CHAPTER ONE

Introduction

1- Introduction:

ISO/IEC 17025 is the global quality standard for testing and calibration laboratories. It is the basis for accreditation from an accreditation body. The current release was published in 2005.

There are two main clauses in ISO/IEC 17025 –2005 **Management Requirements** and **Technical Requirements**. Management requirements are related to the operation and effectiveness of the quality management system within the laboratory, and this clause has similar requirements to ISO 9001. Technical requirements address the competence of staff; testing methodology; equipment and quality; and reporting of test and calibration results. The ISO 9000 series is no different in this respect and consequently, ISO 9001:2000 has been reviewed, amended and updated where necessary and the Standard reissued as ISO 9001:2008. Implementing ISO/IEC 17025 has benefits for laboratories, but the work and costs involved should be considered before proceeding.

Accreditation is an objective way to assure customers that technical competence has been fully implemented to provide reliable and accurate test or calibration results.

ISO/IEC 17025 is an ideal management system model for laboratories because it aims to control quality costs, improve measurement accuracy

And guarantee consistency of results. It is also customer-driven. When implemented correctly, the elements of ISO/IEC 17025 work meticulously together to ensure that required quality levels are met and that customers' needs are satisfied. This can be a powerful strategic tool.

Furthermore, when your company achieves ISO/IEC 17025 accreditation, you will be presented with a certificate of accreditation. This certificate can be used in advertising, promotional literature and stationary to show current and potential customers that your laboratory is committed to quality and has demonstrated technical competency to perform calibration or testing services.

Sudanese Standards and Metrology organization implementing
(ISO 17025: 2005) for (10) laboratories (6 in Khartoum and 4 in Port Sudan) including (Microbiology, General Chemistry (includes water, sugars,

glues and mycotoxins), grain, chromatography, construction, optical spectroscopy, Laboratory Assay and precious metals.
In this research Sudanese Standards and Metrology organization was taken as an example to evaluate the implementation of ISO (17025-2005) in laboratories or know the benefits obtained by following the application of the standard.

1-1 Statement of the problem:

The lack of full implementation of the control systems and quality assurance within the laboratories is the most important reasons that lead to inaccurate results.
This study was tried to answer the following questions:

1. What is the impact of implementation of ISO/IEC17025-2005 standards on improve the performance of the laboratories of Sudanese Standards and Metrology Organization?
2. Is the implementation of ISO/IEC 17025-2005 in the laboratories of Sudanese Standards and Metrology organization led to the optimal use of resources?
3. Is there are any training and skills inside the laboratories of Sudanese Standards and Metrology organization?
4. Is work environment inside the lab suitable and helps in correct testing results and provide reliable and high quality output of services?

1-2 Importance of the research:

Nowadays, quality is important in business and industries world. Many of the customers require high quality product and service. In order to fulfill the requirements of the customers, the company must have a quality system to ensure that their product or service that provided has high quality to fulfill the customer requirement.
For a laboratory that only provide testing and calibration to the customer, it should have a quality system that to ensure the testing and calibration result has high quality that fulfill the requirement of the customers. ISO/IEC 17025

is one of the standard for testing and calibration activities. If the laboratory has been accredited with this standard, the testing and calibration results are being recognize internationally.

1-3 Research Objective:

1-3-1 General objective:

- To evaluate the implementation of ISO 17025 in the laboratories of Sudanese Standards and Metrology Organization (SSMO).

1-3-2 Specific objectives:

1. To examine if implementing ISO 17025 helped the laboratory to provide reliable and high quality result.
2. To examine if implementation of international standards like ISO 17025 contributed in facilitation of trade and economic growth for the laboratory.

1-4 Hypotheses:

The first hypotheses: The awareness and perception of top managers of ISO17025 will helped them in the process of evaluation and measuring the system as well achieving intended result.
The second hypotheses: Work environment inside the laboratory is suitable and helps in correct testing results and provide reliable and high quality result.
The third hypotheses: Implementing ISO17025 system enhances the performance and the quality of the laboratory.
The forth hypotheses: There is a system to identify training needs and staff training in SSMO.

1-5 Methodology of the study:

This study is based on **theoretical background** of methodology and the **quantitative design** using **a hypothesis testing approach a**nd **descriptive approach** because they fits with the nature of this study.

1-6 data collection:

The research selects the laboratories of the Sudanese Standards and Metrology Organization (SSMO) which operate 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.

CHAPTER TWO

Previous studies and Literature review

2-1 previous studies:

Impact of implementing ISO/IEC 17025 in the quality of Sudanese laboratories services.

The problem with the study is that, 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...etc.

The study found a number of result:

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

Recommendations:

1. Implementing the ISO/IEC 17025 inside the NPHL.
2. This research is more useful if it is studied in a larger scope which covers large number of testing laboratories in Sudan.
3. The further research needs to study all the impacts of applying ISO/IEC17025 on the service quality.
4. 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.
5. It is necessary to assess the views of laboratories customers on the value of implementation.

2-2 Literature review:

2-2-1 Background:

ISO 17025 covers every aspect of laboratory management. It involves everyone in the laboratory, including the laboratory manager, assistant laboratory manager, or quality manager. The standard also involves all laboratory staff whose functions relate to the quality of laboratory data generated. A laboratory's fulfilment of the requirements of ISO/IEC 17025:2005 means that the laboratory meets both the technical competence requirements and management system requirements necessary for it to consistently deliver technically valid test results and calibrations.

The standard was revised in 2005, the purpose of which was to align it with ISO 9001:2000. Unlike before, the two standards are now considered to be compatible rather than fully aligned. The revision makes it clear that meeting the requirements of ISO/IEC 17025 does not automatically mean that the requirements of ISO 9001 are met. The standard does however recognize that, by being accredited to ISO/IEC 17025, a laboratory will meet the principles of ISO-9001. Consequently, laboratories may choose to be accredited to ISO/IEC 17025, or be certified to ISO 9001, or both, but the processes of accreditation and certification would be two separate actions.

2-2-2 ISO 17025 accreditation

The definition of 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."**
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 there by increases their potential due to the increase customer satisfaction.

2-2-2-1 ISO/IEC 17025:2005 General Requirements for Competence of Test and Calibration Laboratories:

ISO 17025 contain all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results (ISO/IEC 17025, 2005).
ISO 17025 is applies to all organization that performing tests and/or calibration. Growth in the use of management systems generally has increased the need to ensure that laboratories which form part of larger organization or offer other services can operate to a quality management system that is seen as compliant with ISO 9001 as well as with this International Standard (ISO/IEC 17025, 2005). Therefore, ISO 17025 was written to incorporate all the ISO 9001 requirements that are relevant to the scope of testing and calibration services as well as specifying the technical requirement for technical competence.

2-2-2-2 History and status of ISO 17025:2005:

ISO 17025 was first published in 1999 as a replacement to ISO Guide 25. The first edition referred to ISO 9001:1994 and ISO 9002:1994 (ISO/IEC 17025, 2005). In year 2000, There standard have been superseded by ISO 9001:2000. ISO Guide 25 was a well-used document published by ISO, but did not have the entire management requirement that were outlined in ISO 9001:2000. ISO Guide 25 was revised and reissued in May 2005. An alignment has been made and the ISO Guide 25 was replaced by the ISO/IEC 17025:2005. ISO/IEC 17025:2005 now includes all the management requirements that was incorporated into new ISO 9001:2000 standard. ISO 17025:2005 is the most up to date version.
Accreditation bodies recognize that the competence of testing and calibration laboratories should use this International Standard as the basis for their accreditation (ISO/IEC 17025, 2005).

