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

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Abstract: *The study aimed to determine the impact of personnel (awareness, academic qualification and training) on applying the calibration to laboratory equipments. The study was conducted at East Nile Hospital 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 indicated that there was statistically significant relationship between the awareness of the laboratory equipment calibration, the level of academic qualification and the training of the laboratory technician on the performing of calibration.*

Keywords— Impact; Personnel; Calibration; Laboratory Equipment

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 are hardware items, such as instruments, fixtures, gauges, and templates, software for computer-aided inspections, and process instrumentation. Also included is 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 self-assessment [1]. Personnel performing the calibration procedure required qualification and competence and documentation of it including requirements for education, qualification, training, 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 [2]. Qualification is defined as an official record showing that you have finished a training course or have the necessary skills [2]. 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 [3]. 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) [4] . The main objectives of study were to detect the impact of personnel on applying the calibration to laboratory equipments in East Nile Hospital, Khartoum State- Sudan, to identify the relationship between personnel's awareness of the calibration importance and performing it, to identify the relationship between personnel's qualifications and performing calibration and to identify the relationship between personnel's training and performing calibration.

2. MATERIALS AND METHODS

2.1 Study design:
It is descriptive study.

2.2 Study area:
The study was conducted at East Nile Hospital, Khartoum state, Sudan.

2.3 Study population:
The study was conducted on laboratory technicians at East Nile Hospital.

2.4 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.

2.5 Study period:
The study was conducted during the interval from April 2018 to November 2018.

3. METHODS

3.1 Data collection methods:
Questionnaire 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 coefficient.

$$Validity = \sqrt{Reliability}$$

3.2 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.

3.4 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.

3.5 Ethical considerations
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.

4. RESULTS

Reliability and validity of questionnaire were shown in table (1). 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 2). Out of 29 subjects, 1 (3.4%) had median diploma, 12 (41.4%) had bachelor, 15 (51.7%) had master degree and 1(304%) had doctorate (table 3). Out of 29 subjects, 7 (24.1%) were 2nd technician, 11 (37.9%) were first technician, 10 (34.5%) were specialist, 1 (3.5%) were consultant (table 4). 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 5). Demographic variables and attitude independency test (first hypothesis) were shown in table (6). Demographic variables and knowledge independency test (first hypothesis) were shown in table (7). Demographic variables and attitude

independency test (second hypothesis) were shown in table (8). Demographic variables and knowledge independency test (second hypothesis) were shown in table (9). Demographic variables and attitude independency test (third hypothesis) were shown in table (10). Demographic variables and knowledge independency test (third hypothesis) were shown in table (11).

Table 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

Table 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%

Table 3: Frequency of study subjects according to education level

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%

Table 4: Frequency of study subjects according to the job title

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

Table 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 than10 years	8	27.6%
Total	29	100.0%

Table 6: Demographic variables and attitude independency test (first hypothesis)

Items of questionnaire in first hypothesis	Frequency and Percentage (%)				
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1 Laboratory technicians know what is called calibration of laboratory equipment	0 0%	0 0%	9 31.03%	9 31.03%	11 37.9%
2 Calibration is necessary to ensure the validity of analytical results	0 0%	0 0%	0 0%	8 27.6%	21 72.4%
3 Calibration is necessary to ensure the accuracy of laboratory results	0 0%	0 0%	0 0%	4 13.8%	25 86.2%
4 Calibration contributes to early detection of laboratory malfunctions	0 0%	0 0%	0 0%	10 34.5%	19 65.5%
5 It is known that calibration is one of the international standard organization (ISO)	0 0%	0 0%	0 0%	6 20.7%	19 65.5%

Table 7: Demographic variables and knowledge independency test (first hypothesis)

Items of questionnaire in first hypothesis	χ^2	Df	p-value	Median	Trend
1 Laboratory technicians know what is called calibration of laboratory equipment	0.276	2	0.87	4	Agree
2 Calibration is necessary to ensure the validity of analytical results	5.82	1	0.016	5	Strongly Agree
3 Calibration is necessary to ensure the accuracy of laboratory results	15.21	1	0.000	5	Strongly Agree
4 Calibration contributes to early detection of laboratory malfunctions	2.79	1	0.095	5	Strongly Agree
5 It is known that calibration is one of the international standard organization (ISO)	13.72	2	0.001	5	Strongly Agree
Hypothesis	73.54	2	0.000	4.57	Strongly Agree

Table 8: Demographic variables and attitude independency test (second hypothesis)

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

Table 9: Demographic variables and knowledge independency test (second hypothesis)

	Items of questionnaire in second hypothesis	χ^2	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 calibration systems	23.93	4	0.000	4	Agree
4	The level of academic qualification increases awareness of the need to apply calibration	14.96	2	0.001	5	Strongly Agree
	Hypothesis	112.28	4	0.000	4.26	Strongly Agree

Table 10: Demographic variables and attitude independency test (third hypothesis)

Items of questionnaire thirdly hypotheses		Frequency and Percentage (%)				
		Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1	Training contributes positively to the application of calibration	0 0%	0 0%	0 0%	11 37.9%	18 62.1%
2	The content of the training course is sufficient to actual apply	0 0%	4 13.8%	8 27.6%	13 44.8%	4 13.8%
3	The content of the calibration training courses in keeping with the developments of the laboratory equipment	0 0%	6 20.7%	5 17.2%	12 41.4%	6 20.7%
4	The top management is interested in organizing training courses for calibration	2 6.9%	5 17.2%	8 27.6%	10 34.5%	4 13.8%

Table 11: Demographic variables and knowledge independency test (third hypothesis)

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

5. DISCUSSION

The study showed that most of the laboratory technicians were in age group of less than 30 years with percentage of (72.4%). The majority of the laboratory technicians had academic qualifications of bachelor with percentage (41.4%) and master degree with percentage (51.7%). There was a variety in job title. What should be noticed that most of the laboratory technicians had years of experience less than 5 years with percentage of (72.4%).

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 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) [5].

A study was conducted in the laboratories of Sudanese standards and metrology organization (SSMO), it was opposed to the third hypothesis of this study specifically in training programs which managed by the top management to ensure high quality results [6].

A study done in quality of Sudanese laboratories service, as well as my study, it found that there was defect on the

training method inside the national public health laboratory (NPHL) [7].

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 [8].

6. 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 the technicians on the method of calibration application and performing it.

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