The Impact of Implementation of ISO/ IEC 17025:2005 on Laboratories Performance in Central Laboratory, Khartoum Refinery Company Ltd, Khartoum State- Sudan

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Abstract: This cross-sectional study was conducted in Central Laboratory, Khartoum Refinery Company Ltd, Khartoum State-Sudan to determine the impact of implementation of ISO/ IEC 17025:2005 on laboratories performance during the period from May 2019 to December 2019. A questionnaire was used as data collection tool to achieve research objective. Seventy three questionnaires were distributed to all central laboratory staff in the Khartoum Refinery, (65) of the laboratory staff had responded with percentage of (89.0%), while (8) had not respond. The data were analyzed using Statistical Package for Social Sciences (SPSS). The methodology used was the descriptive correlation. The study showed that there was a relationship between the work accommodation and environmental condition and laboratories performance at Khartoum Refinery Company. The study reflected that there was a relationship between the implementation of documented controlled information system and laboratories performance. In addition to, there was a relationship between the continuous improvement and laboratories performance. The study revealed that there was a relationship between meeting the technical requirements of ISO/IEC 17025:2005 and laboratories performance. The study indicated that implementation of ISO/IEC17025:2005 have impact on laboratories performance in Central Laboratory, Khartoum Refinery Company Ltd, Khartoum State- Sudan.

Keywords- Impact; ISO/ IEC 17025:2005; Laboratories Performance; Khartoum Refinery Company Ltd

1. INTRODUCTION

An ISO/IEC 17025 general requirement for the competence of testing and calibration laboratories is the main ISO standard used by testing and calibration laboratories. In most countries, ISO/IEC 17025 is the standard for which most laboratories must hold accreditation in order to be deemed technically competent. In many cases, suppliers and regulatory authorities will not accept test or calibration results from a laboratory that is not accredited. Originally known as ISO/IEC Guide 25, ISO/IEC 17025 was initially issued by the International Organization for Standardization in 1999. There are many commonalities with the ISO 9000 standard, but ISO/IEC 17025 is more specific in requirements for competence and applies directly to those organizations that produce testing and calibration results and is based on somewhat more technical principles [1]. Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results [2]. It is also the basis for accreditation from an accreditation body. There have been three releases; in 1999, 2005 and 2017. The most significant changes between the 1999 and 2005 release were a greater emphasis on the responsibilities of senior management, explicit requirements for continual improvement of the management system itself, and communication with the customer. It also aligned more closely with the 2000 version of ISO 9001 [3].

The 2005 version of the standard comprises five elements; normative references, terms and definitions, management requirements and technical requirements. Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements include factors that determine the correctness and reliability of the tests and calibrations performed in the laboratory. The version of ISO/IEC 17025 has modified this structure to be scope, normative references, terms and definitions, general requirements, structural requirements, resource requirements, process requirements and management system requirements. General requirements and structural requirements are related to the organization of the laboratory itself. Structure requirements cite those issues related to the people, plant, and other organizations used by the laboratory to produce its technically valid results. Process requirements are the heart of this version of the standard in describing the activities to ensure that results are based on accepted science and aimed at technical validity. Management system requirements are those steps taken by the organization to give itself quality management system tools to support the work of its people in the production of technically valid results [3].

2. Materials and methods

2.1 Study design:

It was a descriptive cross sectional study.

2.2 Study area:

The study was conducted at Khartoum Refinery Company, Central Laboratory, Khartoum state, Sudan.