2-2-2-3 Content of MS ISO/IEC 17025:

Content MS ISO/IEC 17025 has 15 management requirements and10 technical requirements. The 15 management clauses are the requirements for the management in an organization. The management requirement is more on **planning for improvement**, **service for the customer**, **formation of the organization** and **internal auditing system**.
The10 technical clauses are the requirement on **the testing and/or calibration activities**, **equipment**, **reference standard** and **result of report**.

2-2-2-4 Overview of the Content of MS ISO/IEC 17025:2005:

The ISO 17025 standard is comprised of five elements:

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

Element 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 and technical requirement are show in below (ISO/IEC 17025, 2005).

2-2-2-5 Element

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, and 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 them confident in laboratory performance. The feedback from customer should be used for analysis and 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:

The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:
The responsibilities and authorities for the management of nonconforming work are designated and actions are defined and taken when nonconforming work is identified, an evaluation of the significance of the nonconforming work is made, correction is taken immediately.

4.10 Improvement:

Improve the effectiveness of its management system through the quality manual, quality objective, and 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 starts 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 kept as record although a mistake occur in the data records.

4.14 Internal audits:

The internal audit shall be performed periodically and consist of the management system and testing and/or calibration activities. The finding of auditing 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.

5: Technical Requirement

5.1 General:

When carrying 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 laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

5.3 Accommodation and environment condition:

Laboratory shall to ensure that all the testing and/or calibration are carried 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 measuring 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 have to ensure that the testing result using that equipment must be accurate and validate.

5.7 Sampling

The sampling plan and procedures shall be based 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.

2-2-3 Relationship between ISO 17025 and ISO 9001:

According to Pizzolato *et al*. (2008), depending on the laboratory business, the laboratory could assess its QMS according to ISO 9001 or ISO 17015 standard. According to the ISO 17025 standard, the conformity of the quality management system with the requirements of ISO 9001 does not prove, by itself the competence of the laboratory to produce technically valid data and results. A laboratory that is accredited according to the ISO 17025 standard does not guarantee the fulfillment of all ISO 9001 requirements. By the other side, an IS 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. Figure 2 illustrates the interaction between ISO 9001 and ISO 17025.

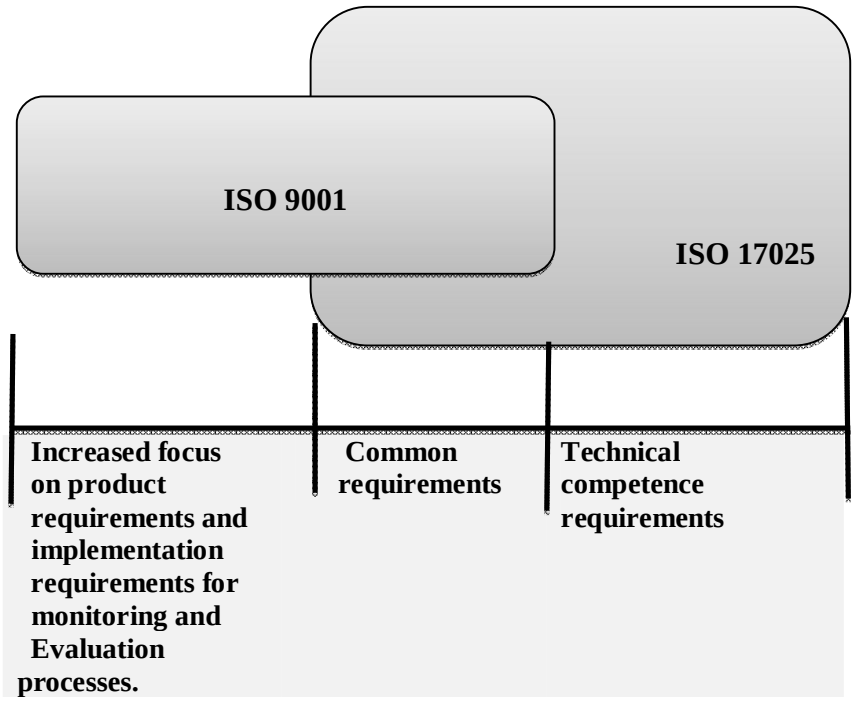

Figure 1-1:
Interaction between ISO 9001 and ISO 17025 standards ISO 17025 ISO 9001

As is illustrated in Figure1, there are some important differences between the two standards, because ISO 17025 does not meet all the ISO 9001 requirements, mainly those related to product requirements and implementation requirements for monitoring and evaluate processes.
Those laboratories that are interested in demonstrate technical competence should adopt the ISO 17025 standard. Moreover, those laboratories that are already accredited by the ISO 17025 standard and that are embedded in organizations that also carry out activities such as accounting, marketing, consulting, training and other, should evolve to an ISO 9001 quality management system.

2-2-4 The Advantages of Being an Accredited Laboratory:

A Recognition of Testing Competence:

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

Accredited laboratories usually issue test or calibration reports bearing the accreditation body's symbol or endorsement, as an indication of their accreditation. Clients are encouraged to check with the laboratory as to what specific tests or measurements they are accredited for, and for what ranges or uncertainties. This information is specified in the laboratory's scope of accreditation, issued by the accreditation body. The description in the scope of accreditation also has advantages for the customers of laboratories in enabling them to find the appropriate laboratory or testing service.

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.

Unlike certification to ISO9001, laboratory accreditation uses criteria and procedures specifically developed to determine technical competence, thus assuring customers that the test, calibration or measurement data supplied by the laboratory or inspection service are accurate and reliable.

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.

Finally, through a system of international agreements (see later in this brochure) 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.

In addition to commercial testing and calibration services, manufacturing organizations may use laboratory accreditation to ensure the testing of their products by their own in-house laboratories is being done correctly.

CHAPTER THREE
Material and method

3- Material and method:

3-1 materials:

3-1-1 study design:

Based on research objective, researcher developed the objective, design and the framework of the research.

According to objectives of research four hypotheses are assumed to evaluate the implementation of ISO17025 on the quality of laboratory's services.

Questionnaire survey was conducted and data was analyzed by using SPSS software program.

3-1-2 Study area:

The study was conducted in Khartoum state during 2014 / 2015.

3-1-3 a- Study population:

The target population of this study including personal from all department of in Sudanese standards & metrology organization (SSMO) in Khartoum state Sudan.

3-1-3 b- Sampling:

Random sampling technique is used to select 30 samples from target population.

3-1-4 Inclusion criteria:

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

1- Top management of Sudanese Standards and Metrology Organization (SSMO).
2- All heads of department of testing labs.
3- Senior technicians of testing labs.
4- Professional personal from supporting department.

3-1-5 Exclusion criteria:

The participant is excluded if has experience was less than 3 years.

3-1-6 Ethical consideration:

Participant's opinions were treated honestly, fairly and respectfully. Professional and scientific responsibility were adhere to sticking to highest scientific and professional standard and accept response.

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

3-1-8 Data analysis:

After data collection has finished the researcher used SPSS 11.5 software for the analysis of collected data by using cronbach‘s Alpha (a) test, Chi-square test and frequency test.
30 questionnaires were distributed, four of them were incomplete. Therefore the number of remaining samples to analyze was 26.

