

## Sudan University of Science and Technology College of Graduate Studies



# Assessment of Laboratory Technicians Awareness, Qualifications and Training Regarding Applying Laboratories Equipments Calibration in East Nile Hospital, Khartoum State- Sudan

تقييم مفهوم معرفة و مؤهلات و تدريب تقنيي المختبرات فيما يتعلق بتطبيق معايرة الجهزة المختبرات في مستشفى شرق النيل، ولاية الخرطوم - السودان

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

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### الآية

#### قال تعالى:

بسم الله الرحمن الرحيم

(وَمِنْ آيَاتِهِ أَنَّكَ تَرَى الْأَرْضَ خَاشِعَةً فَإِذَا أَنزَلْنَا عَلَيْهَا الْمَاءَ الْمَوْتَىٰ آيَاتِهِ أَنَّكَ تَرَى الْأَرْضَ خَاشِعَةً فَإِذَا أَنزَلْنَا عَلَيْهَا الْمَاءَ اهْتَزَّتْ وَرَبَتْ آلِنَ الَّذِي أَحْيَاهَا لَمُحْيِي الْمَوْتَىٰ آلِنَّهُ عَلَىٰ كُلِّ اهْتَزَّتْ وَرَبَتْ آلِنَ الَّذِي أَحْيَاهَا لَمُحْيِي الْمَوْتَىٰ آلِنَهُ عَلَىٰ كُلِّ الْهَوْتَىٰ آلِنَ اللَّذِي أَحْيَاهَا لَمُحْيِي الْمَوْتَىٰ آلِنَهُ عَلَىٰ كُلِّ الْهَوْتَىٰ آلِنَ اللَّذِي أَحْيَاهَا لَمُحْيِي الْمَوْتَىٰ آلِيَ اللَّهُ عَلَىٰ كُلِّ الْمَوْتَىٰ آلِيَ اللَّهُ عَلَىٰ كُلِّ اللَّهُ اللَّهُ اللَّهُ عَلَىٰ اللَّهُ اللَّ

صدق الله العظيم سورة فصلت: الآية 39

#### **Dedication**

To my home country "Sudan" which I wish to be the best all over the world in quality industry.

To my beloved wonderful mother for her measureless support, encouragement and love over the years.

To my precious father, whose wise guidance has made me a good person.

To my lovely husband who always hope to see me the best in everything.

To my beautiful son (Yaseen)

I dedicate this work

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Also, I am so grateful to Dr. Somaya the laboratory senior technician who helped me in distribution and collection of questionnaires.

Deep appreciation and thanks also go to Dr. Khalid Rahama for his assistance in statistical analysis of data, support and cooperation.

#### **Abstract**

The study aimed to assess the laboratory technicians awareness, qualifications and training regarding applying laboratories equipments calibration in East Nile Hospital, Khartoum State- Sudan. The study was conducted during the period from April 2018 to November 2018. A questionnaire was used as data collection tool. Thirty six questionnaires were distributed to all laboratory technicians in the hospital, 29 of the laboratory technicians had respond with percentage of (80.5%), while 7 had not respond. The data were analyzed using the statistical package for the social sciences (SPSS); the methodology used was the descriptive correlation.

The study showed that there was a significant response to the statement of (calibration is necessary to ensure the accuracy of laboratory results) with percentage of (86.2%) for strongly agree.

The study showed that there was statistically significant relationship between knowing the importance of laboratory calibration and applying it. The results showed that there was statistically significant relationship between the academic qualification and applying calibration. The study revealed that there was statistically significant relationship between the training and applying calibration.

#### المستخلص

هدفت هذه الدراسة لتقييم مفهوم معرفة و مؤهلات و تدريب تقنيي المختبرات فيما يتعلق بتطبيق معايرة اجهزة المختبرات في مستشفى شرق النيل، ولاية الخرطوم- السودان. أجريت الدراسة خلال الفترة من ابريل 2018 إلى نوفمبر 2018م. استخدمت الاستبانة كآداة لجمع البيانات. 36 استبانة تم توزيعها على جميع تقنيي المعمل بالمستشفى، استجاب منهم 29 بنسبة (80.5%) ولم يستجب تم تم تم التحليل الوصفي الارتباطي في تحليل البيانات باستخدام الحزمة الإحصائية للعلوم الاجتماعية . (Statistical Package for Social Sciences (SPSS)

اظهرت الدراسة ان هنالك استجابة للعبارة (المعايرة ضرورية لضمان دقة النتائج المعملية) بنسبة (86.2%) للموافقة بشدة.

اظهرت الدراسة وجود علاقة ذات دلالة إحصائية بين معرفة اهمية معايرة الأجهزة المعملية و تطبيقها. أظهرت النتائج وجود علاقة ذات دلالة إحصائية بين مستوى التأهيل الأكاديمي لتقنيي المختبرات و تطبيق المعايرة. كشفت الدراسة وجود علاقة ذات دلالة إحصائية بين التدريب و تطبيق المعايرة.