2.2.1 Khartoum Refinery Company and Central Laboratory (KRC):

Khartoum Refinery Company is a modern refinery of oil and Gas Industry, the main business of company is to refine the Crude oil. The company is a joint venture between Sudan and China, investment by china National Petroleum Corporation and Sudan Ministry of Petroleum on 50% basis. The refinery units consist of (Crude distillation Unit, Residue Catalytic Delayed Coking Unit, Continuous Catalytic Reforming Unit, Gasoline / Diesel Hydro Treating Unit, storage tanks for crude oil, storage tanks for products, utilities such as water treatment, air separation, power station, steam production, industrial waste water treatment and central laboratory for hydrocarbon and water analysis. All the refinery units are controlled automatically by a very advance control system. The production capacity for Khartoum Refinery Company is (100.000bb/Day). The company structure consists of five divisions: administration, production, maintenance, technical and utilities). Every division consists of many departments. The central laboratory is a department in technical division. The central laboratory structure consists of five sections: quality, instrument, water analysis, classic chemistry and physical chemistry testing. The laboratory provides services of testing materials such as finish products, under process crude oil and refinery gases. Most of testing follows American Society for Testing Materials methods (ASTM). Also the Laboratory provide support service by testing the oxygen and explosive gases level in confine spaces area as a safety issues during maintenance and overall period. The manpower of central laboratory is 73 employees, classified to: one department, five sections head, chemists and technicians. The central laboratory staff is mainly divided into two parts (Day time staff which working for 8 hours/ day and shift staff which working 12 hours/ day). The laboratory is certified in ISO 9001:2015 and ISO 17025:2005. The central laboratory ensures that policies, procedures and instructions are implemented to ensure the accuracy, reliability of the results (Khartoum Refinery Company, 2005) [4].

2.3 Study population:

The study was conducted on all central laboratory staff, targeted to all staff (department manager, section heads, engineers, chemists and technicians) at Khartoum Refinery Company, Khartoum state, Sudan.

2.4 Sample size:

The targeted sample of this research was the total population of the laboratory staff (73) but the actual sample number was (65) who had responded to fulfill the questionnaire.

2.5 Study period:

The study was conducted during the interval from May 2019 to December 2019.

3. Methods

3.1 Data collection methods:

Questionnaire was used as the basic tool in this study. The quantitative survey consisted of questionnaire contained four hypotheses that covered the research questions which were distributed to all laboratory staff. The study depends on the questionnaire as a key to offer gathering information from the study population, as for questionnaire advantages including: can be applied to get information on the number of individuals, the low cost and ease of application, ease of put the questionnaire questions and 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 =
$$\sqrt{\text{Reliability}}$$

Where reliability was calculated using Cranach's alpha equation shown below:

Reliability coefficient =

$$n = 1 - \text{Total variations questions}$$

N-1 variation college grades
Validity =
$$\sqrt{\frac{n}{N-1} * \frac{1 - \text{Total variations questions}}{\text{variation tatal grades}}}$$

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... etc. 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 and designed to evaluate the four hypotheses below:

1- First hypothesis: There is a relationship between the work accommodation and environmental condition and laboratories performance at Khartoum Refinery Company.

2- Second hypothesis: There is a relationship between the implementation of documented controlled information system and laboratories performance at Khartoum Refinery Company.

3- Third hypothesis: There is a relationship between the continuous improvement and laboratories performance at Khartoum Refinery Company.

4- Fourth hypothesis: There is a relationship between meeting the technical requirements of ISO/IEC 17025:2005 and laboratories performance.

3.3 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.

3.4 Ethical consideration:

Study permissions were obtained from College of Graduate Studies- Sudan University of Science and Technology, then from management of Khartoum Refinery Company. Also, permission was taken from all individuals before being included in the study. Each individual was informed on the nature of the study.

4. Results

he study was conducted on 65 employees at central laboratory in Khartoum Refinery Company. The study indicated that most of the staff (93.8%) were males, the study illustrated that most of the laboratory staff ages (49.2%) were in group of 25 to 35 years old, most of the laboratory staff (60.0%) were having academic level of diploma, most of the laboratory staff (27.7%) had experience of less than five years, most of the laboratory staff (83.1%) were under job title technician and most of the laboratory staff (38.5%) were have a level of very good training on ISO 17025:2005 requirement. Reliability and validity of questionnaire were shown in table (1). Table (2) showed: There are procedures to protect samples under testing from contaminated by surrounding environment or any other samples or solutions by the strongly agree (41.5%) and agree by (43.1%) and neutral by (9.2%) and disagree by (1.5%) and strongly disagree by (4.6%). There are procedures to monitor the general environmental situation inside the laboratory by the strongly agree (38.5%) and agree by (36.9%) and neutral by (9.2%) and disagree by (9.2%) and strongly disagree by (6.2%). There are control procedures for the environmental condition such as humidity, radiation, dust, noise level, temperature and lighting intensity by the strongly agree (18.5%) and agree by (35.4%) and neutral by (27.7%) and disagree by (12.3%) and strongly disagree by (6.2%). Analysis and testing shall be discontinued if the laboratory's environmental condition does not match the environmental condition required by the ASTM standard by the strongly agree (12.3%) and agree by (32.3%) and neutral by (21.5%) and disagree by (23.1%) and strongly disagree by (10.8%). Employees perform analysis in an excellent environment in terms of lighting, ventilation, humidity and temperature by the strongly agree (16.9%) and agree by (55.4%) and neutral by (9.2%) and disagree by (9.2%) and strongly disagree by (9.2%). Laboratory management provides all analysis needs of materials, devices, calibration