3-2 Method:

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

CHAPTER FOUR

Data Analysis

4-1 Reliability test:

Reliability Analysis – Scale (ALPHA):-

Alpha value is = (0.88), so the Reliability percent is = (88%)

Table (4-1): Work

	Frequency	***Percent (%)***
Chemical analyst	17	65.4
Heads of units	9	34.6
Total	***26***	***100.0***

Table (4-2): Education

Education	***Frequency***	***Percent (%)***
Bachelor	18	69.2
Master	8	30.8
Total	***26***	***100.0***

Table (4-3): year of Experience

Experience year	***Frequency***	***Percent (%)***
1-3 y	1	3.8
3-5 y	15	57.7
>5 y	10	38.5
Total	***26***	***100.0***

4-2 Frequency Test:

Management system:

Table (4-4): Administration has a mechanism to determine the quality of the potential problems and take action to prevent them:

	Frequency	*Percent (%)*
Strongly disagree	4	15.4
Disagree	1	3.8
Neutral	8	30.8
Agree	12	46.2
Strongly agree	1	3.8
Total	***26***	***100.0***

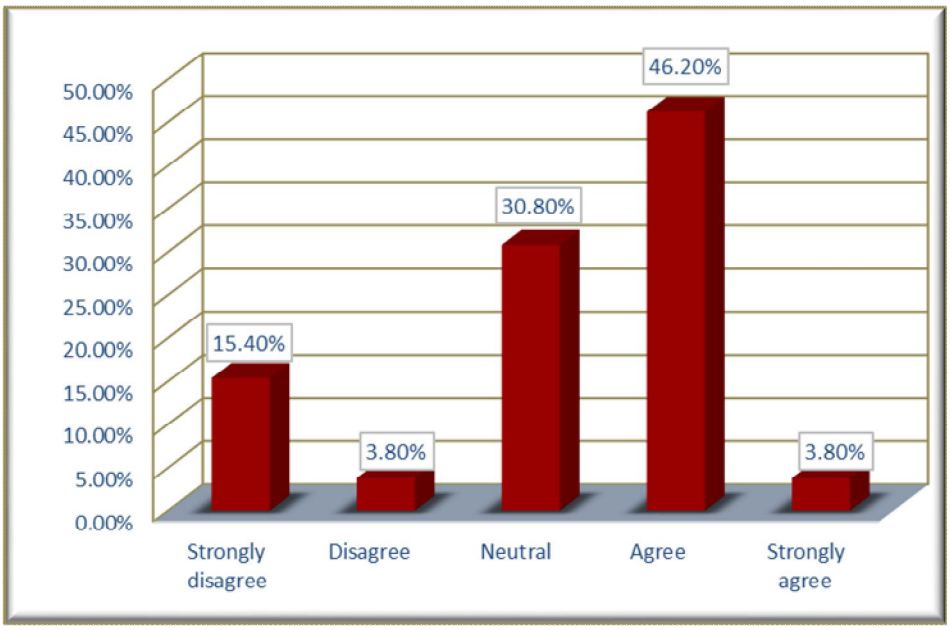

Figure (4-1): Administration has a mechanism to determine the quality of the potential problem and take action to prevent them

Table (4-5): There is a mechanism for identifying opportunities to improve the effectiveness of quality system:

	Frequency	*Percent (%)*
Strongly disagree	3	11.5
Disagree	5	19.2
Neutral	2	7.7
Agree	14	53.8
Strongly agree	2	7.7
Total	***26***	***100.0***

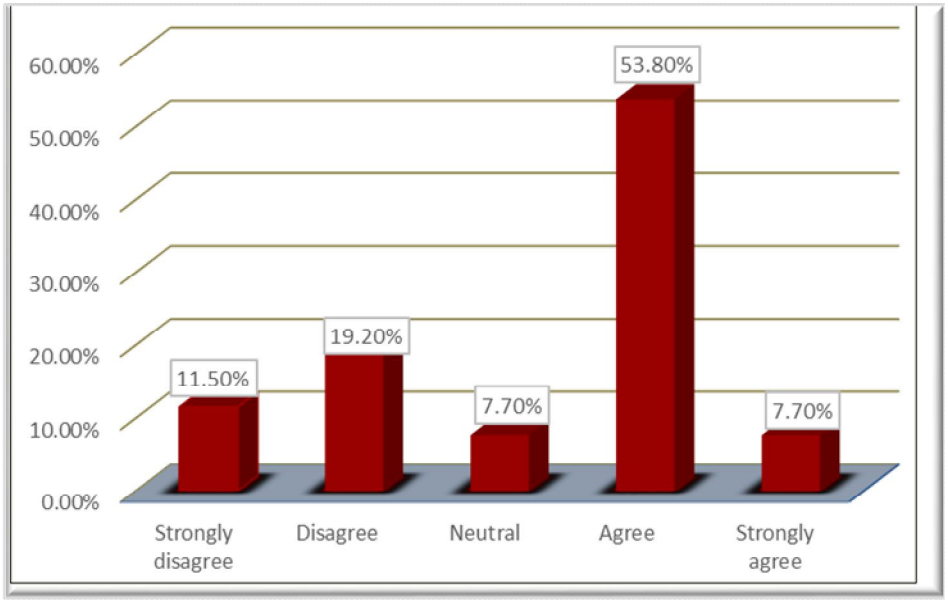

Figure (4-2): There is a mechanism for identifying opportunities to improve the effectiveness of quality system

Table (4-6): Implementation of international standards like iso17025 contributed in facilitating trade and economic growth:

	Frequency	***Percent (%)***
Strongly disagree	1	3.8
Neutral	6	23.1
Agree	15	57.7
Strongly agree	4	15.4
Total	***26***	***100.0***

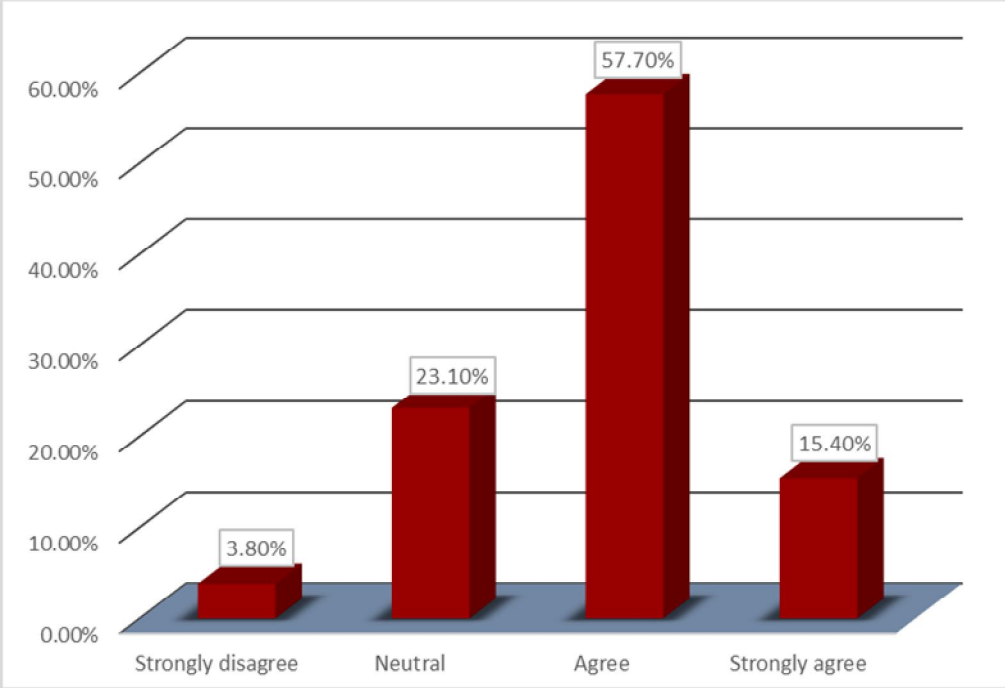

Figure (4-3): Implementation of international standards like iso17025 contributed in facilitating trade and economic growth