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# CHAPTER ONE Introduction, Rationale and Objectives

#### Chapter 1

#### Introduction

A calibration is a process used to compare the inspection, measuring, and test instruments to a recognized reference standard of known certified accuracy and precision, noting the difference and adjusting the instrument, where possible, to agree with the standard. Fundamental to a systematic program of instrument calibration and periodic recalibration is the idea that the instruments are not constant. Extended use, wear, design, environment, and time are some of the factors that degrade the instrument performance and its accuracy. A calibration system is designed to assure the verification, maintenance, and validation of the instrument's desired accuracy and precision. Selection of appropriate inspection, measuring, and test equipment is an integral part of inspection planning, and success depends on such factors as measurements to be made and accuracy requirements. Included hardware items, such as instruments, fixtures, gauges, and templates, software for computer-aided inspections, and process instrumentation. Also included all testing equipment used in the development, manufacture, installation, and servicing of a product. Requirements and control of accuracy and precision of inspection, measuring, and testing equipment is an important element of a company's Quality System. In order to improve the consistency of these requirements, they are incorporated in specific standards that are often referenced contractually by the purchaser of the products and services. The requirements for the calibration laboratories are include requirements such as legal identity impartiality, premises, equipment, and technical competency of personnel, procedures, and selfassessment (Zurich Insurance Group Ltd, 2013). Personnel performing the calibration procedure required qualification and competence

documentation of it including requirements for education, qualification, technical knowledge (awareness), skills and experience. Awareness is defined as knowledge that something exists, or understanding of a situation or subject at the present time based on information or experience (Cambridge University Press, 2018). Qualification is defined as an official record showing that you have finished a training course or have the necessary skills (Cambridge University Press, 2018). Personnel competence is defined as knowledge+ experience= competence, this formula is generally considered to be an accurate reflection of what is required for an individual to be deemed 'competent'. The need for competent staff is prevalent in both hazardous locations and environment monitoring industries, and in fact forms the basis of many industry codes of practice and plant safety procedures. Canadian Standard Association (CSA) group believes that competent staff is just an necessary as compliant product and site processes, which is why we have developed a range of personnel certifications schemes that allow individuals to obtain a 'visible' mark of competence (CSA Group, 2018). The laboratory management has to ensure the competence of and authorize all who operate specific equipment, perform tests and/or calibrations, develop methods, evaluate and analysis results, state conformity, gives opinions and interpretations and sign test reports and calibration certificates. First the laboratory has to express the needs, for example, in team or individual job descriptions giving information on expertise and experience required; diploma required qualifications and training programmes required; access to knowledge database at networks; and other matters (human behaviour, spoken languages) (Eurolab, 2017).

#### **Rationale:**

The healthcare sector is one of the most important sectors, unfortunately in Sudan as a developing country it suffers from low quality of healthcare service. Recently many quality studies had been done in this sector in order to participate in improvement process.

As a sample for private sector hospitals, East Nile Hospital was chosen to be the case study of this research in a try to understand the relationship between the laboratory technicians (awareness, qualification and training) and performing calibration to laboratory equipments, so that the study can participate in indirect way in warranty of analytical results accuracy.

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#### **Objective of the study:**

To assess the laboratory technicians awareness, qualifications and training regarding applying laboratories equipments calibration in East Nile Hospital, Khartoum State- Sudan.

#### The hypothesis:

- There is a statistically significant relationship between knowing the importance of laboratory calibration and its application.
- The level of academic qualification for laboratory technicians contributes positively to the application of calibration.
- Training the technicians on the method of calibration application increases the application rate.

# **CHAPTER TWO Literature Review**

#### Chapter 2

#### Literature review

#### 2.1 Calibration definition:

It's an operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in second step, uses this information to establish a relation for obtaining a measurement result from an indication. A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty. Calibration should not be confused with adjustment of measuring system, often mistakenly called "self-calibration" nor with verification of calibration. Often, the first step alone in the above definition is perceived as being calibration (JCGM 200: 2012).

#### 2.2 Calibration importance

There are technical and legal reasons why calibration is performed. Four main reasons for having an instrument calibrated are, e.g. outlined in the Euramet handbook "metrology-in short" (2008):-

- 1. To establish and demonstrate metrological traceability.
- 2. To ensure readings from the instrument are consistent with other measurements.
- 3. To determine the accuracy of the instrument readings.
- 4. To establish the reliability of the instrument, i.e., that it can be trusted to guarantee interchangeability of parts, it is fundamental to establish

Traceability of measurements to national standards by means of calibration. In particular, suppliers and customers producing and assembling parts with other components must ensure valid measurement results and need to measure parts with the "same measure".

#### 2.3 Documentation of calibration results:

The results obtained by calibration are documented in calibration certificate or calibration report. The associated measurement uncertainty must be stated information gained with calibration may be expressed by a statement, a function, an additive or multiplicative correction of the indication, a calibration diagram, or calibration curve. For the latter ones, the international vocabulary of metrology gives the following definitions:

Calibration diagram: graphical expression of the relation between indication and corresponding measurement result. A calibration diagram is the strip of the plane defined by the axis of measurement result that represents the relation between an indication and a set of measured quantity values. A one-to-many relation is given, and the width of the strip for a given indication provides the instrumental measurement uncertainty. Alternative expressions of the relation include a calibration curve and associated measurement uncertainty, a calibration table, or a set of functions. This concept pertains to a calibration when the instrumental measurement uncertainty is large in comparison with the measurement uncertainties associated with the quantity values of measurement standards (JCGM 200: 2012).

