )
-The environment inside the labor	oratory:-
Excellence ( )	very good ( )
Good ( )	fair ( )
-Devices (preservation cond- calibration) are it in the case of c	itions, operating, periodic maintenance, and continuous improvement is:-
Always ( )	periodically ( )
Sometimes ( )	never ( )
-purchase orders of equipment, by percentage:	consumables, and work requirement are available
100% ( )	70% ( )
50% ( )	30% ( )
-Control and archiving of docum	nents and records in a laboratory are:-
Excellence ( )	very good ( )
Good ( )	Fair ( )

-The appropriaten	ess and efficiency of	of individual inside laboratory:
Excellence (	( )	very good ( )
Good	( )	fair ()
	-	the organizational structure of the lab-quality tive positions for individuals and is being
Yes	( )	No ()
-	nsibilities and powe to avoid inconsiste	ers of the members of the laboratory have been encies and overlap:
Yes	( )	No ( )
-Do accreditation technical laborato	•	a description of all operations and activities
Yes	( )	No ( )
-Are the policies stated in the quali	· ·	the lab match in terms of quality with what
Yes	( )	No ()
-Is there a list of a	ıll the laboratory me	ethods used system?
Ye	es ()	No ()
•		nal and external documents alike, which must ng documents relating to computer programs?
Yes	( )	No ()

-Is senior management involved in the review of the laboratory?
Yes ( ) No ( )
-Is the agreement on the procedures carried out according to the time period specified?
Yes ( ) No ( )
-Has defined the settings for non matching system process:
Yes () No ()
-Is it the definition of responsibilities for dealing with non conforming work, as well as with regard to the work?
Yes ( ) No ( )
-Did they stop working to inform the client if necessary?
Yes ( ) No ( )
-Did they take immediate action if necessary?
Yes () No ()
-Are corrective and preventive actions carried out the necessary and be verified:
Yes () No ()
-Does the lab have clear conditions for subcontracting and deal only with accredited laboratories:
Yes () No ()
-Is the lab keeps up to date records of members with competence and experience?
Yes () No ()

-Is it laboratory used procedures and test methods and processes of modern calibration?
Yes () No ()
If not, how is this justified
-Does the quality manual laboratory describe the formation and system documentation?
Yes () No ()
-Is the laboratory monitors non matching processes with possibility of providing opportunities for improvement it?
Yes () No ()
-Is the system applied in the laboratory allows the implementation of internal audits whenever necessary for that:
Yes () No ()
-Is there a specific laboratory method to validate test methods?
Yes () No ()
-Is the laboratory has system to practice the process of withdrawal and sample processing?
Yes () No ()
-Is the laboratory has a specific way to make sure of the validity of the test results?
Yes ( ) No ( )
-Does the lab follow up to a customer survey procedures?
Yes ( ) No ( )

# Appendix 2:

	نات	طلب تحليل/ إرجاع عي		
				التاريخ: /
			ة الرقابة وتوكيد الجودة	
	NA · Email · · · · cts/ · · · tt	لبلدية مع شارع المك نمر. الفاكس: 249183793101+	يطوم شر <i>ق</i> تقاطع شارع اا 249183749+	
-	البريد الإلكتروني Email: N.A			
_		تبر المقترح لإجراء ألاختبارات		
			لطلوبة:	الاختبارات ا،
	ملاحظات	لمطلوبة	الاختبارات ال	م
	القادية: / /	, tî	أحضر العينة :-	•
	ليفةالتاريخ: / /			
			وفية لشروط الاستلام: , / ألإرجاعا/	
	الوظيفة:التأريخ /			
	الوطيفةالناريح /	التوقيع	بالمحتابل	اشم المستمر
				<u> </u>
			﴿حاء:-	 في حالة 1
			٠.5،	أسياب
				ألإرجاع
	يس قسم المختبرات	يس ألوحدةرأ	رئي	رئيس المختبر:
				<u>:</u>
		التوقيع:		التوقيع
	التاريخ: /	التاريخ: / /	/	التاريخ: /
	ألوظيفةالتاريخ	التوقيع:	من قسم التفتيش):	اسم المستلم(
				/ /

# Appendix 3:

## استمارة نتائج اختبارات داخلية

			مى ان وجد: خ دخول العينة	الأسم العا	نوع العينة:	
القائم ب	الحدود	± اللايقين	النتيجة	معامل التصحيح	نوع الاختبار	٩
•••••	اد رئيس الوحد	إعتم سم: وقيع:	기 기		التاريخ:	الاسم: التوقي
				•••••	التاريخ:	

# Appendix 4:

		صفحة : 1/1	المختبر: تاريخ الإصدار:	وحدة : التقرير :	
	qcqalabs@ssm	ني no.gov.sd :Email	+249183762 البريد الإلكتروا	: قسم النَّقْتِيشُ ــوان : الخرطوم شارع البلدية ن : 249183762737 الفاكس :737: ف البيئية :	<b>لعنــــ</b> لتليفون
		,	الرطوبة النسبية: %	درجة الحرارة: س° العينة :	باثات
	•••		الاسم التجاري :	ينه	
				العلمى (أن وجد):	
20 / / -	الاختبار: <i>ا ا</i>	20 تاريخ	استلام العينة للمختبر: 1 /	بينة : ١ / ١ تاريخ	
				الاختبارات:	نائج ا
حدود المواصفة	وحدة القياس	النتيجة	طريقة الاختبار	الاختبار	م
					1
					2
					3
					4
					5
					6
					7
					8
					9
					10
				التعليق:	
				المسيى . أجربت التحاليل أعلاه وفق	
	ں المختبرات	رئيس	رئيس الوحدة	رئيس المختبر	
		الإسم:	الإسم:	لإسم:	1
	20 / /		التوقيع : التاريخ : / / 20	لتوقيع : لتاريخ : / / 20	
سرية مكتوب من ماير قسم				ساريح :     /	
				هذه التصوير ما إليهداره عبد المصدود المواصف التيم المختبرات بالهيئة ، مع العلم بأن النتيجة لاتمثل الإ	
	. ,			ه ، صلاحيه هذا التقرير 8 أسابيع من تاريخ الإصدار	

# Appendix 5:

## **Corrective Action Report**

Report No. :	Date: / / 20
·	
Initiator:	
Activity/aspect: Reason :	
Keason .	
Non-Conformity:	
Correction :	
Tutation	• • • • • • • • • • • • • • • • • • • •
Initiator:	Responsible:
Objective	ISO 17025 : 2005
Evidence	related clause
Root Causes:	
Corrective Action & Estimated date	e for close :
	Estimated date for close: / / 20
FOLLOW UP: Approved	
Audit Officer	Quality Manager
D. ( ) ( ) ( ) ( )	D. ( ) / 20
Date: / / 20	Date: / / 20

## **Appendix 6:**

