
بسم الله الرحمن الرحيم

الإستهلال

﴿وَتَرَى الْجِبَالَ تَحْسَبُهَا جَامِدَةً وَهِيَ تَمُرُّ مَرَّ السَّحَابِ صُنْعَ اللَّهِ الَّذِي أَتْقَنَ كُلَّ شَيْءٍ إِنَّهُ خَبِيرٌ بِمَا تَفْعَلُونَ﴾

النمل الآية 88

Dedication

To my mother, my father, my brothers and sisters

To the spirit that inspired me, to my special world

To my friends and colleagues

I dedicate my humble effort

ACKNOWLEDGEMENT

ACKNOWLEDGEMENT

I thank god for what he gave me graces and for all facilities which provided to me.

And thanks a lot for Sudan University of Science and Technology, the place where we gain knowledge.

I would like to express my special appreciation and thanks to my advisor Professor Dr. Abbas Ibrahim Abdel Ghafour, you have been a tremendous mentor for me. I would like to thank you for encouraging my research, your advice on both research as well as on my career have been priceless. Thanks to you.

I would especially like to thank Mis. Eslam, Mr. Hassan, Dr. Amira and others from the Total Quality Centre, Sudan University of Science and Technology.

*A lot of thanks to my dear friends Hanan Husien, Motasim Mahmod and Haga Salah form the National Public Health Lab (**NPHL).***

A special thanks to my family. Words cannot express how grateful I am. To my mother and father for all of the sacrifices that you've made on my behalf. Your prayer for me was what sustained me thus far.

I would also like to thank all of my friends who supported me in writing, and incented me to strive towards my goal.

All of you have been there to support me, so thanks to all

Abstract

This research presents a study of current situation of Sudanese testing laboratories and aim to emphasize the impact of implementing ISO/IEC 17025:2005 standard in quality of Sudanese laboratories' services.

An evaluation of the management system in a case study laboratory - National Public Health Laboratory (**NPHL) –** was carried out in some aspects like the quality of the service, the management system, the qualification & participation of the staff and working environment.

The ISO/IEC 17025:2005 – General Requirements for the Competence of Testing and Calibration Laboratories is the standard used for laboratory accreditation and have a sound effect in improving the quality of the services provided by international laboratories.

The study tried to answer the following questions:

Is there is quality management system inside the Sudanese laboratories?

Is the laboratories offer service with the required quality?

Can ISO/IEC 17025 improve the quality of services provided by Sudanese laboratories?

The objectives of this study are: study and identify the clauses of ISO/IEC 17025:2005, examine if implementing ISO/IEC 17025:2005 can provide high quality working environment, and examine if implementing ISO/IEC 17025:2005 can help the lab to provide reliable and high quality results.

To achieve the objectives of the study a questionnaire was designed to carry the situational analysis and to answer the research questions. The SPSS 11.0 software is used to analyze the data by using Cronbach's Alpha (α) test, Chi-Square test and Frequency Test.

The study found that the service provided by **NPHL** is low quality, there is no clear management system with known responsibilities in side **NPHL**, there is defect on the training method inside **NPHL** and working environment inside **NPHL** is not suitable and not helps in correct testing results.

المستخلص

يقدم هذا البحث دراسة للوضع الراهن للمختبرات السودانية وهو يهدف إلى التأكيد على أثر تطبيق المواصفة أيزو 17025 في جودة خدمات المختبرات السودانية وذلك بتقييم نظام الإدارة في المعمل القومي للصحة العامة كنموزج للدراسة وذلك بالتركيز علي بعض الجوانب مثل جودة الخدمة ونظام الإدارة و تأهيل الموظفين وبيئة العمل.

والمواصفة الدولية ISO/IEC 17025:2005 - المتطلبات العامة لكفاءة مختبرات الفحص و المعايرة - هو المعيار المستخدم لإعتماد المختبرات و لها تأثير عميق في تحسين نوعية الخدمات التي تقدمها المختبرات الدولية.

وقد حاولت الدراسة الاجابة على الاسئلة التالية:

هل هناك نظام لادارة الجودة داخل المعامل السودانية؟

هل تقدم المعامل السودانية خدمات بالجودة المطلوبة؟

هل المواصفة ايزو 17025 يمكن ان تحسن من جودة الخدمات المقدمة بواسطة المعامل السودانية؟

أهداف هذه الدراسة هي: دراسة وتحديد بنود ISO / IEC 17025:2005 ، ودراسة اثر تنفيذ ISO / IEC 17025:2005في توفر بيئة عمل عالية الجودة ، وتحديد اثر تنفيذ ISO / IEC 17025:2005في تقديم نتائج ذات جودة عالية وموثوق بها.

ولتحقيق اهداف الدراسة جرى تصميم استبانة لاجراء الدراسة الميدانية من اجل اختبار الفرضيات والاجابة علي اسئلة الدراسة. وقد جرى استخدام برنامج التحليل الاحصائي SPSS لتحليل البيانات.

وقد توصلت الدراسة الي مجموعة من النتائج اهمها ان الخدمات المقدمة بواسطة المعمل ليست بالجودة المطلوبة حيث لا يوجد نظام اداري واضح لادارة الجودة داخل المعمل ولا توجد آلية واضحة لتدريب الكادر البشري بالاضافة الى ان بيئة العمل لا تساعد في الحصول علي نتائج دقيقة.

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List of Abbreviations

Abbreviation	Definition
ISO	International Organization for Standardization
IEC	International Electro technical Commission
ILAC	International Laboratory Accreditation Corporation
CASCO	ISO Council Committee on Conformity Assessment
NPHL	National public health laboratory
CLSI	Clinical and Laboratory Standards Institute

n

CHAPTER ONE

INTRODUCTION AND LITERATURE REVIEW

1. Introduction and literature review

1.1 Introduction

Today the world has become a global village and domestic and export trade is vital to the development of any country's economy. The key to lowering of the barriers to international trade is accreditation, the whole basis of which is to create confidence in the work carried out by certification and inspection bodies, as well as testing and calibration laboratories, located anywhere in the world.

Accreditation also has larger role to play within the country's economy because it provides confidence to the buyer or user of services. In the internal economy accredited laboratories are used to test medical specimens (blood, urine, body fluids,….etc), food and water, concrete and other building materials, electrical and telecommunication test equipment, and basic measuring instruments used in the manufacturing industry.

1.1.1 Research problem:

The weakness in quality of laboratories' services reflect in the total quality of products and services in many sectors in Sudan such as the pharmaceutical industry, electricity industry, oil & gas industry, agriculture, real estate industry, ….etc.

This study was tried to answer the following questions:

1. Is there is quality management system inside the Sudanese laboratories?
2. Is the laboratories offer service with the required quality?
3. Can ISO/IEC 17025 improve the quality of services provided by Sudanese laboratories?

1.1.2 Importance of the Research:

Nowadays, quality is important in business and industries world. Many of the customer required high quality product and service. In order to fulfill the requirement of the customer, organizations must have a

quality system to ensure that their product or service has high quality to fulfill the customer requirement.