Calibration curve: expression of the relation between indication and corresponding measured quantity value. A calibration curve expresses a one-to-one relation that doesn't supply a measurement result as it pears no information about the measurement uncertainly (JCGM 200:2012). While

calibration curve needs a separate statement for measurement uncertainly, a calibration diagram delivers a complete statement of the information obtained with calibration, including the measured value and the associated measurement uncertainty

#### 2.4 Calibration hierarchy:

To ensure metrological traceability made at a local level, such as an industrial internal calibration (also called in-house calibration), must be linked to a national standard by an unbroken chain of calibration, with each step explicitly supported by appropriate documentation (ILAC, 2013). The measurement uncertainty necessarily increases along the sequence of calibration, starting from the national level down to the local level. Therefore, the prerequisite of metrological traceability is the establishment of a calibration hierarchy as shown in figure (2.1). The calibration hierarchy is defined in the International Vocabulary of Metrology as follows.

Calibration hierarchy: sequence of calibrations from a reference to the final measuring system, where the outcome of each calibration depends on the outcome of the previous calibration. Measurement uncertainty necessarily increases along the sequence of calibrations. The elements of a calibration hierarchy are one or more measurement standards and measuring system operated according to measurement procedures. For this definition, the "reference" can be a definition of a measurement unit through its practical realization or measurement procedure or measurement standard. A comparison between two measurement standards may be viewed as calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards (JCGM, 2012).

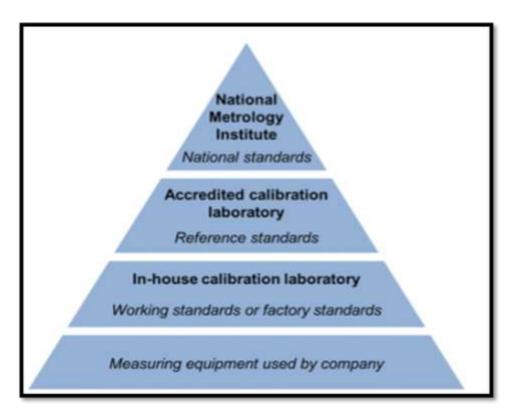


Figure (2.1): Illustration of calibration hierarchy (JCGM 200:2012)
2.5 Organizations performing calibration:

Different organizations perform calibrations (figure 2.1): national metrology institutes, accredited calibration laboratories (ILAC P10:01/2013). In each step of the calibration chain, measurement standards are used to calibrate measuring equipment of the next step. For example, an accredited laboratory can calibrate a company's working standards against a reference standard. Accredited laboratories must fulfill the requirements of (ISO 17025:2005). Above the national organizations, at the international level, decisions concerning the international system of units (SI) and the realization of the primary standards are taken by the Conference Generale des Poids et Mesures (CGPM, 2018). The development and maintenance of primary standards is coordinated by the Bureau International des Poids et Mesures (BIPM, 2018), which also organizes inter comparisons on the highest level.

The international laboratory accreditation cooperation (ILAC) promotes laboratory accreditation and the recognition of competent calibration and test facilities around the world.

#### 2.6 Calibration interval:

Calibrations must be repeated at appropriated intervals (ILAC G24:2007). A measurement instrument, for example, should be periodically recalibrated because changes in its characteristics can occur during its use and after some time. Recalibration on appropriate intervals ensured detection of these possible changes.

#### **2.7** Competence of the calibration laboratory:

competence (skill of calibration personnel)- means that the personnel performing the calibration procedure and signing the calibration certificates and test reports have been trained to perform this task and have been assessed as a competent at doing so by the equipment manufacturer or a testing authority such as national association of testing authorities-Australia (NATA). A laboratory that is audited and complies with ISO 17025 is assessed as competent to produce testing and calibration results and can issue a NATA endorsed test report to the customer (Celemetrix, 2013).

### 2.8 Minimum requirements for the operation of calibration laboratories:

The laboratory shall have competent personnel for operation of specific equipment, perform calibration, evaluate results and sign calibration certificates. Personnel performing specific tasks shall be qualified on the basis of appropriate education training and experience and skills, or as required. All technical personnel involved in calibration need to have at least a college in science or engineering and at least a minimum of three months training on a specific filed of calibration. The laboratory head need to have

minimum B.Sc. degree in science or engineering, and minimum of two years of experience in calibration. The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in calibrations (ENAO, 2011).

#### 2.9 Competency categories:

- Safe work practices conduct professional practice according to established protocol, safety guidelines, and existing legislation.
- Data collection and specimen procurement/ Receipt verify relevant data and ensure that appropriate specimens are procured according to established protocols.
- Analysis of specimens and validation of results analyze specimens and validates results using established protocols.
- Analytical techniques understand the principles and perform analytical techniques on specimens that originate from a variety of sources.
- Interpretation and reporting of results using scientific knowledge as the basis, interprets, communicates, and documents confidential data.
- Quality management practices and promotes the principles of quality management and the efficient utilization of resources.
- Critical thinking applies critical thinking skills to constructively solve problems.
- Applied investigation demonstrates research skills to investigate, evaluate or problem-solve.
- Resource management address workplace challenges by applying skills involving human resources, as well as skills in change management, materials management, financial management and information management.
- Communication and interaction interacts with clients/patients in a professional and competent manner, using effective listening, verbal and

written communication in dealings with laboratory colleagues, patients, clients and other health professionals. The medical laboratory professional projects a professional image and follows generally accepted practices regarding interactions with clients, patients and colleagues.

- Professionalism meets the legal and ethical requirements of practice and protects the patient's right to a reasonable standard of care. Professional responsibility encompasses scope of practice, accountability, and professional development (CSMLS, 2005).