Table (4-7): There is an increase in the volume of business due to the high level of customer confidence and satisfy them:

	Frequency	***Percent (%)***
Strongly disagree	1	3.8
Neutral	4	15.4
Agree	16	61.5
Strongly agree	5	19.2
Total	***26***	***100.0***

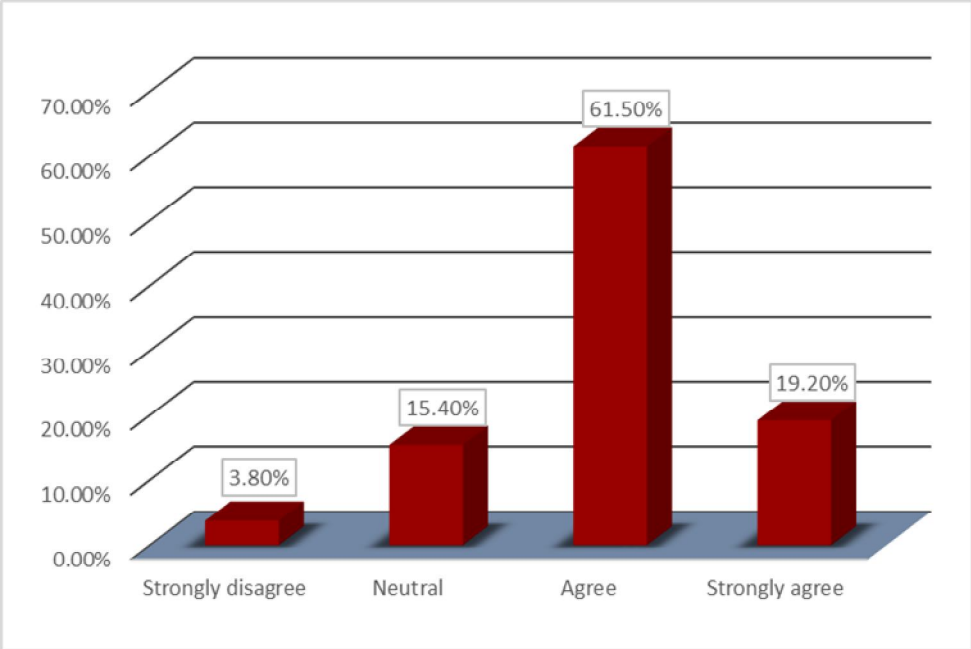

Figure (4-4): There is an increase in the volume of business due to the high level of customer confidence and satisfy them

Work environment:

Table (4-8): There are access control to areas which may influence the quality of tests:

	Frequency	*Percent (%)*
Strongly disagree	3	11.5
Disagree	5	19.2
Neutral	3	11.5
Agree	6	23.1
Strongly agree	9	34.6
Total	***26***	***100.0***

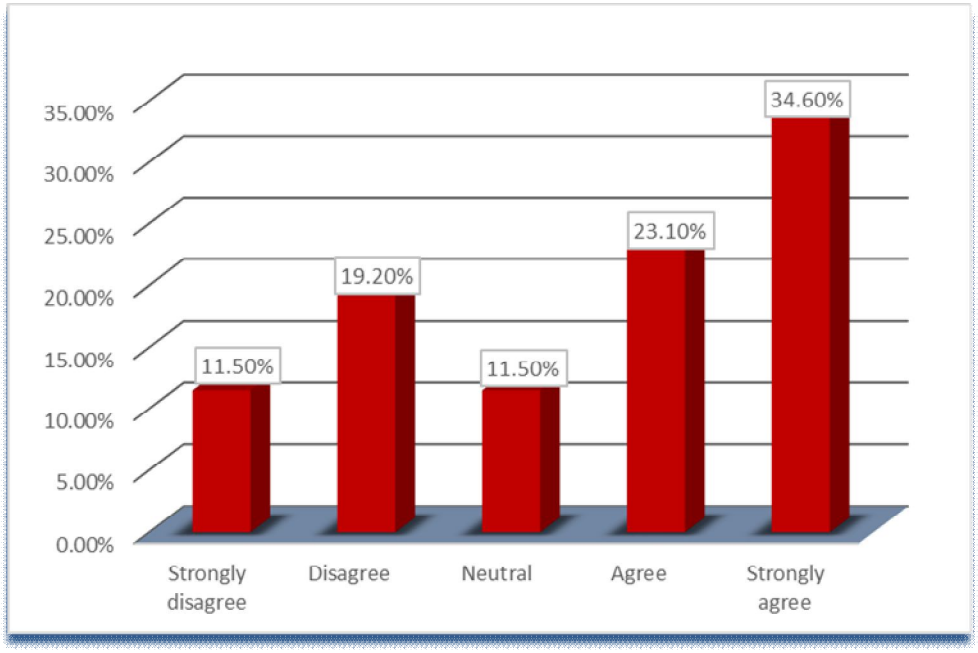

Figure (4-5): There are access control to areas which may influence the quality of tests

Table (4-9): When incompatible activities are carried out in different areas of the laboratory there is an effective separation which avoids cross contamination:

	Frequency	***Percent (%)***
Disagree	4	15.4
Neutral	1	3.8
Agree	12	46.2
Strongly agree	9	34.6
Total	***26***	***100.0***

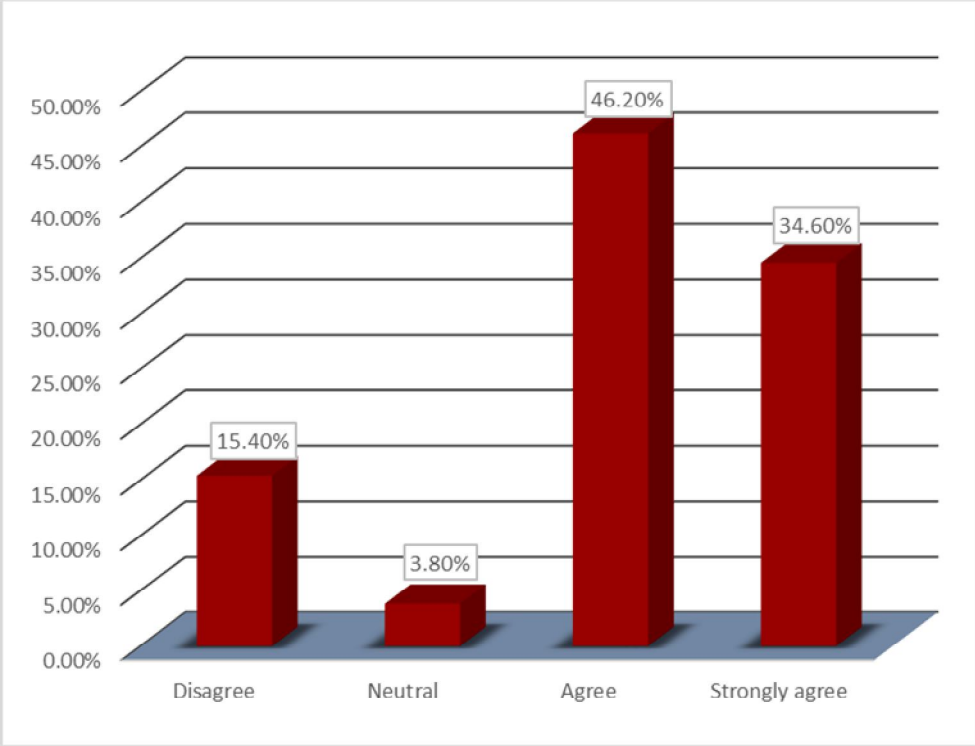

Figure (4-6): When in compatible activities are carried out in different areas of the laboratory there is an effective separation which avoids cross contamination