solutions and any resources for analysis in the analysis sites by the strongly agree (53.8%) and agree by (36.9%) and neutral by (1.5%) and disagree by (3.1%) and strongly disagree by (4.6%). Laboratory analysis equipment is calibrated periodically and continuously by external calibration bodies by the strongly agree (44.6%) and agree by (24.6%) and neutral by (10.8%) and disagree by (12.3%)and strongly disagree by (7.7%). The validity and efficiency of analytical instruments are tested with standard samples before the analysis begins by the strongly agree (49.2%) and agree by (36.9%) and neutral by (9.2%) and disagree by (3.1%) and strongly disagree by (1.5%). The results of table (3) interpreted as follows: the value of Chi-square calculated to signify the differences between "There are procedures to protect samples under testing from contaminated by surrounding environment or any other samples or solutions" was (54.92) with p.value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "There are procedures to monitor the general environmental situation inside the laboratory" was (34.15) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chisquare calculated to signify the differences between "There are control procedures for the environmental condition such as humidity, radiation, dust, noise level, temperature and lighting intensity" was (17.84) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Analysis and testing shall be discontinued if the laboratory's environmental condition does not match the environmental condition required by the ASTM standard" was (10.00) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Employees perform analysis in an excellent environment in terms of lighting, ventilation, humidity and temperature" was (52.30) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Laboratory management provides all analysis needs of materials, devices, calibration solutions and any resources for analysis in the analysis sites" was (74.61) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Laboratory analysis equipment is calibrated periodically and continuously by external calibration bodies" was (30.00) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Validity and efficiency of analytical instruments are tested

with standard samples before the analysis begins" was (61.23) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. Table (4) showed: The document control system clearly identify the difficulty of implementing some of the procedures described in the document by the strongly agree (43.1%) and agree by (24.6%) and neutral by (27.7%) and disagree by (3.1%) and strongly disagree by (1.5%). The application of documentation and control system helps to facilitate and understand the work instructions by the strongly agree (52.3%) and agree by (33.8%) and neutral by (6.2%) and disagree by (6.2%) and strongly disagree by (1.5%). The application of the documentation system sometimes complicates work procedures by the strongly agree (4.6%) and agree by (15.4%) and neutral by (29.2%) and disagree by (32.3%) and strongly disagree by (18.5%). Controlling the procedures and instructions of the work through documentation reduces the work pressure through the clarity of responsibilities and authorities for employees by the strongly agree (60.0%) and agree by (21.5%) and neutral by (12.3%) and disagree by (3.1%) and strongly disagree by (3.1%). All procedures related to laboratory activities are available, understood and clearly documented to the employees by the strongly agree (40.0%) and agree by (26.2%) and neutral by (16.9%) and disagree by (15.4%) and strongly disagree by (1.5%). Documents are reviewed, updated and controlled periodically by the strongly agree (52.3%) and agree by (18.5%) and neutral by (20.0%) and disagree by (6.2%) and strongly disagree by (3.1%). There is documentation and archiving of external source documents and procedures (such as calibration procedures, standard samples, maintenance procedures and spare parts for devices) by the strongly agree (49.2%) and agree by (27.7%) and neutral by (18.5%) and disagree by (%3.1) and strongly disagree by (1.5%). When the document expires, it is canceled immediately and another replacement document is issued by the strongly agree (50.8%) and agree by (23.1%) and neutral by (23.1%) and disagree by (3.1%) and strongly disagree by (0.0%). The laboratory management maintains all documents related to all devices in addition to the procedures of the periodic maintenance plan by the strongly agree (53.8%) and agree by (18.5%) and neutral by (23.1%) and disagree by (3.1%) and strongly disagree by (1.5%). The results of table (5) interpreted as follows: The value of Chi-square calculated to signify the differences between "The document control system clearly identify the difficulty of implementing some of the procedures described in the document" was (40.30) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The application of documentation and control system helps to facilitate and understand the work instructions" was (63.69) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences.