#### 2.10 Previous studies:

A study done by Hamza (2015) in impact of implementing ISO/IEC 17025-2005 and its role in improving performance of laboratories of Sudanese standards and metrology organization laboratories of Sudanese standards and metrology organization (SSMO), the study found that: 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, work environment inside the laboratory is suitable and helps in correct testing results and provide reliable and high quality result, implementing ISO system enhance the performance and the quality of the performance, there is a system to identify training needs and staff training in Sudanese standards and metrology (SSMO).

Another study done by Fadul (2014) in impact of implementing ISO/IEC 17025 in the quality of Sudanese laboratories' service, the study found that the service provided by the national public health laboratory (NPHL) is low quality, there is no clear management system with known responsibilities inside 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.

A study done by Silva *et al.* (2013) in cause analysis for unsatisfactory results in proficiency testing activities: a case study of Brazilian calibration laboratories accredited under ISO/IEC 17025:2005, the study found that the main root causes observed by the laboratories were related to personnel, equipment, and calibration standard and methods. Some items that considered needing more careful investigation include authorization for equipment operation, use of updated calibration correction factors, protection of hardware and software, segregation of equipment out of

service, purchase of calibration services, and adequacy of environmental conditions.

# CHAPTER THREE Materials and Methods

#### Chapter 3

#### **Materials and Methods**

#### 3.1 Study design:

It is descriptive study.

#### 3.2 Study area:

The study was conducted at East Nile Hospital, Khartoum state, Sudan.

#### 3.3 Study population:

The study was conducted on laboratory technicians at East Nile Hospital.

#### 3.4 Sample size:

The targeted sample of this research was the total population of the laboratory technicians (36) but the actual sample number was (29) who had respond to the questionnaire.

#### 3.5 Study period:

The study was conducted during the interval from April 2018 to November 2018.

#### 3.6 Data collection methods:

Questionnaire (appendix) was used as the basic tool in this study. The quantitative survey consisted of questionnaire contain three hypothesis that cover the research questions which distributed for personnel included and limited to laboratory technicians.

The study depends on the questionnaire as a key to offer gathering information from the study population, as for questionnaire advantages including:

- 1.Can be applied to get information on the number of individuals.
- 2. The low cost and ease of application.
- 3. Ease of put the questionnaire questions

4. The questionnaire save responder time and give him a chance to think, this effect the reliability and validity of the answers, stability means that measures give the same results if used more than once under similar conditions.

Reliability is defined as the extent to which a questionnaire, test, observation or any measurement procedure produces the same results on repeated trials. Validity is defined as the extent to which the instrument measures what it purports to measure and calculate in many ways represents the easiest being the square root of the reliability coefficientValidity =  $\sqrt{\text{Reliability}}$ .

#### 3.7 Questionnaire design:

The following five steps of questionnaire design process were followed:

Firstly, the information was determined to be drawn from the research objectives, questions and hypothesis with consideration to who will be able to supply the information. Secondly, the structure and the length of the questionnaire were determined, the questionnaire was self-administrated and thus the gave clear instructions with direct and simple questions. Thirdly a draft questionnaire was prepared considering the content, format, layout ...ect. Fourthly, the questionnaire was pre-tested and revised. Fifthly, the questionnaire reliability and validity were assessed.

Based on the above mentioned steps, the questionnaire was divided into 3 sections:

Section 1: personnel awareness with laboratory equipment calibration which fulfilled by the laboratory technicians of East Nile Hospital.

Section 2: personnel qualifications which were also fulfilled by the laboratory technicians of East Nile Hospital.

Section 3: personnel training which were fulfilled by the laboratory technicians of East Nile Hospital.

#### 3.8 Data analysis:

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

#### 3.9 Ethical consideration:

Study permissions (appendices) were obtained from College of Graduate Studies- Sudan University of Science and Technology, then from management of Private Therapeutic Institutions to carrying out the study in East Nile Hospital.

# CHAPTER FOUR Results

#### **Chapter 4**

#### **Results**

#### 4.1 Reliability and validity of questionnaire:

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

Table (4.1): Reliability and validity of questionnaire

The hypothesis	Reliability coefficient	Validity coefficient
The first Hypothesis	0.67	0.82
The second Hypothesis	0.61	0.78
The third Hypothesis	0.69	0.83
All questionnaire	0.71	0.84

#### 4.2 Frequency of study subjects according to age:

Out of 29 subjects, 21 (72.4%) were in age group of (less than 30 years), 8 (27.6%) were in age group of (30-40 years) (table 4.2).

Table (4.2): Frequency of study subjects according to age groups

Age groups (years)	Frequency	Percentage (%)
Less than 30	21	72.4%
30-40	8	27.6%
Total	29	100%

#### 4.3 Frequency of study subjects according to education level:

Out of 29 subjects, 1 (3.4%) had median diploma, 12 (41.4%) had bachelor, 15 (51.7%) had master degree and 1(3.4%) had doctorate (table 4.3).

Table (4.3): Frequency of study subjects according to academic qualification

Level of education	Frequency	Percentage (%)
Median diploma	1	3.4%
Bachelor	12	41.4%
Master degree	15	51.7%
Doctorate	1	3.4%
Total	29	100.0%

#### 4.4 Frequency of study subjects according to the job title:

Out of 29 subjects, 7 (24.1%) were 2<sup>nd</sup> technician, 11 (37.9%) were first technician, 10 (34.5%) were specialist, 1 (3.5%) were consultant (table 4.4).