Quality of the service:

Table (4-10): Increase confidence in the test data and in the performance of staff and continuing improvement in the quality of the data and the effectiveness of the laboratory:

	Frequency	*Percent (%)*
Strongly disagree	1	3.8
Disagree	1	3.8
Neutral	3	11.5
Agree	11	42.3
Strongly agree	10	38.5
Total	***26***	***100.0***

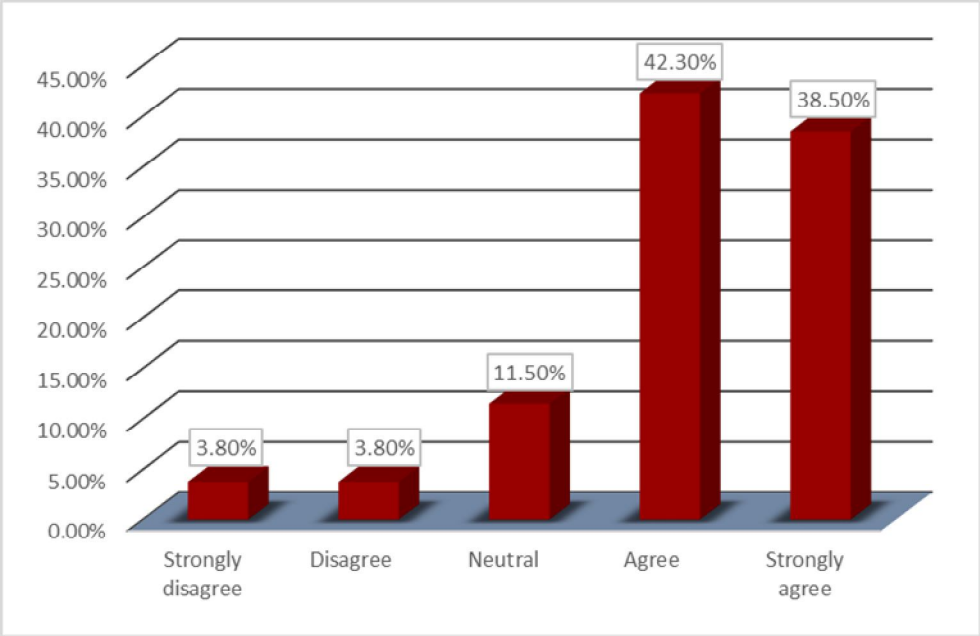

Figure (4-7): increase confidence in the test data and in the performance of staff and continuing improvement in the quality of the data and the effectiveness of the laboratory

Table (4-11): ***No need for re-testing, leading to save time and money***

	Frequency	***Percent (%)***
Strongly disagree	1	3.8
Disagree	2	7.7
Neutral	6	23.1
Agree	10	38.5
Strongly agree	7	26.9
Total	***26***	***100.0***

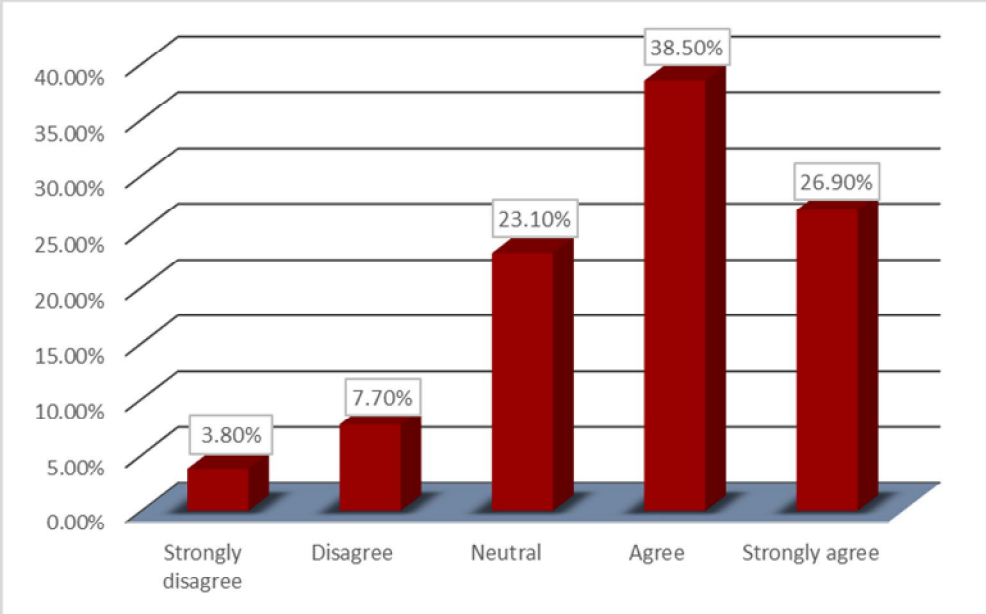

Figure (4-8): ***No need for re-testing, leading to save time and money***

Table (4-12): wherever quality problems occur administration has a mechanism for taking corrective action which seeks to develop and improve the quality system so that repetition of the problem is unlikely:

	Frequency	*Percent (%)*
Strongly disagree	2	7.7
Disagree	3	11.5
Neutral	1	3.8
Agree	17	65.4
Strongly agree	3	11.5
Total	***26***	***100.0***

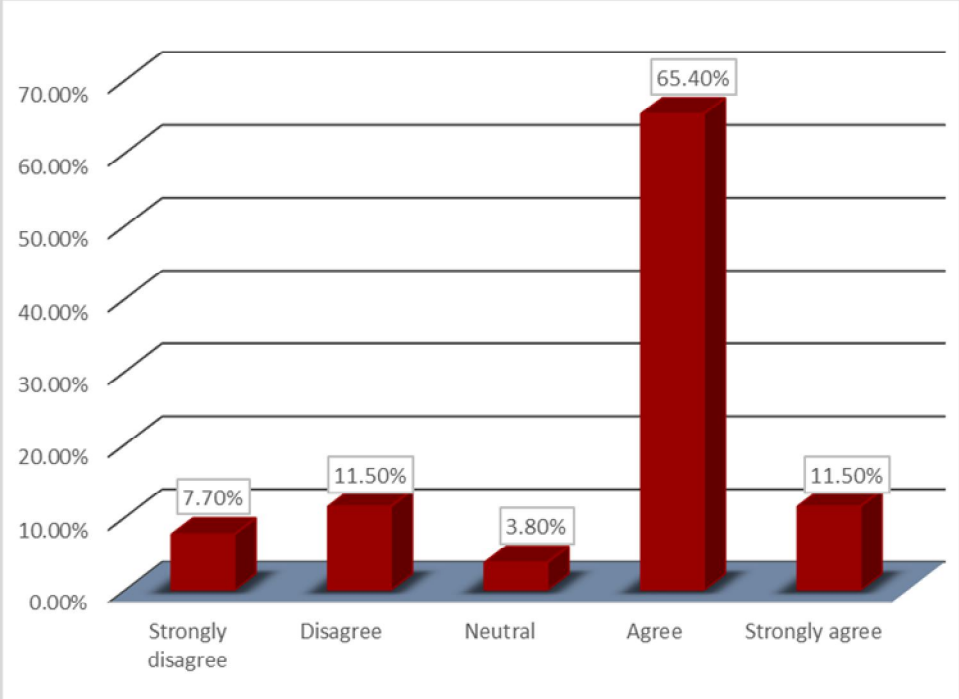

Figure (4-9): wherever quality problems occur administration has a mechanism for taking corrective action which seeks to develop and improve the quality system so that repetition of the problem is unlikely