For the laboratories which provide testing and calibration to the customer, the laboratory should have a quality system to ensure that the testing and calibration result has high quality and fulfill the requirements of the customers.

ISO/IEC 17025 is one of the standards which provide guidance on how to develop quality system inside testing and calibration laboratories to increase the quality of services deliver to their customers.

The Importance of this research is that it reflects the extent of the impact of implementing **ISO/IEC 17025** on the quality of services provided by the Sudanese laboratories.

1.1.3 Hypotheses

The First Hypothesis: the service provided by the **N**ational **P**ublic **H**ealth **L**aboratory (**NPHL**) is poor and with low quality.

The Second Hypothesis: there is no clear management system with known responsibilities in side **NPHL**.

The Third Hypothesis: there is defect on the training method inside **NPHL**.

The Forth Hypothesis: working environment inside **NPHL** is not suitable and not helps in correct testing results.

1.2 Literature review

1.2.1 ISO/IEC 17025:2005:

1.2.1.1 Background

ISO/IEC 17025 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/IEC 17025:2005,p.vi)

The standard will form the basis for the accreditation of competence of laboratories by accreditation bodies.

1.2.1.2 History and status of ISO/ IEC 17025:2005

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

Accreditation was based on national standards. However, there was a considerable level of uniformity between the requirements expressed in these various standards due to the existence of ISO Guide 25, a document drawn up by the ISO Council Committee on Conformity Assessment (CASCO) in response to a request by the International Laboratory Accreditation Cooperation (ILAC) held in Auckland, New Zealand, in October 1988.(UNIDO, 2009, p.1)

The declared purpose of ISO Guide 25, taken from its foreword, is to establish the principle that "third party certification systems [for laboratories] should, to the extent possible, be based on internationally agreed standards and procedures". ISO guides are intended to be used by local standards institutions when preparing their own national standards. By this means, it is hoped to achieve a high degree of compatibility

between standards prepared in different countries "so as to facilitate bilateral and multilateral agreements". (ISO Guide 25, 3rd Edition)

The document now known as ISO 17025 began life as a revision of the third edition of ISO Guide 25, but during the revision process it was decided to convert the guide to a standard, so providing a truly global basis for accreditation. It was also decided to introduce as much compatibility as possible between ISO 17025 and the generic quality management system standard ISO 9001, which was also under revision at the same time.

The objective appears to have been to create a logical connection between ISO 9001 and ISO 17025 such that the former would be seen as a master standard with ISO 17025 being a specific application of that standard to testing and calibration laboratories.

ISO 17025: 1999 was accepted by ISO subscribing countries in late 1999 and came into effective use during the first quarter of 2000 after its adoption as a national standard by most countries around the world. The new version of ISO 9001, the 2000 edition, was accepted at a later date.

The exercise intended to harmonize ISO 17025 and ISO 9001 was, in the event, regarded as imperfect, especially in that ISO 9001 placed great emphasis on continual improvement in the quality system. Although this was included in ISO 17025, its importance as a part of the standard was not strongly emphasized. Hence a revision of ISO 17025 was undertaken and this led to ISO 17025:2005 which was adopted as an ISO standard in late May of 2005.

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:-

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

The transitional period between ISO 17025:1999 and ISO 17025:2005 lasted two years, with the two standards running together. In May 2007 ISO 17025:1999 became defunct and existing laboratories who had not been assessed against the 2005 version ceased to be accredited.

1.2.1.3 Relationship to ISO 9001:

ISO 9001 is the general standard which specifies 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 calibration and testing activities.

The management systems certification and accreditation differ with respect to the aim and standard. According to the ISO 17000 standard, certification (management systems, products, and people) is one of conformity assessment activities. On the other hand, accreditation is the recognition of technical competence to carry out conformity assessment activities, according to the same standard.

According to Prado Filho (2010), if a laboratory has been certified according to the ISO 9001 standard there is a guarantee that calibration or tests are conducted in accordance with written procedures and grounds to

ensure the requirements of the standard concerned. By the other side, the accreditation according to the ISO 17025 standard goes beyond the execution of calibration according to a written procedure and required for a confirmation of technical competence of who performs the proper calibration (Duarte, 2007).

One of the most important benefits of accreditation according to the ISO 17025 standard is to endorse the cooperation and partnership between laboratories and other institutions with the aim of exchanging information promoting the harmonization and standardization of procedures and standards. According to Ramjun (2009), a laboratory accreditation strengthens the organization performance through a better control of laboratory procedures and thereby increases their potential due to the increase customer satisfaction.

According to Pizzolato *et al.* (2008), depending on the laboratory business, the laboratory could assess its QMS according to ISO 9001 or ISO 17025 standard.

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, an ISO 9001 certified laboratory could not have enough technical competence to assess conformity of certain equipment, products or services or people. According to Dick *et al.* (2002), ISO 9001 standards is concerned mainly with what the laboratory does to ensure the compliance of their products or services according to customer requirements.

So, Laboratory accreditation uses criteria and procedures specifically developed to determine technical competence. Specialist technical assessors conduct a thorough evaluation of all factors in a laboratory that affect the production of test or calibration data. The criteria are based on the international standards called ISO/IEC 17025 or ISO15189, which are

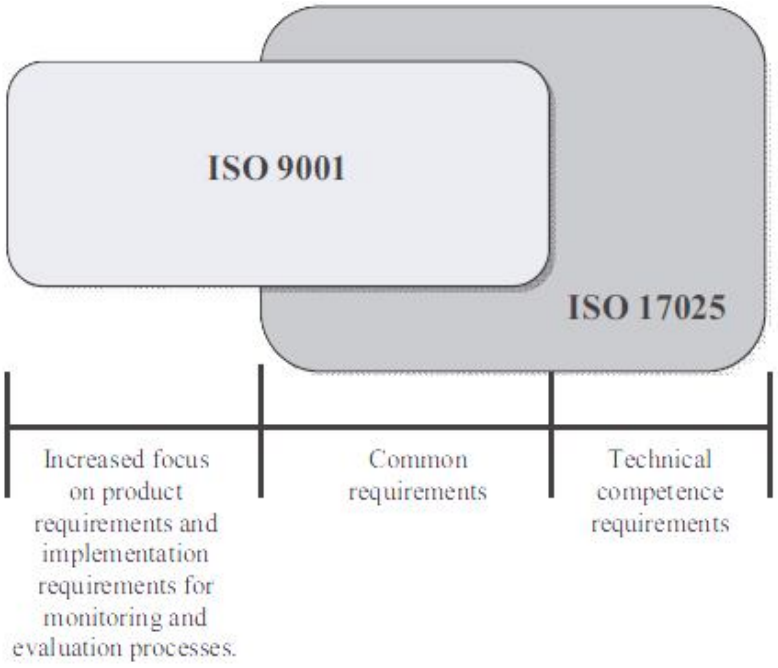
used for evaluating laboratories throughout the world. Laboratory accreditation bodies use this standard specifically to assess factors relevant to the laboratory's technical competence, including the:

- Technical competence of staff
- Validity and appropriateness of test methods
- Traceability of measurements and calibrations to national standards
- Suitability, calibration and maintenance of test equipment
- Testing environment
- Sampling, handling and transportation of test items
- Quality assurance of test and calibration data

By this process, laboratory accreditation aims at assuring you or your customers that your laboratory's test or calibration data are accurate and reliable.