Table (4.4): Frequency of study subjects according to the job title

Job substantive	Frequency	Percentage (%)
2 <sup>nd</sup> technician	7	24.1%
First technician	11	37.9%
Specialist	10	34.5%
Consultant	1	3.5%
Total	29	100.0%

#### 4.5 Frequency of study subjects according to the years of experience:

Out of 29 subjects 21 (72.4%) had less than 5 years of experience, while 8 (27.6%) had 5 years and less than 10 years of experience (table 4.5).

Table (4.5): Frequency of study subjects according to the years of experience

Years of experience	Frequency	Percentage (%)
Less than 5years	21	72.4%
5 years and less than 10 years	8	27.6%
Total	29	100.0%

### **4.6 Demographic** variables and attitude independency test (first hypothesis):

Demographic variables and attitude independency test (first hypothesis) were shown in table (4.6).

Table (4.6): Demographic variables and attitude independency test (first hypothesis)

		Frequency and				
Items of	of questionnaire	re Percentage (%)				
in first	hypothesis	Strongly	Disagree	Neutral	Agree	Strongly
		disagree				agree
1 Lab	oratory	0	0	9	9	11
tech	nnicians know	0%	0%	31.03%	31.03	37.9%
wha	at is called				%	
cali	bration of					
labo	oratory					
equ	ipment					
2 Cal	ibration is	0	0	0	8	21
nec	essary to ensure	0%	0%	0%	27.6%	72.4%
the	validity of					
ana	lytical results					
3 Cal	ibration is	0	0	0	4	25
nec	essary to ensure	0%	0%	0%	13.8%	86.2%
the	accuracy of					
labo	oratory results					
4 Cal	ibration	0	0	0	10	19
con	tributes to early	0%	0%	0%	34.5%	65.5%

	detection	of					
	laboratory						
	malfunctions						
5	It is known	that	0	0	0	6	23
	calibration is o	one of	0%	0%	0%	20.7%	65.5%
	the interna	tional					
	standard						
	organization (	ISO)					

### 4.7 Demographic variables and knowledge independency test (first hypothesis):

Demographic variables and knowledge independency test (first hypothesis) were shown in table (4.7).

Table (4.7): Demographic variables and knowledge independency test (first hypothesis)

Items	s of questionnaire in	χ χ	Df	p-value	Median	Trend
first hypothesis						
1	Laboratory	0.276	2	0.87	4	Agree
	technicians know					
	what is called					
	calibration of					
	laboratory equipment					
2	Calibration is	5.82	1	0.016	5	Strongly
	necessary to ensure					Agree
	the validity of					
	analytical results					
3	Calibration is	15.21	1	0.000	5	Strongly
	necessary to ensure					Agree
	the accuracy of					
	laboratory results					
4	Calibration	2.79	1	0.095	5	Strongly
	contributes to early					Agree
	detection of					
	laboratory					
	malfunctions					
5	It is known that	13.72	2	0.001	5	Strongly

	calibration is one of					Agree
	the international					
	standard organization					
	(ISO)					
Нуро	thesis	73.54	2	0.000	4.57	Strongly
						Agree

# **4.8** Demographic variables and attitude independency test (second hypothesis):

Demographic variables and attitude independency test (second hypothesis) were shown in table (4.8.)

Table (4.8): Demographic variables and attitude independency test (second hypothesis)

			Frequency and						
Items	s of questionnaire in		Per	centage (%	5)				
secon	nd hypotheses	Strongly	Disagree	Neutral	Agree	Strongly			
		disagree				agree			
1	The level of	1	0	6	13	9			
	academic	3.4%	0%	20.7%	44.8%	31.0%			
	qualification is								
	directly								
	proportional to the								
	application of								
	calibration								
2	The level of	1	0	0	18	10			
	academic	3.4%	0%	0%	62.1%	34.5%			
	qualification								
	contributes to the								
	obligation to apply								
	calibration								
3	The level of	1	1	3	10	14			
	academic	3.4%	3.4%	10.3%	34.5%	48.3%			
	qualification								
	increases the degree								
	of compliance with								
	calibration systems								

4	The	level	of	0	1	0	10	18
	academic			0%	3.4%	0%	34.5%	62.1%
	qualifi	ication						
	increa	ses aware	ness					
	of the	need to a	pply					
	calibra	ation						

## 4.9 Demographic variables and knowledge independency test (second hypothesis):

Demographic variables and knowledge independency test (second hypothesis) were shown in table (4.9).

Table (4.9): Demographic variables and knowledge independency test (second hypothesis)

	Items of questionnaire in second hypothesis	χ χ	Df	p-value	Median	Trend
1	The level of academic qualification is directly proportional to the application of calibration	10.58	3	0.14	4	Agree
2	The level of academic qualification contributes to the obligation to apply calibration	14.96	2	0.001	4	Agree
3	The level of academic qualification increases the degree of compliance with	23.93	4	0.000	4	Agree

	calibration systems					
4	The level of academic qualification increases awareness of the need to apply calibration	14.96	2	0.001	5	Strongly Agree
Hypot	hesis	112.28	4	0.000	4.26	Strongly Agree

## 4.10 Demographic variables and attitude independency test (third hypothesis):

Demographic variables and attitude independency test (third hypothesis) were shown in table (4.10).