Table (4-13): There is mechanisms to monitor trends in quality performance so that failures can be anticipated and dealt with before they become critical:

	Frequency	***Percent (%)***
Strongly disagree	1	3.8
Neutral	12	46.2
Agree	11	42.3
Strongly agree	2	7.7
Total	***26***	***100.0***

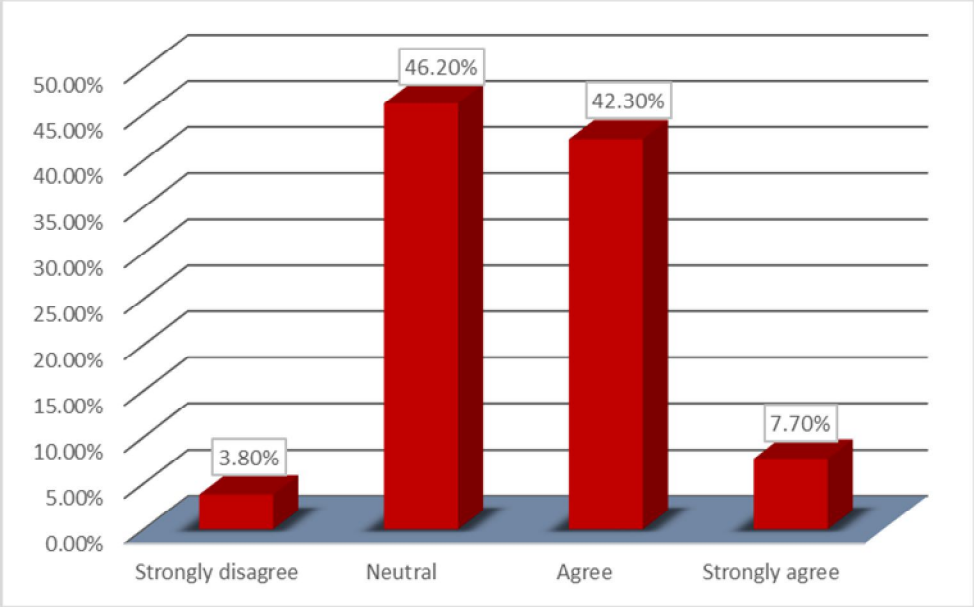

Figure (4-10): There is mechanisms to monitor trends in quality performance so that failures can be anticipated and dealt with before they become critical

Table (4-14): There are a review on the performance of quality system to determine whether it is deliver the objectives which have identified:

	Frequency	***Percent (%)***
Neutral	4	15.4
Agree	16	61.5
Strongly agree	6	23.1
Total	***26***	***100.0***

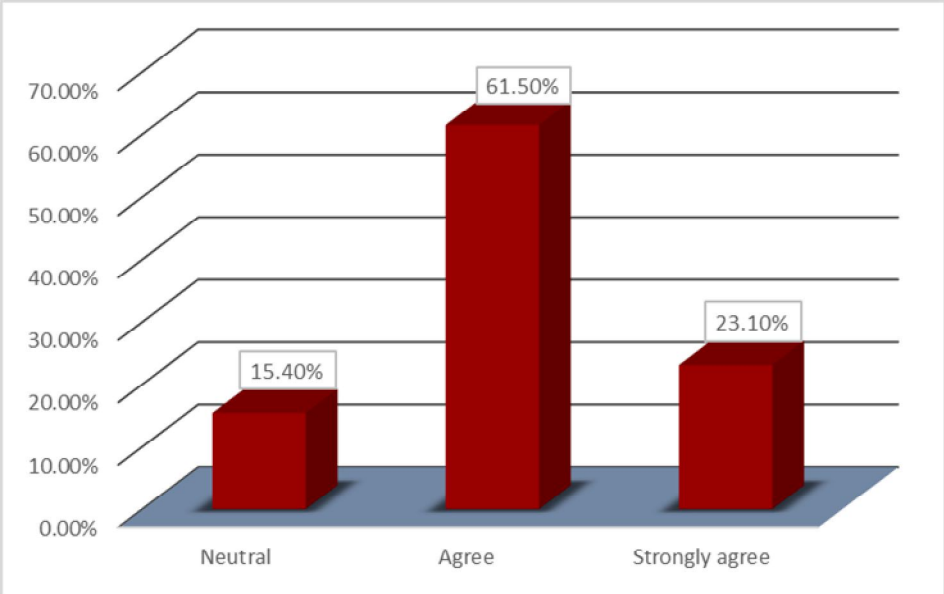

Figure (4-11): There are a review on the performance of quality system to determine whether it is deliver the objectives which have identified

Personal:

Table (4-15): The system been establish to identify training requirements and to train the staff:

	Frequency	***Percent (%)***
Strongly disagree	2	7.7
Disagree	5	19.2
Neutral	3	11.5
Agree	15	57.7
Strongly agree	1	3.8
Total	***26***	***100.0***

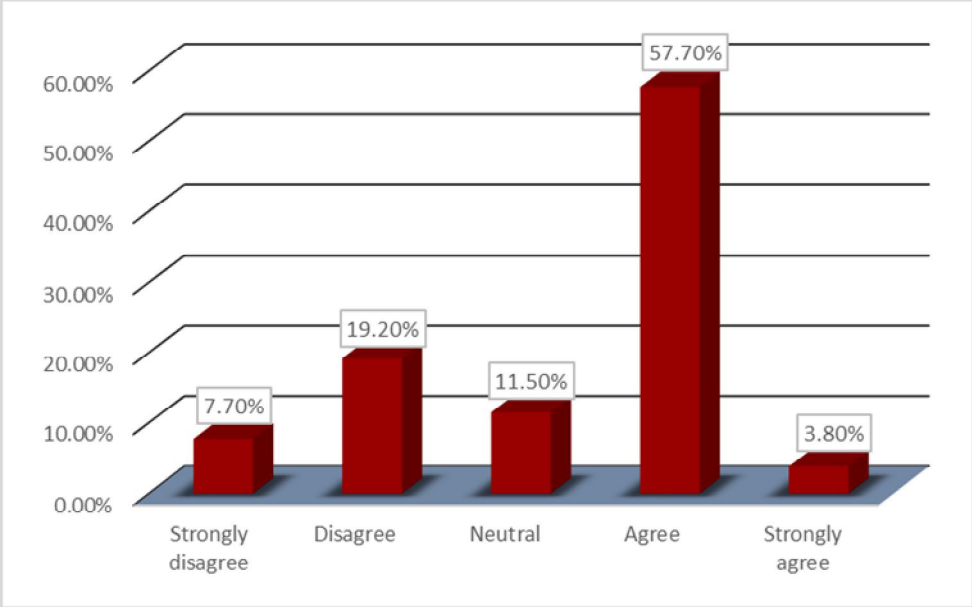

Figure (4-12): The system been establish to identify training requirements and to train the staff:

Table (4-16): There are documented procedure for conducting evaluation of the competence of staff after training and before authorizing them for the procedure in which they were trained:

	Frequency	*Percent (%)*
Strongly disagree	1	3.8
Disagree	3	11.5
Neutral	1	3.8
Agree	15	57.7
Strongly agree	6	23.1
Total	***26***	***100.0***