The ISO9001 standard is widely used in manufacturing and service organizations to evaluate their system for managing the quality of their product or service. Certification of an organization's quality management system against ISO9001 aims at confirming the compliance of the management system to this standard. Whilst laboratories may be certified to ISO9001, such certification does not make any statement about the technical competence of a laboratory.

Figure 1.1: Interaction between ISO 9001 and ISO 17025 standards



Source: Quality Management and Practices, p.222

1.2.1.4 Relationship to ISO 15189

ISO 15189, Medical laboratories--Particular requirements for quality and competence was prepared by ISO/TC212, Clinical laboratory testing and in vitro diagnostic test systems, and its first edition published in 2003 and the second edition in 2007. Its purpose is to be used by medical laboratories in developing their quality management systems and assessing their own competence, also for use by accreditation bodies in confirming or recognizing the competence of medical laboratories. Since its publication, it has been recognized officially by the International Laboratory Accreditation Cooperation (ILAC) to be used as the international standard for the accreditation of medical laboratories worldwide.

Table 1.1: ISO 17025 & ISO 15189

ILAC		**CLSI**	
International Laboratory Accreditation Cooperation		Clinical and Laboratory Standards Institute	
1986	**Conference to establish a common guide for assessment of laboratories**	**1999**	**Vancouver conference begin align with Guide 25**
1990	**Guide 25**	**2000**	**Dublin Conference to realign with 9000**
1994	**Join with ISO**	**2001**	**Sydney Conference to re-realign with 17025**
1999	**ISO 17025**	**2003**	**Publish 15189**
2005	**Begin Revision**	**2004**	**Begin Revision**

Source: Michael A. Noble () History of Quality for the Modern Medical Laboratory

1.2.1.5 Overview of the Content of MS ISO/IEC 17025:2005

The ISO 17025 standard is comprised of 5 clauses:

1. **Scope**
2. **Normative references**
3. **Terms and definition**
4. **Management requirements**
5. **Technical requirements**

Clause **4** and **5** contains the actual accreditation requirements. There are 15 management requirements and 10 technical requirements. These requirements outline what a laboratory must do to become accredited.

The overview details of management requirement technical requirement are show in below (ISO/IEC 17025, 2005).

1.2.1.5.a Clause 4: Management Requirement

4.1 Organization

The laboratory needs to define the organization management structure. Specify the responsibility of the organization and personnel in testing and calibration activities.

4.2 Management system

Establish, implement and maintain the management system. The quality policy statement should be defined in quality manual. The quality manual includes quality service; standard service; the roles and implement the policy and procedure; responsibilities of testing and calibration.

4.3 Document control

All the documents issued to personnel should be review and approved for use by authorized personnel prior to issue. Revised to ensure that continuing suitability and compliance with applicable requirements.

4.4 Review of request, tenders and contracts

Establish and maintain procedures for the review of requests, tenders and contracts including the method use for requirement. Record of review shall be maintained. It covers any work that is subcontracted by the laboratory. Contract review process shall be repeated and any amendments shall be communicated to all affected person.

4.5 Subcontracting of test and calibration

When the overload works occur, the work will sub to the subcontractor. Laboratory is responsible with the subcontractor work and maintains a register of all subcontractors that it uses for

test and/or calibrations add as record of the evidence of compliance.

4.6 Purchasing service and supplies

The reception, storage of reagents and laboratory consumable material relevant for tests and/or calibration as complying with standard requirements. Record of action taken to check compliance shall be maintain and evaluate supplies of critical consumables and supplier service.

4.7 Service to the client

Laboratory should be cooperate and provide the high quality service for the customer to ensure they confident in laboratory performance. The feedback from customer should be used to analyze for improvement purpose in management system.

4.8 Complaints

Record all the complaints from the customer, then investigate and corrective action to overcome it by laboratory.

4.9 Control of non-conforming testing and/or calibration work

Laboratory shall responsibilities and authorities for the management of nonconforming work. They should evaluation of the nonconforming work and correction action is taken. The correction action procedures should be promptly followed.

4.10 Improvement

Improve the effectiveness of its management system through the quality manual, quality objective, audit result, analysis of data, correction and preventive actions.

4.11 Corrective action

Corrective action is an action to eliminate the root cause of non-conforming work.

The process of corrective action is start with investigation to determine the root cause, select the appropriate corrective action, implement and monitor the action taken.

4.12 Preventive action

Preventive action is an action to prevent the potential root cause of non-conforming work.

4.13 Control of records

Quality record should include report from internal audit and management review and also records of corrective and prevention. All record is legible. The record of testing and/or calibration shall be original with the specification information. All the data shall be keeping as record although a mistake occur in the data records.

4.14 Internal audits

The internal audit shall be perform in periodically and consist of the management system and testing and/or calibration activities. The finding of audit shall be recorded as implementation and effectiveness of the correction action that have been taken.

4.15 Management review

The top management needs to have a review on the management system and testing and/or calibration activities to ensure their suitability, effectiveness and necessary changes or improvement on their laboratory. The review covers all the documentation and the action that arises from them should be recorded.

1.2.1.5.b Clause 5: Technical Requirement

5.1 General

When carry out a testing and/or calibration activity, many factor are been determine for the correctness and reliability. The laboratory shall take account the factor that influent the result of testing and/or calibration.

5.2 Personnel

The laboratory management shall ensure the operator for specific equipment testing and/or calibration must have education requirement or have been undergo the training. The personnel should responsible with the job description in managerial, technical involve in testing and/or calibration.

5.3 Accommodation and environment condition

Laboratory shall to ensure that all the testing and/or calibration are carry out under a good environment condition such as lightning and safety.

5.4 Test and calibration method validation

Laboratory shall prepare the method, procedures and instruction for each testing and/or calibration including sampling, handling, transport and storage. The laboratory shall have instruction on the method use the equipment for testing and/or calibration. Laboratory should establish procedures for measure the uncertainty.

5.5 Equipment

The equipment must achieve the international standard and the software shall be recorded for each testing and calibration including the specification. The equipment shall be operated by authorized personnel. Laboratory have highlight the safety and maintained to ensure the equipment can functional well.

5.6 Measurement traceability

The laboratory should establish a programme and procedure for the equipment that use for testing and/or calibration purpose. Laboratory shall ensure that the testing result using that equipment must accurate and validate.

5.7 Sampling

The sampling plan and procedures shall base on appropriate statistical methods and to ensure the validity of the test and calibration results. The laboratory shall have the procedures for recording relevant data which include the sampling procedures, identification of the sample and environment condition.

5.8 Handling of test and calibration items

Laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and disposal of test and calibration items. Laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the testing and calibration during storage and handling process.