Table (4.10): Demographic variables and attitude independency test (third hypothesis)

Iten	ns of questionnaire			quency an centage (%		
	dly hypotheses	Strongly	Disagree	· · ·	Agree	Strongly
1	Training contributes	disagree 0	0	0	11	agree 18
	positively to the	0%	0%	0%	37.9%	62.1%
	application of calibration					
2	The content of the	0	4	8	13	4
	training course is	0%	13.8%	27.6%	44.8%	13.8%
	sufficient to actual apply					
3	The content of the	0	6	5	12	6
	calibration training	0%	20.7%	17.2%	41.4%	20.7%
	courses in keeping					
	with the					
	developments of the					
	laboratory					

	equipment					
4	The top management	2	5	8	10	4
	is interested in	6.9%	17.2%	27.6%	34.5%	13.8%
	organizing training					
	courses for					
	calibration					

## 4.11 Demographic variables and knowledge independency test (third hypothesis):

Demographic variables and knowledge independency test (third hypothesis) were shown in table (4.11).

Table (4.11): Demographic variables and knowledge independency test (third hypothesis)

	ns of questionnaire in	Chi-squire	Df	p-value	Median	Trend
seco	and hypotheses					
1	Training contributes	1.69	1	0.194	5	Strongly
	positively to the					Agree
	application of					
	calibration					
2	The content of the	7.55	3	0.56	4	Agree
	training course is					
	sufficient to actual					
	apply					
3	The content of the	4.2	3	0.23	4	Agree
	calibration training					
	courses in keeping with					
	the developments of the					
	laboratory equipment					
4	The top management is	7.034	4	0.13	3	Neutral
	interested in organizing					
	training courses for					
	calibration					
Нур	othesis	48.22	4	0.000	4	Agree

## **CHAPTER FIVE**

**Discussion, Conclusion and Recommendations** 

#### Chapter 5

#### Discussion, conclusion and recommendations

#### 5.1 Discussion

The present study found that there was statistically significant relationship between knowing the importance of laboratory calibration and its application and in favor of strongly agree. Also the study showed that there was statistically significant relationship between the level of academic qualification for laboratory technicians and performing calibration, and in favor of agrees. The study revealed that there was statistically significant relationship between training of the technicians on the method of calibration application and performing it, and in favor of agrees.

The results of testing the study hypotheses was correspond to the international standard ISO/IEC 17025 in clause 6 specifically in clause 6.2.2 (ISO/IEC 17025: 2005) with trend of strongly agree for academic qualification, and trend of agree for training.

A study was conducted in the laboratories of Sudanese standards and metrology organization (SSMO), it was opposed to the third hypothesis of the present study specifically in training programs which managed by the top management to ensure high quality results (Hamza, 2015).

A study done in quality of Sudanese laboratories service, it found that there was defect on the training method inside the national public health laboratory (NPHL) these findings were disagreed with the findings obtained from the present study (Fadul, 2014).

A case study of Brazilian calibration laboratories accredited under ISO/IEC 17025:2005 analyzed the cause of unsatisfactory results in proficiency testing activities, reached to three main causes, one of them was the personnel with the highest percentage of causes (23%), this result reflect the

direct importance of personnel in providing satisfactory and accurate results, the study addressed the education levels percentages which had found similar to present study were most of them has university education with percentage of 82% from the total population, this indicate that is education level is necessarily positively participate in providing satisfactory and accurate result, this point also has been proven by the present study