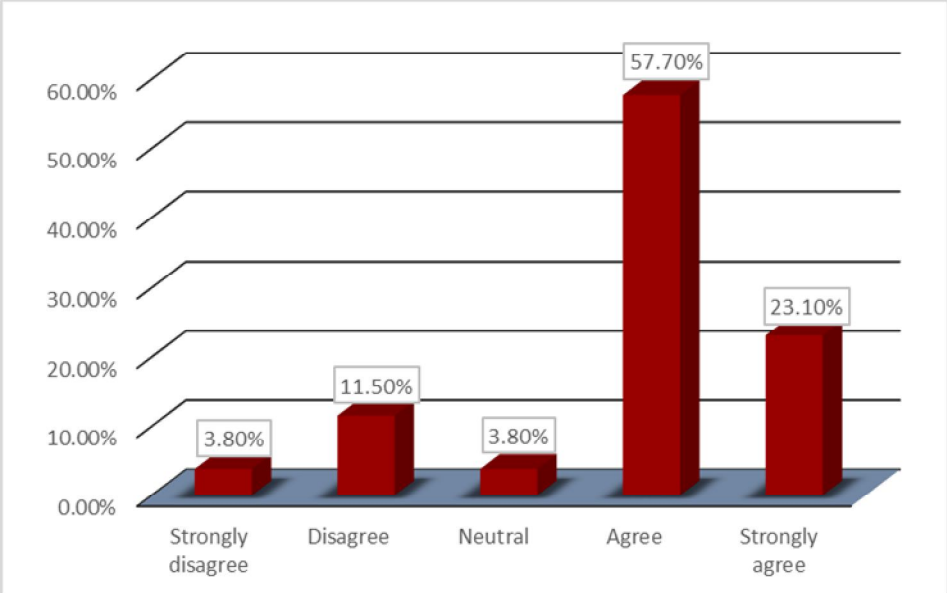

Figure (4-13): There are documented procedure for conducting evaluation of the competence of staff after training and before authorizing them for the procedure in which they were trained

Table (4-17): There are a mechanisms for identifying which staff conducted each procedure or test:

	Frequency	***Percent (%)***
Strongly disagree	1	3.8
Disagree	5	19.2
Neutral	1	3.8
Agree	14	53.8
Strongly agree	5	19.2
Total	***26***	***100.0***

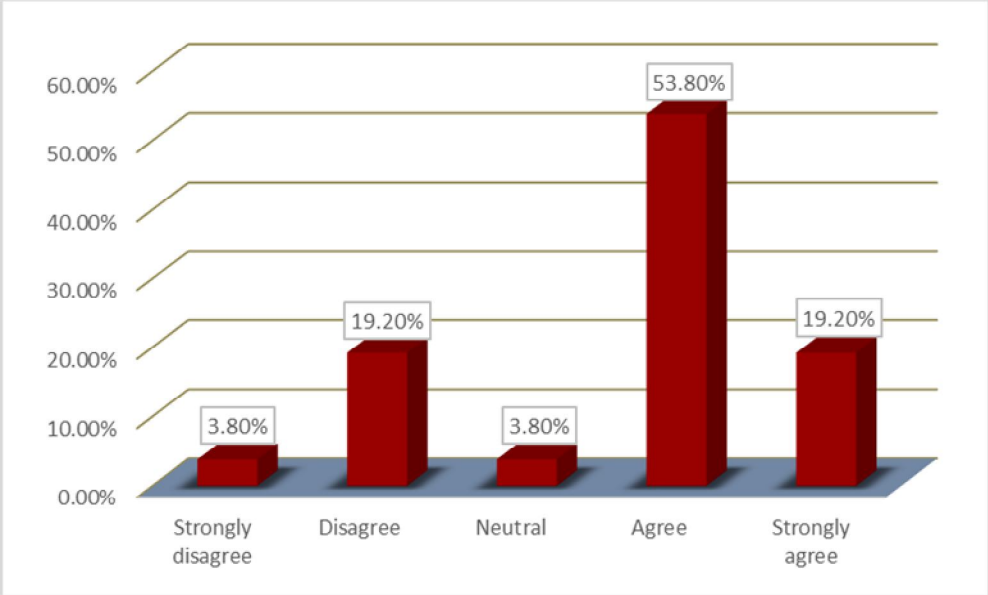

Figure (4-14): There are a mechanisms for identifying which staff conducted each procedure or test:

4-2 Chi-square Test (test of hypothesis):

Table (4-18):

Management system:

No	*The questions*	*Chi-value*	*P-value*	*Mode*	*S.D*
1	Administer has a mechanism to determine the quality of the potential problems and take action to prevent them	17.462	.002	4	1.13205
2	There is a mechanism for identifying opportunities to improve the effectiveness of quality system	19.769	.001	4	1.21845
3	Implementation of international standards like iso17025 contributed in facilitating trade and economic growth	16.769	.001	4	.84943
4	There is an increase in the volume of business due to the high level of customer confidence and satisfy them	19.846	.000	4	.84489

- The value of chi-square for the first phrase is (17.462) with (p-value=.002 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study individuals.
- The value of chi-square for the second phrase is (19.769) with (p-value=.001< 0.05), this indicates that there is significant differences at the level (5%) between answers of study.
- The value of chi-square for the third phrase is (16.769) with (p-value=.001< 0.05), this indicates that there is significant differences at the level (5%) between answers of study individuals.

- The value of chi-square for the fourth phrase is (19.846) with (p-value=.000 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study individuals.

Table (4-19): Work environment:

No	*The questions*	*Chi-value*	*P-value*	*Mode*	*S.D*
1	There are access control to areas which may influence the quality of tests	4.769	.312	5	1.44914
2	When in compatible activities are carried out in different areas of the laboratory there is an effective separation which avoids cross contamination	11.231	.011	4	1.01980

- The value of chi-square for the first phrase is (4.769) with (p-value=.312 > 0.05), this indicates that there is no significant differences at the level (5%) between answers of study individuals in this question and this does not different because all the questions have a statistically significant and the mode 5.
- The value of chi-square for the second phrase is (11.231) with (p-value=.011 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study.

Table (4-20): Quality of the service:

No	*The question*	*Chi-value*	*P-value*	*Mode*	*S.D*
1	Increase confidence in the test data and in the performance of staff and continuing improvement in the quality of the data and the effectiveness of the laboratory	18.615	.001	4	1.01678
2	No need for re-testing, leading to save time and money	10.538	.032	4	1.06987
3	wherever quality problems occur administration has a mechanism for taking corrective action which seeks to develop and improve the quality system so that repetition of the problem is unlikely	34.000	.000	4	1.09825
4	There is mechanisms to monitor trends in quality performance so that failures can be anticipated and dealt with before they become critical	15.538	.001	3	.81240
5	There are a review on the performance of quality system to determine whether it delivers the objectives which have been identified	9.538	.008	4	.62757

- The value of chi-square for the first phrase is (18.615) with (p-value=.001 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study individuals.
- The value of chi-square for the second phrase is (10.538) with (p-value=.032 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study.
- The value of chi-square for the first phrase is (34.000) with (p-value=.000 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study individuals.
- The value of chi-square for the second phrase is (15.538) with (p-value=.001 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study.
- The value of chi-square for the second phrase is (9.538) with (p-value=.008 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study.

Table (4-21): Personal:

No	***The questions***	***Chi-value***	***P-value***	***Mode***	***S.D***
1	The system been establish to identify training requirements and to train the staff	24.769	.000	4	1.08699
2	There are documented procedure for conducting evaluation of the competence of staff after training and before authorizing them for the procedure in which they were trained	26.308	.000	4	1.04661
3	There are mechanisms for identifying which staff conducted each procedure or test	21.692	.000	4	1.12933

- The value of chi-square for the first phrase is (24.769) with (p-value= .000 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study individuals.
- The value of chi-square for the second phrase is (26.308) with (p-value=.000 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study.
- The value of chi-square for the third phrase is (21.692) with (p-value=.000 < 0.05), this indicates that there is significant differences at the level (5%) between answers of study individuals.