5.9 Assuring the quality of test and calibration results

Laboratory shall have quality control procedures for monitoring the validity of tests and calibration activities. The monitoring plan and review may include regular use of certification and correlation of result for different characteristic of an item.

5.10 Reporting of results

The result of the testing and/or calibration should be clearly and accurate defined in the report or a calibration certificate.

1.2.2 Laboratory Accreditation

1.2.2.1 Definitions

Conformity assessment is a term used to describe the whole process of accreditation and certification and the process of determining whether the products, processes, systems and people meet specified requirements.

Accreditation (according to the ISO 17000 standard) is the "third party attestation, related to a conformity assessment body, which is a formal recognition of their competence to perform specific activities of conformity assessment."

The core inherent value of accreditation for laboratories is that a test or measurement carried out on a sample or physical artifact in one country should produce the same result (within the limits of uncertainty of measurement) when carried out by another accredited laboratory elsewhere in the world.

1.2.2.2 The Advantages of Being an Accredited Laboratory (according to **ILAC**)

- **Recognition of Testing Competence**

  Laboratory accreditation provides formal recognition to competent laboratories, thus providing a ready means for customers to identify and select reliable testing, measurement and calibration services. To maintain this recognition, laboratories are re-evaluated regularly by the accreditation body to ensure their continued compliance with requirements, and to check that their standard of operation is being maintained. The laboratory is also required to participate in relevant proficiency testing programs between

- **A Marketing Advantage**

  Accreditation is an effective marketing tool for testing, calibration and measurement organizations, and a passport to submit tenders to contractors that require independently verified laboratories.

  Laboratory accreditation is highly regarded both nationally and internationally as a reliable indicator of technical competence. Many industries, such as the construction materials industry, routinely specify laboratory accreditation for suppliers of testing services.

  Many accreditation bodies also publish a directory of their accredited laboratories, which includes the laboratories' contact

details plus information on their testing capabilities. This is another means of promoting a laboratory's accredited services to potential clients.

Through a system of international agreements accredited laboratories receive a form of international recognition, which allows their data to be more readily accepted in overseas markets. This recognition helps to reduce costs for manufacturers and exporters that have their products or materials tested in accredited laboratories, by reducing or eliminating the need for retesting in another country.

- **A benchmark for Performance**

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

A regular assessment by an accreditation body checks all aspects of a facility's operations related to consistently producing accurate and dependable data. Areas for improvement are identified and discussed, and a detailed report provided at the end of each visit.

Where necessary, follow-up action is monitored by the accreditation body so the facility is confident that it has taken the appropriate corrective action.

1.3 Objectives:

1.3.1 General objective:

To study the impact of implementing ISO/IEC 17025 standard in quality of Sudanese laboratories' services.

1.3.2 Specific objectives:

1. To study and identify the clauses of ISO/IEC 17025:2005.
2. To examine if implementing ISO/IEC 17025:2005 can provide high quality working environment.
3. To examine if implementing ISO/IEC 17025:2005 can help the lab to provide reliable and high quality results.

CHAPTER TWO

MATERIAL AND METHODS

2. Material and methods

2.1 Materials:

2.1.1 Study design:

Based on the research, researcher developed the objectives, design and the framework of the research.
National public health laboratory (**NPHL**) was chosen as a research area because it is the first reference lab in Sudan and has wide scope of testing and research services.
According to objectives of research four hypotheses are assumed to evaluate the impact of implementing ISO/IEC 17025 on the quality of **NPHL**'s services.
Questionnaire survey was conducted and data was analyzed by using SPSS software program.

2.1.2 Study area:

The study was conducted in the **National Public Health Laboratory (NPHL)** in Khartoum state during November 2013 to May 2014.

2.1.3a Study population:

The target population of this study including personnel from all departments of national public health laboratories in Khartoum state, Sudan.

2.1.3b Sampling:

Random sampling technique is used to select 50 samples from target population.

2.1.4 Inclusion criteria:

The participant in this study is chosen according to the following criteria:

- Top managers of **NPHL**
- All head departments of testing labs
- Senior technicians of testing labs
- Professional personnel from supporting departments

2.1.5 Exclusion criteria:

The participant is excluded if has experience less than 5 years.

2.1.6 Ethical consideration

Participants opinions were treated honestly, fairly and respectfully, professional and scientific responsibility were adhering to highest scientific and professional standard and accept responses.

Information provided by participants were kept confidential and used only for this study.

2.1.7 Data collection

The research selects the National Public Health Laboratory which operating in testing services. A survey questionnaire was developed using 5 point Likert scale (1=Strongly disagree; 2=Disagree; 3=Neutral; 4= Agree; 5=Strongly Agree) to obtain feedbacks about the opinions of participants on different variables.

2.1.7 Data Analysis

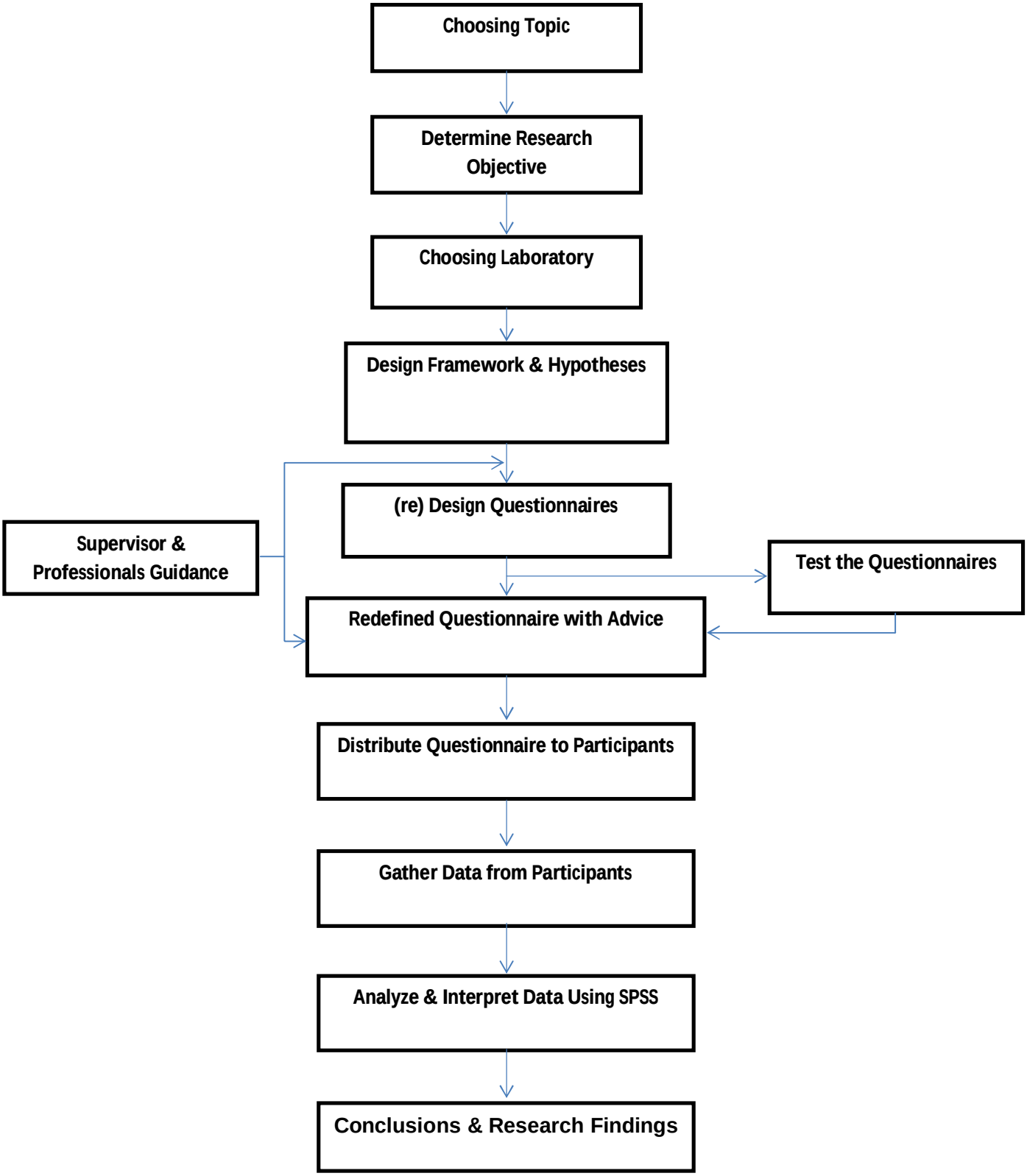
After data collection has finished, the researcher used SPSS 11.0 software for the analysis of collected data by using Cronbach's Alpha (α) test, Chi-Square test and Frequency Test.