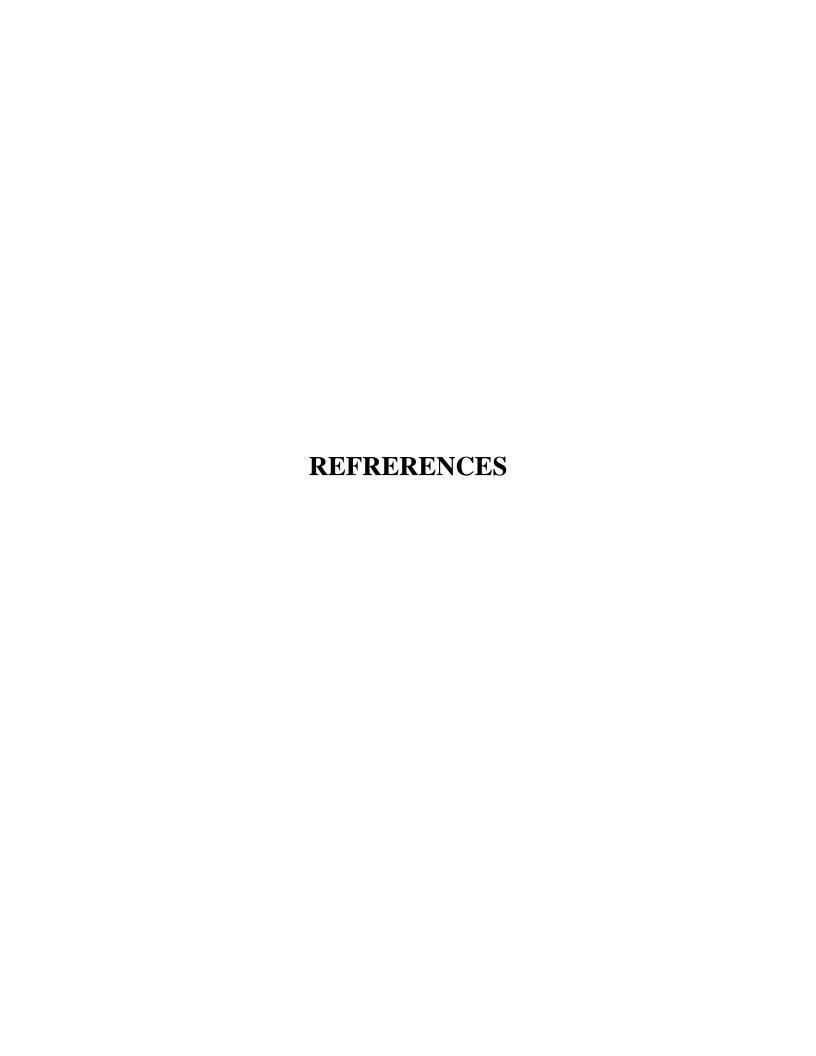
#### **5.2 Conclusion**

The study concluded that there was statistically significant relationship between knowing the importance of laboratory calibration and its application. There was statistically significant relationship between the level of academic qualification for laboratory technicians and performing calibration. There was statistically significant relationship between training of the technicians on the method of calibration application and performing it.

### **5.3** The recommendations

Based on the results the study recommended that:

Further study should be done in observation design.

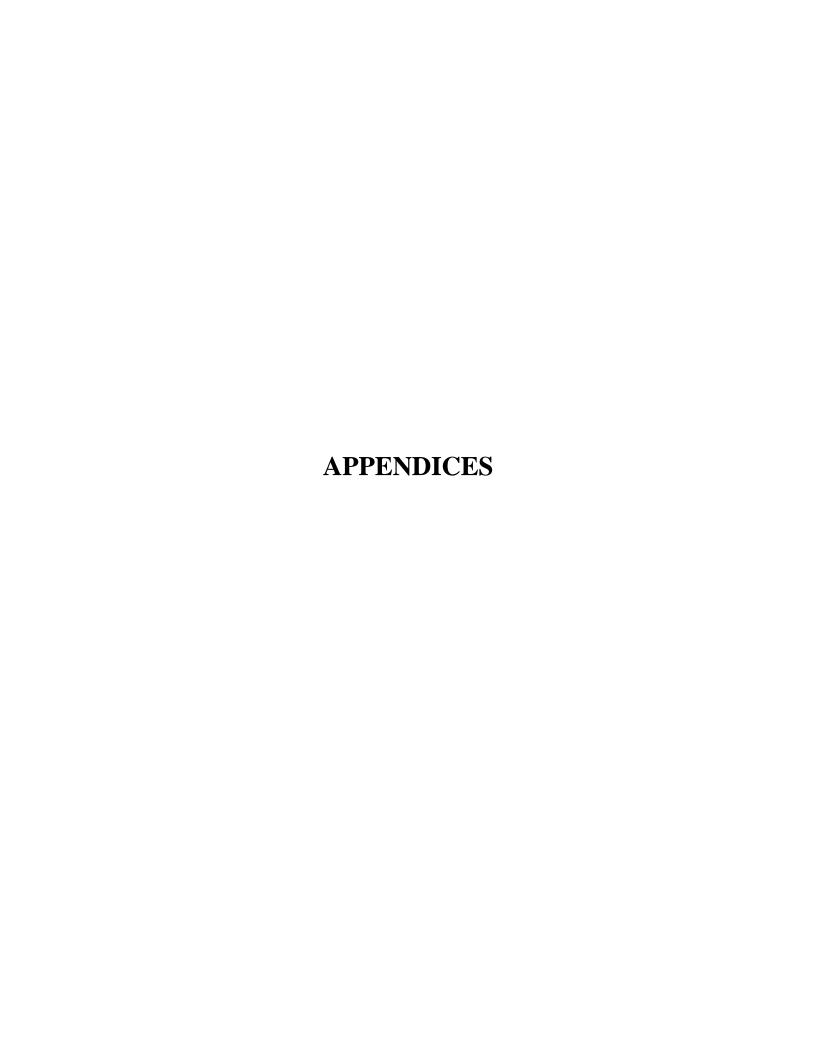


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#### **Appendices**

### Appendix (1):



## بسم الله الرحمن الرحيم جامعه السودان للعلوم و التكنولوجيا كليه الدراسات العليا



الاخ/ الاخت ......المحترم/المحترمة

# السلام عليكم ورحمه الله وبركاته الموضوع: استبانة

تقوم الباحثة بإعداد بحث علمي كأحد متطلبات الحصول على درجة الماجستير في اداره الجودة الشاملة و الامتياز بعنوان:

# (تأثير الموظفين على تطبيق المعايرة على اجهزة المعامل في مستشفى شرق النيل ، ولاية الخرطوم- السودان)

و عليه نرجو التكرم بإبداء رأيكم على عبارات الاستبانة علماً بان البيانات المتحصل عليها سوف تستخدم لغرض البحث العلمي فقط و ستعامل بسريه تامة.