CHAPTER FIVE

Discussion, Conclusion and Recommendation

5- Discussion, Conclusion and Recommendation:

5-1 Discussion:

When the implementation of ISO / IEC 17025 at the Sudanese Standards and metrology Organization (SSMO) was evaluation it has been found that the laboratories of SSMO are applying the IS 17025 accurately as there is an existence of a quality management system, provide human resource training and participation and good environment which are main issues in good quality system.

As ISO 17025 emphasizes of all these issues and more, application of this standards and other international standards increase the quality of service, the qualification of personal and the suitability of working environment.

According to Chi-square test result 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.

Table5-1

Hypotheses	**Result**
The awareness and perception of top managers of ISO will helped them in the process of evaluation and measuring the system as well achieving intended result.	True
Work environment inside the laboratory is suitable and helps in correct testing results and provide reliable and high quality result.	True
Implementing ISO system enhances the performance and the quality of the laboratory.	True
There is a system to identify training needs and staff training in SSMO.	True

5-2 Conclusion:

- The awareness and perception of top managers of ISO helped them in the process of evaluation and measuring the system as well achieving intended result.
- Work environment inside the laboratory is suitable and helps in correct testing results and provide reliable and high quality result.
- Implementing ISO system enhances the performance and the quality of the laboratory of SSMO.
- There is a system to identify training needs and staff training.
- The research was convinced that the Sudanese Standards and Metrology organization is working to educate all employees and their knowledge of procedures for the application of ISO 17025-2005,the Sudanese Standards and Metrology organization is maintain improvement measurement accuracy and ensuring the consistency of the results and ensuring that customers' needs are met in high level of quality.

5-3 Recommendation:

- Keep improving measurement accuracy and ensure the consistency of the results.
- Always ensure that meeting the needs of customers to highest level of quality.
- Continuous improvement and development to achieve customer satisfaction.
- Continuous training of staff and finding out their needs.
- Maintain continues review of the management system and testing and/or calibration activities to ensure their suitability, effectiveness and necessary changes or improvement on their laboratory.

References:

- Bhavan "bob" Mehta (2013) implementing ISO/IEC 17025-2005. ASQ Quality press.
- Donnell R. Christian , Jr., Stephanie Drilling (2010) Laboratory policies and processes CRC press.
- Golze M. (2003) Quality Management in Analytical Laboratories According to ISO / IEC 17025, from: http://www.ecasia03.bam.de/pdf/golze_iso_17025.pdf
- How Does Using an Accredited Laboratory Benefit Government & Regulators ,from: http://www.cala.ca/ilac_how_does_using_benefit.pdf
- ILAC .The Advantages of Being an Accredited Laboratory www.cala.ca/ilac_the_advantages_of_being.pdf
- ILAC (2002) introducing the concept of uncertainty in association with the application of the standard ISO/IEC17025.
- Impact of implementing ISO/IEC 17025 in the quality of Sudanese laboratories services.
- ISO 9001-2008, quality management system requirement.
- ISO/IEC17025-2005, general requirements for the competence of testing and calibration laboratories.
- José Barradas , Paulo Sampaio , ISO 9001 and ISO 17025 standards in a metrology laboratory, from: http://repositorium.sdum.uminho.pt/bitstream/1822/15144/1/Barradas-Sampaio.pdf
- K Balgobin (2011) Implementation and Practical Benefits of ISO/IEC 17025:2005 in a Testing Laboratory. Faculty of Engineering, University of Mauritius Reduit ,from: www.ajol.info/index.php/umrj/article/download/70730/59326 umpir.ump.edu.my/798/1/Lew,_Hon_Chung.pdf
- Lew Hon Chung (2009) Development of MS ISO/IEC 17025 quality system (general requirements for the competence of testing and calibration laboratories) for FKM laboratory. University Malaysia Pahang ,from: umpir.ump.edu.my/798/1/Lew,_Hon_Chung.pdf
- Dr. Ludwig Huber (2008) .Understanding and Implementing ISO/IEC 17025 pdf ,from: www.chem.agilent.com/Library/.../5990-4540EN.**p**..

- MS ISO 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories. ISO, Geneva (2005) ,from: www.iso.org/iso/catalogue *https://www.iso.org/obp/ui/#iso:std:iso-iec:17025:ed-2:v1:en*
- Perry Johnson (2009) Steps to ISO/IEC 17025 Accreditation pdf. 755 W. Big Beaver Rd., Suite 1325 Troy, MI 48084 U.S.A ,from: www.pjlabs.com/downloads/**Steps_17025**_Rev%207-09.**pdf**
- UNIDO (2009) Complying with ISO 17025 , from : http://172.19.66.103/videoplayer/Final%20V-%20COMPLYING_WITH_ISO_17025-V20091204.pdf?ich_u_r_i=ee322920a903e4e16b02209073d06f8d&ich_s_t_a_r_t=0&ich_e_n_d=0&ich_k_e_y=f41340cc00bd483706ca7d6cb669b1bfd3fd53faeea6d854abf1b99de276a7ba&ich_t_y_p_e=1&ich_d_i_s_k_i_d=10&ich_s_e_q=264313510&ich_u_n_i_t=1

Appendix 1:

Questionnaire was designed and revised several times, it was refereed and refined by:

Dr. Elfatih Ahmed Hassan.

Dr. Abbas Ibrahim.

Dr. Awadia Alkhateeb.

Appendix 2:

بسم الله الرحمن الرحيم

Questionnaire to know the impact of implementing ISO/IEC17025-2005 standards and its role in improving the performance of the laboratories of Sudanese Standards and Metrology Organization

Management: work:

Educational Qualification: secondary: ☐ Bachelor: ☐

Master: ☐ PhD: ☐

Years of Experience:

Less than a year: ☐ from one year to three years: ☐

From three to five years: ☐ more than five years: ☐

Quality of the service:

	strongly disagree	disagree	neutral	agree	strongly agree
1. Increase confidence in the test data and in the performance of staff and continuing improvement in the quality of the data and the effectiveness of the laboratory.					
2. No need for re-testing, leading to save time and money.					
3. Wherever quality problems occur administration has a mechanism for taking corrective action which seeks to develop and improve the quality system so that repetition of the problem is unlikely.					
4. There is mechanisms to monitor trends in quality performance so that failures can be anticipated and dealt with before they become critical.					
5. There are a review on the performance of quality system to determine whether it is deliver the objectives which have identified.					

Personal:-

	strongly disagree	disagree	neutral	agree	strongly agree
1. The system been establish to identify training requirements and to train the staff.					
2. There are documented procedure for conducting evaluation of the competence of staff after training and before authorizing them for the procedure in which they were trained.					
3. There are mechanisms for identifying which staff conducted each procedure or test.					

Management system:-

	strongly disagree	disagree	neutral	agree	strongly agree
1. Administer has a mechanism to determine the quality of the potential problems and take action to prevent them.					
2. There is a mechanism for identifying opportunities to improve the effectiveness of quality system.					
3. Implementation of international standards like iso17025 contributed in facilitating trade and economic growth.					
4. There is an increase in the volume of business due to the high level of customer confidence and satisfy them.					

Work environment:-

1. There are access control to areas which may influence the quality of tests.	strongly disagree	disagree	neutral	agree	strongly agree
2. When in compatible activities are carried out in different areas of the laboratory there is an effective separation which avoids cross contamination.					