50 questionnaires were distributed, 3 of them were incomplete. Therefore, the number of remaining samples to analyze was 47.

2.2 Method:

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

1.2.1 Research structure



Source: Researcher

CHAPTER THREE

ANALYSIS

3.1 Reliability Test

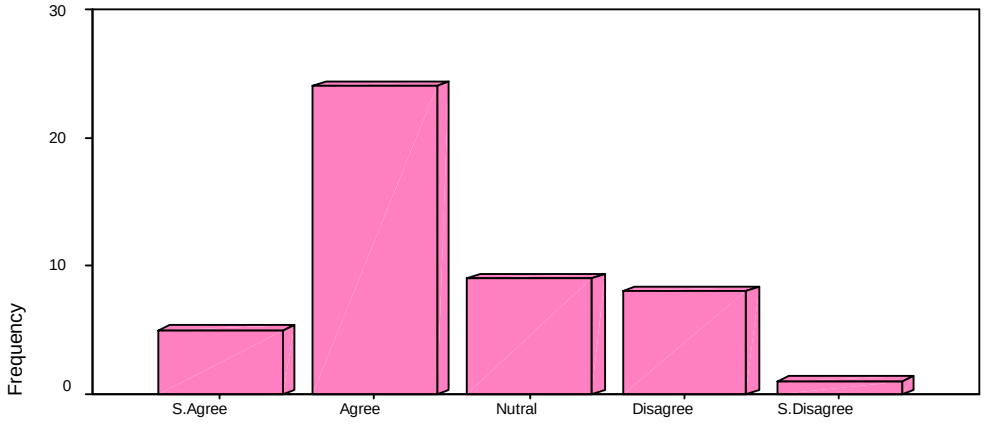
```
****** Method 1 (space saver) will be used for this analysis ******


  R E L I A B I L I T Y   A N A L Y S I S   -   S C A L E   (A L P H
A)


Reliability Coefficients

N of Cases =     47.0                    N of Items = 11

Alpha =    .8360
```

3.2.1 Frequency Tests

Table 3.1: The **NPHL** has leading position in the competitive market in Sudan

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	S.Agree	5	10.6	10.6	10.6
	Agree	24	51.1	51.1	61.7
	Nutral	9	19.1	19.1	80.9
	Disagree	8	17.0	17.0	97.9
	S.Disagree	1	2.1	2.1	100.0
	Total	47	100.0	100.0	

Figure 3.1: The **NPHL** has leading position in the competitive market in Sudan



The NPHL has leading position in the competitive market in Sudan

Table 3.2: There is increasing in the range & availability of services provided by NPHL

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	S.Agree	3	6.4	6.4	6.4
	Agree	9	19.1	19.1	25.5
	Nutral	5	10.6	10.6	36.2
	Disagree	27	57.4	57.4	93.6
	S.Disagree	3	6.4	6.4	100.0
	Total	47	100.0	100.0	

Figure 3.2: There is increasing in the range & availability of services provided by NPHL

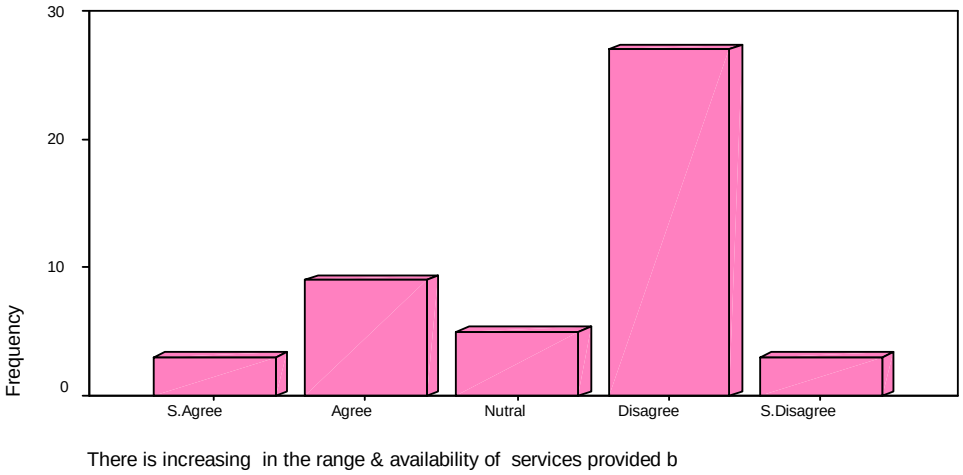


Table 3.3: The testing time is adequate and there is no delay in the service provided by **NPHL**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	4	8.5	8.5	8.5
	Nutral	6	12.8	12.8	21.3
	Disagree	23	48.9	48.9	70.2
	S.Disagree	14	29.8	29.8	100.0
	Total	47	100.0	100.0	

Figure 3.3: The testing time is adequate and there is no delay in the service provided by **NPHL**