و لكم خالص شكري و تقديري""""

الباحثة: الاء عاطف عبد الرحمن

		صية:	اولاً: البيانات الشخ
	ابة المناسبة:	امام الأج $()$	الرجاء وضع علاما
			1. العمر:
	40-30 سنة		اقل من 30 سنة
	من 50 سنه	<u> </u>	50-41 سنة
			2- المؤهل العلمي:
	بكالوريوس		دبلوم وسيط
	دكتوراه		ماجستير
			اخرى
			المسمى الوظيفي:
	تقني ثاني		نقني اول
	استشاري		اخصائي
			اخرى
			سنوات الخبرة:
و اقل من 10 سنوات	سنوات		اقل من 5 سنوات
ﻪ ﻓﺄﮐـﺜﺮ	15 سن	ن 15 سنوات	10 سنوات و اقل مر

### ثانياً: قياس متغيرات الدراسة:-

الرجاء وضع علامة  $(\sqrt{})$  امام مستوى الموافقة المناسب:

### الفرضية الاولى:-

### توجد علاقه ذات دلالة احصائية بين معرفة اهمية معايرة الاجهزة المعملية و تطبيقها :-

لا اوافق بشدة	لا اوافق	محايد	اوافق	اوافق بشدة	العبارة	الرقم
					تقنيو المعامل يعرفون ما	1
					يسمي (معايرة الاجهزة	
					المعملية)	
					المعايرة ضرورية لضمان	2
					صحه النتائج التحليلية	
					المعايرة ضرورية لضمان	3
					دقة النتائج المعملية	
					المعايرة تساهم في الكشف	4
					المبكر عن اعطال الاجهزة	
					المعملية	
					من المعروف ان المعايرة	5
					واحدة من متطلبات منظمة	
					المعايير الدولية (ISO)	

الفرضية الثانية: -مستوى التأهيل الاكاديمي لتقنيي المعمل يساهم ايجابياً في تطبيق المعايرة: -

لا اوافق بشدة	لا اوافق	محايد	اوافق	اوافق بشدة	العبارة	الرقم
					مستوي التأهيك	1
					الاكاديمي يتناسب	
					طرديا مع تطبيق	
					المعايرة	
					يساهم مستوى	2
					التأهيل الاكاديمي في	
					الالتـــزام بتطبيـــق	
					المعايرة	
					مستوى التأهيك	3
					الاكاديمي يزيد من	
					درجة الالتزام بنظم	
					المعايرة	
					مستوى التأهيك	4
					الاكاديمي يزيد من	
					الــوعي بضــرورة	
					تطبيق المعايرة	

الفرضية الثالثة: -تدريب التقنيين على طريقة تطبيق المعايرة يزيد من نسبه تطبيقها: -

لا اوافق بشدة	لا اوافق	محايد	اوافق	اوافق بشدة	العبارة	الرقم
					يساهم التدريب	1
					ايجابياً في تطبيق	
					المعايرة	
					محتوى الدورات	2
					التدريبية كافي	
					لتطبيقها فعلياً	
					محتوى الدورات	3
					التدريبية الخاصة	
					بالمعايرة مواكبه	
					لتطورات الاجهزة	
					المعملية	
					الادارة العليا تهتم	4
					بتنظيم الدورات	
					التدريبية الخاصة	
					بالمعايرة	



### Sudan University of Science and Technology College of Graduate Studies



Mr./Mrs	
---------	--

#### **The subject: Questionnaire**

The researcher prepares scientific research as one of the requirements for obtaining a master's degree in total quality management and excellence entitled:

(The Impact of Personnel on Applying the Calibration to Laboratory Equipments in East Nile Hospital, Khartoum State- Sudan)

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

.

Researcher: Alla Atif Abdelrahman

### Firstly: personal information

Please put $()$ in the appropriate answer square which suit for you:					
1. Age (years):					
a. Less than 30	c. 41 to 50				
b. 30 to 40	d. more than 50				
2. Academic qualification:					
a. Median diploma	c. Master				
b. Bachelors	d. Doctorate				
3. Job title:					
a. Second technician c	. Specialist				
b. First technician d	. Consultant				
e. Else					
4. Years of experience:					
a. Less than 5 years	c. 10 and less than 15	year			
b. 5 and less than 10 years	d. 15 years and more	e			

### **Secondly: Measuring the study variables**

Please put  $(\sqrt{})$  mark in the answer square that suits your opinion:

### The first hypothesis:

# There is a statistically significant relationship between knowing the importance of laboratory calibration and it is application

No.	Statement	Strongly	Agree	Natural	Disagree	Strongly
		Agree				disagree
1	Laboratory					
	technicians know					
	what is called					
	calibration of					
	laboratory					
	equipment					
2	Calibration is					
	necessary to					
	ensure the					
	validity of					
	analytical results					
3	Calibration is					
	necessary to					
	ensure the					
	accuracy of					
	laboratory results					
4	Calibration					
	contributes to					
	early detection of					
	laboratory					
	malfunctions					
5	It is known that					
	calibration is one					
	of the					
	international					
	standard					
	organization					
	(ISO)					

### **Second hypothesis:**

# The level of academic qualification for laboratory technicians contributes positively to the application of calibration

No.	Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	The level of academic qualification is directly proportional to the application of calibration	ugiec				disagree
2	The level of academic qualification contributes to the obligation to apply calibration					
3	The level of academic qualification increases the degree of compliance with calibration systems					
4	The level of academic qualification increases awareness of the need to apply calibration					

### The third hypothesis:

# Training the technicians on the method of calibration application increases the application rate.

No.	Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	Training contributes					
	positively to the					
	application of calibration					
2	The content of the					
	training course is					
	sufficient to					
	actual apply					
3	The content of the					
	calibration					
	training courses					
	in keeping with					
	the developments					
	of the laboratory					
	equipment					
4	The top					
	management is					
	interested in					
	organizing					
	training courses					
	for calibration					