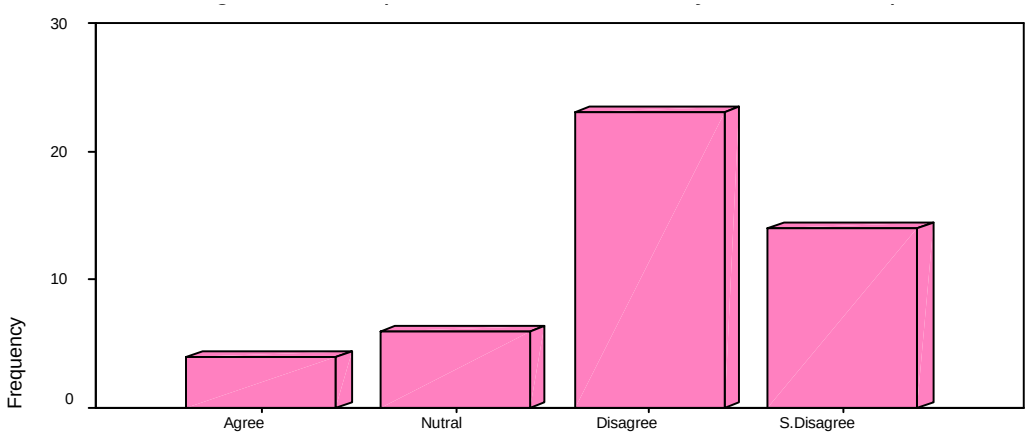


Table 3.4: There is an overall management system in **NPHL** and known for everyone

There is an overall management system in NPHL and known for everyone

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	S.Agree	2	4.3	4.3	4.3
	Agree	14	29.8	29.8	34.0
	Nutral	10	21.3	21.3	55.3
	Disagree	16	34.0	34.0	89.4
	S.Disagree	5	10.6	10.6	100.0
	Total	47	100.0	100.0	

Figure 3.4: There is an overall management system in **NPHL** and known for everyone

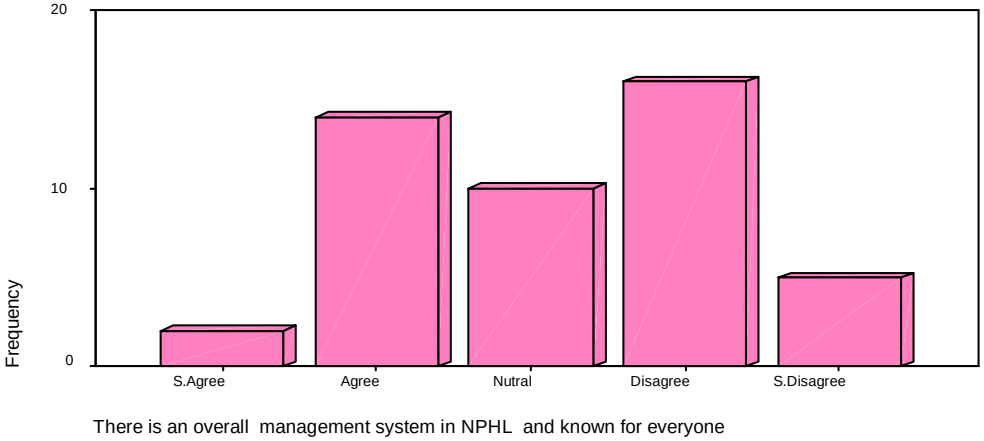


Table 3.5: There is an internal management system in the lab (department) and known for everyone

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	S.Agree	3	6.4	6.4	6.4
	Agree	20	42.6	42.6	48.9
	Nutral	8	17.0	17.0	66.0
	Disagree	11	23.4	23.4	89.4
	S.Disagree	5	10.6	10.6	100.0
	Total	47	100.0	100.0	

Figure 3.5: There is an internal management system in the lab (department) and known for everyone

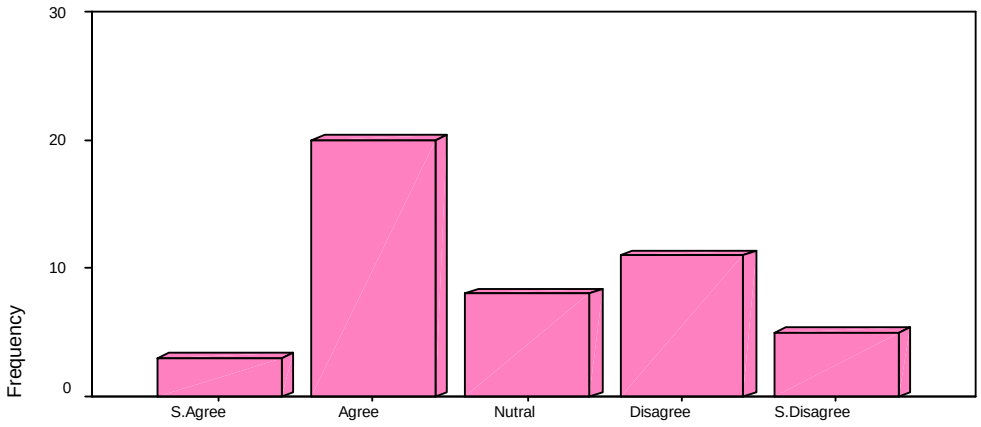


Table 3.6: The internal system of the lab is part of the overall system of **NPHL**

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	S.Agree	4	8.5	8.5	8.5
	Agree	20	42.6	42.6	51.1
	Nutral	6	12.8	12.8	63.8
	Disagree	10	21.3	21.3	85.1
	S.Disagree	7	14.9	14.9	100.0
	Total	47	100.0	100.0	

Figure 3.6: The internal system of the lab is part of the overall system of **NPHL**

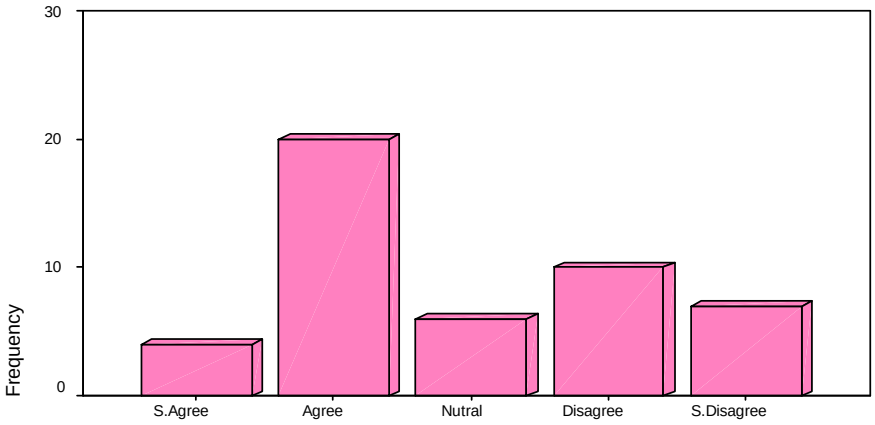


Table 3.7: The staff is competent and qualified

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	S.Agree	8	17.0	17.0	17.0
	Agree	26	55.3	55.3	72.3
	Nutral	8	17.0	17.0	89.4
	Disagree	4	8.5	8.5	97.9
	S.Disagree	1	2.1	2.1	100.0
	Total	47	100.0	100.0	

Table 3.7: The staff is competent and qualified

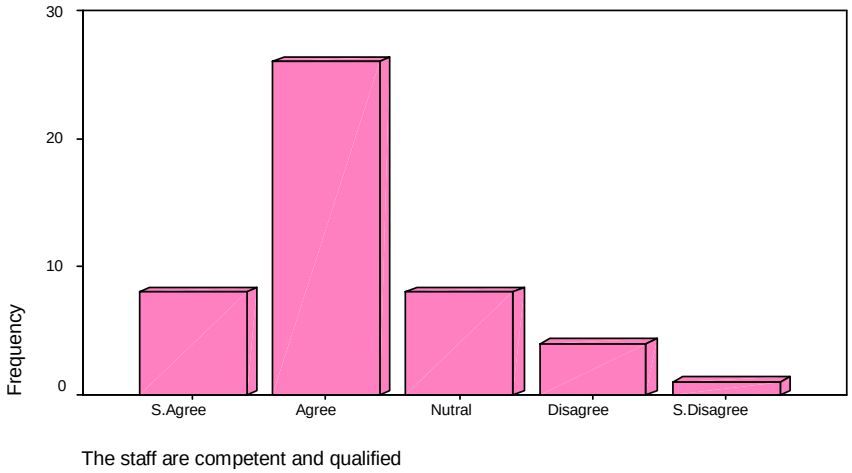


Table 3.8: Staff is trained periodically and when needed

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	S.Agree	1	2.1	2.1	2.1
	Agree	1	2.1	2.1	4.3
	Nutral	8	17.0	17.0	21.3
	Disagree	19	40.4	40.4	61.7
	S.Disagree	18	38.3	38.3	100.0
	Total	47	100.0	100.0	

Figure 3.8: Staff is trained periodically and when needed

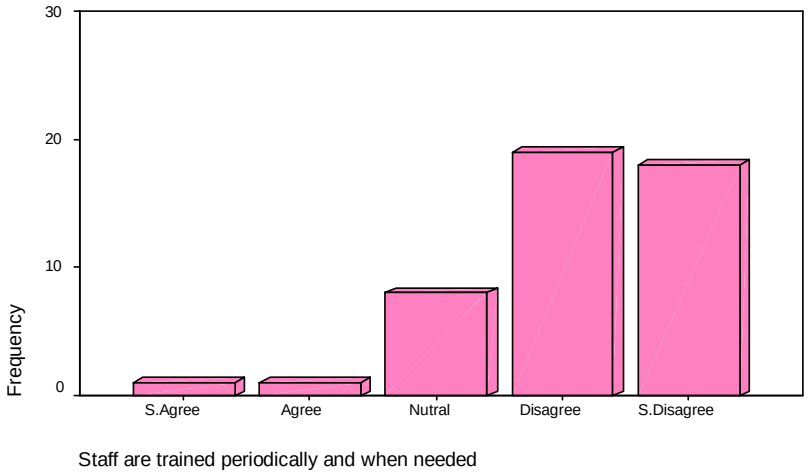


Table 3.9: Anyone of the staff know his responsibilities

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	S.Agree	1	2.1	2.1	2.1
	Agree	17	36.2	36.2	38.3
	Nutral	14	29.8	29.8	68.1
	Disagree	13	27.7	27.7	95.7
	S.Disagree	2	4.3	4.3	100.0
	Total	47	100.0	100.0	

Figure 3.9: Anyone of the staff know his responsibilities

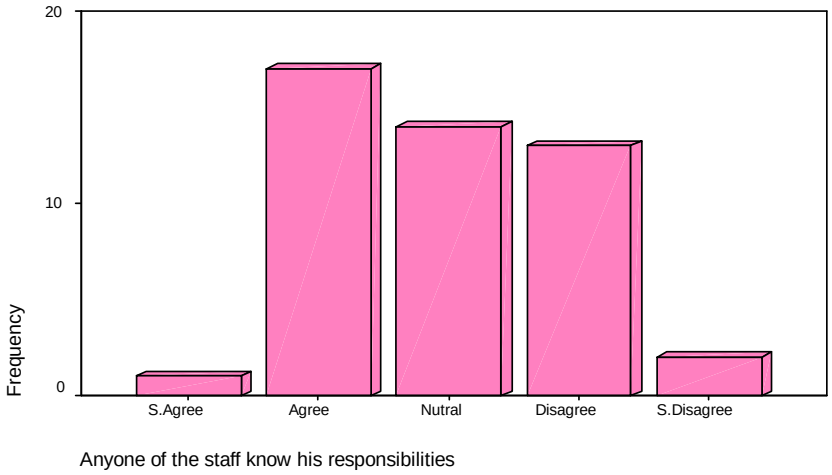


Table 3.10: The staff contributes in the system setting and lab policy

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	S.Agree	1	2.1	2.1	2.1
	Agree	9	19.1	19.1	21.3
	Nutral	15	31.9	31.9	53.2
	Disagree	18	38.3	38.3	91.5
	S.Disagree	4	8.5	8.5	100.0
	Total	47	100.0	100.0	

Figure 3.10: The staff contributes in the system setting and lab policy

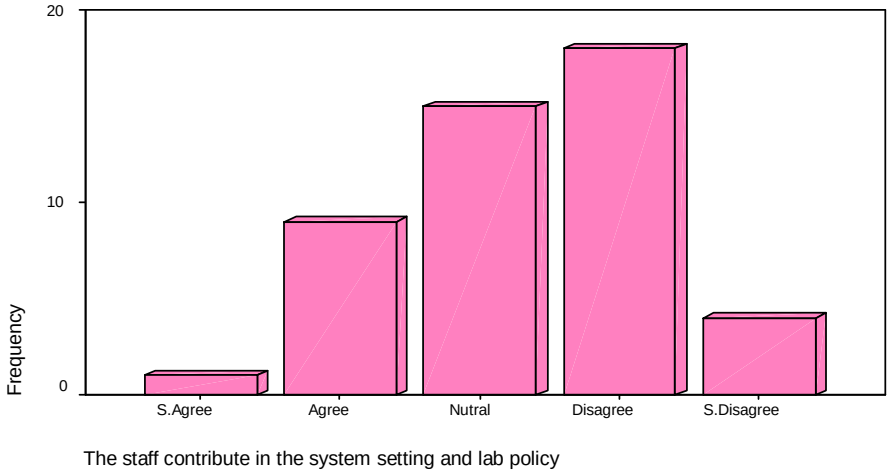
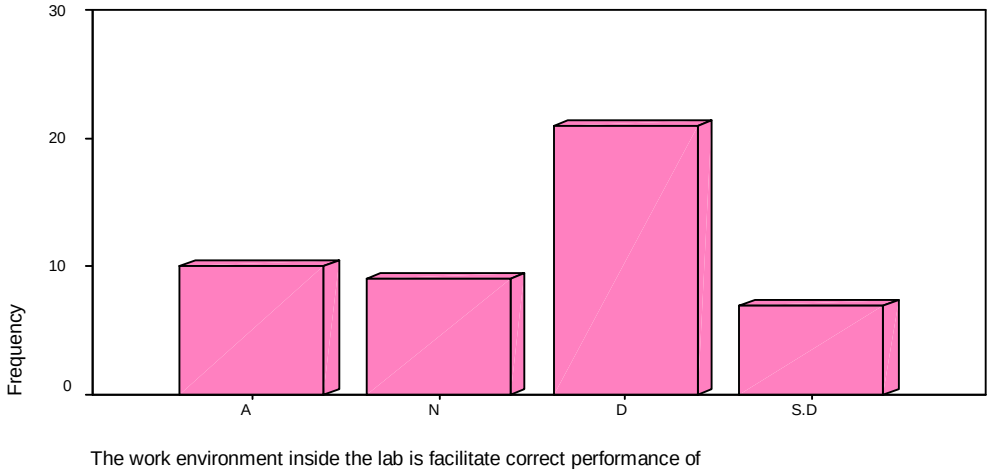


Table 3.11: The work environment inside the lab is facilitate correct performance of the tests

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	A	10	21.3	21.3	21.3
	N	9	19.1	19.1	40.4
	D	21	44.7	44.7	85.1
	S.D	7	14.9	14.9	100.0
	Total	47	100.0	100.0	

Figure 3.11: The work environment inside the lab is facilitate correct performance of the tests



3.3 Chi-Square Test (Test of Hypothesis)

The First Hypothesis:

Table 3.3.1: The service provided by the **N**ational **P**ublic **H**ealth **L**aboratory (**NPHL**) is poor and with low quality

Test Statistics

	The NPHL has leading position in the competitive market in Sudan	There is increasing in the range & availability of services provided by NPHL	The testing time is adequate and there is no delay in the service provided by NPHL
Chi-Square [a,b]	32.468	43.745	19.128
df	4	4	3
Asymp. Sig.	.000	.000	.000

a. 0 cells (.0%) have expected frequencies less than 5. The minimum expected cell frequency is 9.4.

b. 0 cells (.0%) have expected frequencies less than 5. The minimum expected cell frequency is 11.8.

The Second Hypothesis:

Table 3.3.2: There is no clear management system with known responsibilities in side **NPHL**

Test Statistics

	There is an overall management system in NPHL and known for everyone	There is an internal management system in the lab (department) and known for everyone	The internal system of the lab is part of the overall system of NPHL
Chi-Square[a]	14.809	18.851	16.936
df	4	4	4
Asymp. Sig.	.005	.001	.002

a. 0 cells (.0%) have expected frequencies less than 5. The minimum expected cell frequency is 9.4.

The Third Hypothesis:

Table 3.3.3: There is defect on the training engine inside **NPHL**

Test Statistics

	The staff are competent and qualified	Staff are trained periodically and when needed	Anyone of the staff know his responsibilities	The staff contribute in the system setting and lab policy
Chi-Square[a]	40.340	32.894	23.106	21.830
df	4	4	4	4
Asymp. Sig.	.000	.000	.000	.000

a. 0 cells (.0%) have expected frequencies less than 5. The minimum expected cell frequency is 9.4.

The Forth Hypothesis:

Table 3.3.4: working environment inside **NPHL** is not suitable and not helps in correct testing results.

Test Statistics

	The work environment inside the lab is facilitate correct performance of the tests
Chi-Square [a]	10.106
df	3
Asymp. Sig.	.018

a. 0 cells (.0%) have expected frequencies less than 5. The minimum expected cell frequency is 11.8.

CHAPTER FOUR

DISCUSSION, CONCLUSION & RECOMMENDATIONS

4. Discussion, conclusion and recommendation

4.1 Discussion:

when the researcher study the impact of implementing ISO/IEC 17025 in the quality of Sudanese laboratories' services by taken the national public health lab as case study, the research has find out the that the Sudanese laboratories is suffering from decreasing of service quality due to the absent of quality management system, lake of human resource training and participating, and poor environment which are main issues in good quality system.

ISO 17025 emphasizes of all these issues and more, so if the Sudanese Laboratories implement this standard and other international standards - and guidelines related to lab quality - this will increase the quality of services, the qualification of personnel and the suitability of working environment.

According to Chi-square tests results in the previous chapter which result sig.value < 0.05 for all hypotheses and which reject the null hypotheses and accept the researcher hypotheses as shown in the following table.

Table 4.1: Results of hypotheses

Hypothesis	**Result**
The service provided by NPHL is low quality	True
There is no clear management system with known responsibilities in side NPHL	True
There is defect on the training method inside NPHL	True
Working environment inside NPHL is not suitable and not helps in correct testing results	True

4.2 Conclusion

From this study we can conclude that:

1. The service provided by **NPHL** is low quality.
2. There is no clear management system with known responsibilities in side **NPHL**.
3. There is defect on the training method inside **NPHL**.
4. Working environment inside **NPHL** is not suitable and not helps in correct testing results.

4.3 Recommendations

This research recommends that further research will help solving limitations of it's by taking the following points in account:

1- This research is more useful if it is studied in a larger scope which covers large number of testing laboratories in Sudan.

2- The further research needs to study all the impacts of applying ISO/IEC 17025 on the service quality.

3- Other factors such as economic environment, society, culture (politic institutions, national culture, etc.) along with this research will offer us with the acknowledgement of impacts of implementing ISO/IEC 17025 on the performance of service quality.

4- It is necessary to assess the views of laboratories' customers on the value of implementation.

Finally; Change is occurring at an accelerating rate; today is not like yesterday, and tomorrow will be different from today. Continuing today's strategy is risky; therefore Sudanese laboratories must develop a new strategy to meet this change successfully.

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Appendix

Questionnaire

1- Service quality

#	question	Strongly disagree	Disagree	neutral	agree	Strongly agree
1	The **NPHL** has leading position in the competitive market in Sudan					
2	There is increasing in the range & availability of services provided by **NPHL**					
3	The testing time is adequate and there is no delay in the service provided by **NPHL**					
4	The implementation of international standards like ISO 17025 can increase the quality of **NPHL's** services					

2- Management system

#	question	Strongly disagree	Disagree	neutral	agree	Strongly agree
1	There is an overall management system in **NPHL** and known for everyone					
2	There is an internal management system in the lab (department) and known for everyone					
3	The internal system of the lab is part of the overall system of **NPHL**					
4	The implementation of international standards like ISO 17025 can support the management system and improve it					

3- Personnel

#	question	Strongly disagree	Disagree	neutral	agree	Strongly agree
1	The staff are competent and qualified					
2	Staff are trained periodically and when needed					
3	Anyone of the staff know his responsibilities					

4	The staff contribute in the system setting and lab policy					
5	The implementation of international standards like ISO 17025 can enhance the competence of the staff					

4- Work environment

#	question	Strongly disagree	Disagree	neutral	agree	Strongly agree
1	The work environment inside the lab is facilitate correct performance of the tests					
2	The implementation of international standards like ISO 17025 can enhance the good environmental conditions inside the lab which increase the quality of the results					