The value of Chi-square calculated to signify the differences between "The application of the documentation system sometimes complicates work procedures" was (16.15) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The Controlling the procedures and instructions of the work through documentation reduces the work pressure through the clarity of responsibilities and authorities for employees" was (72.61) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The all procedures related to laboratory activities are available, understood and clearly documented to the employees" was (26.30) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chisquare calculated to signify the differences between "The Documents are reviewed, updated and controlled periodically" was (49.53) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chisquare calculated to signify the differences between "There is documentation and archiving of external source documents and procedures (such as calibration procedures, standard samples, maintenance procedures and spare parts for devices)" was (50.15) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chisquare calculated to signify the differences between the "When the document expires, it is canceled immediately and another replacement document is issued" was (29.95) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory management maintains all documents related to all devices in addition to the procedures of the periodic maintenance plan" was (58.00) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. Table (6) showed: The laboratory management maintains clear and effective policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives by the strongly agree (15.4%) and agree by (44.6%) and neutral by (9.2%) and disagree by (23.1%) and strongly disagree by (7.7%). There is a certain procedures and effective decision making to corrective actions in cases of errors in the analysis by the strongly agree (32.3%) and agree by (41.5%) and neutral by (9.2%) and disagree by (13.8%) and strongly disagree by (3.1%). When an error occurs in the analysis, there is a procedures lead to the root causes of the error by the strongly agree (27.7%) and agree by (38.5%) and neutral by (16.9%) and disagree by (15.4%)and strongly disagree by (1.5%). There is a clear

methodology to monitor the effectiveness of the corrective action to ensure that errors are fundamentally resolved at the planned time by the strongly agree (29.2%) and agree by (29.2%) and neutral by (29.2%) and disagree by (10.8%) and strongly disagree by (1.5%). Laboratory management takes a series of preventive actions to ensure that there are no errors during the analysis process, through analysis and assessment of the risks that may accompany the analysis by the strongly agree (32.3%) and agree by (30.8%) and neutral by (15.4%)and disagree by (18.5%) and strongly disagree by (3.1%). Laboratory management conducts an assessment of preventive and corrective actions to ensure their effectiveness in preventing future errors by the strongly agree (35.4%) and agree by (26.2%) and neutral by (21.5%)and disagree by (13.8%) and strongly disagree by (3.1%). Proactive preventive procedures and measures are in place to discover opportunities for continuous improvement by the strongly agree (21.5%) and agree by (32.3%) and neutral by (20.0%) and disagree by (20.0%) and strongly disagree by (6.2%). The results of table (7) interpreted as follows: The value of Chi-square calculated to signify the differences between "The laboratory management maintains clear and effective policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives" was (29.38) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "There is a certain procedures and effective decision making to corrective actions in cases of errors in the analysis" was (34.30) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between the "When an error occurs in the analysis, there is a procedures lead to the root causes of the error" was (25.07) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "There is a clear methodology to monitor the effectiveness of the corrective action to ensure that errors are fundamentally resolved at the planned time" was (22.15) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory management takes a series of preventive actions to ensure that there are no errors during the analysis process, through analysis and assessment of the risks that may accompany the analysis" was (18.76) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory management conducts an assessment of preventive and corrective actions to ensure their effectiveness in preventing future errors" was (19.53) with p. value (0.000) which was

lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chisquare calculated to signify the differences between "The proactive preventive procedures and measures are in place to discover opportunities for continuous improvement" was (11.23) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. Table (8) showed: Laboratory management provides all conditions that lead to accurate and reliable results by the strongly agree (38.5%) and agree by (33.8%) and neutral by (20.0%) and disagree by (4.6%) and strongly disagree by (3.1%). The laboratory management monitors and controls the working conditions and provide suitable environment for the employees, samples and devices by the strongly agree (%29.2) and agree by (33.8%) and neutral by (20.0%) and disagree by (12.3%) and strongly disagree by (4.6%). Every individual working in the lab knows his/ her duties (responsibilities and authorities) by obtaining a copy of the job description by the strongly agree (44.6%) and agree by (27.7%) and neutral by (18.5%) and disagree by (4.6%) and strongly disagree by (4.6%). The job description clearly describes the responsibilities and authorities powers by the strongly agree (44.6%) and agree by (18.5%) and neutral by (23.1%) and disagree by (7.7%)and strongly disagree by (6.2%). There is a procedure in the laboratory to determine the training needs of all employees by the strongly agree (15.4%) and agree by (16.9%) and neutral by (19.6%) and disagree by (27.7%) and strongly disagree by (23.1%). The laboratory has a clear training plan to raise the technical capabilities of workers by the strongly agree (13.8%) and agree by (15.4%) and neutral by (24.6%)and disagree by (21.5%) and strongly disagree by (24.6%). The laboratory management supports the training program and the development of personal skills of the laboratories and provide them to staff by the strongly agree (13.8%) and agree by (30.8%) and neutral by (10.8%) and disagree by (18.5%) and strongly disagree by (26.2%). Laboratory management determines mechanisms to evaluate factors that affect the validity of the results, for example, calibration of instruments, the samples, the experience of the analyst person, the environmental conditions ... (etc.) by the strongly agree (43.1%) and agree by (21.5%) and neutral by (24.6%) and disagree by (6.2%) and strongly disagree by (4.6%). The laboratory management controls all data related to the analysis (results- calibration data- and others) by the strongly agree (49.2%) and agree by (29.2%) and neutral by (20.0%) and disagree by (1.5%) and strongly disagree by (0.0%). Instruments are calibrated on both (Software and Hardware) and completely isolated so that the settings are not changed by unauthorized person the one by the strongly agree (29.2%) and agree by (33.8%) and neutral by (27.7%) and disagree by (7.7%) and strongly disagree by (1.5%). The results of table (9) interpreted as follows: The value of Chisquare calculated to signify the differences between "The laboratory management provides all conditions that lead to accurate and reliable results" was (34.30) with p. value

(0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory management monitors and controls the working conditions and provide suitable environment for the employees, samples and devices" was (18.61) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Every individual working in the lab knows his/ her duties (responsibilities and authorities) by obtaining a copy of the job description" was (37.07) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The job description clearly describes the responsibilities and authorities powers" was (31.23) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "There is a procedure in the laboratory to determine the training needs of all employees" was (23.53) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory has a clear training plan to raise the technical capabilities of workers" was (23.38) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory management supports the training program and the development of personal skills of the laboratories and provide them to staff" was (28.18) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Laboratory management determines mechanisms to evaluate factors that affect the validity of the results, for example, calibration of instruments, the samples, the experience of the analyst person, the environmental conditions ... (etc.)" was (32.00) with p. value (0.000) which

was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "The laboratory management controls all data related to the analysis (results- calibration data- and others)" was (30.69) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. The value of Chi-square calculated to signify the differences between "Instruments are calibrated on both (Software and Hardware) and completely isolated so that the settings are not changed by unauthorized person the one" was (26.92) with p. value (0.000) which was lower than the level of significant value (5%), these refer to the existence of statistically differences. Table (10) showed that the value of the Chi-square test (15.67) by significant value (0.000) it is less than the probability value (0.05), this means that there was a relationship between the work accommodation and environmental condition and laboratories performance at Khartoum Refinery Company. Table (11) showed that the value of the Chi-square test (39.84) by significant value (0.000) it is less than the probability value (0.05), this means that there was a relationship between the implementation of documented controlled information system and laboratories performance at Khartoum Refinery Company. Table (12) showed that the value of the Chi-square test (19.53) by significant value (0.000) it is less than the probability value (0.05), this means that there was a relationship between the continuous improvement and laboratories performance at Khartoum Refinery Company. Table (13) showed that the value of the Chi-square test (61.46) by significant value (0.000) it is less than the probability value (0.05) and Pearson's R (0.75), this means that there was a relationship between meeting the technical requirements of ISO/IEC 17025:2005 and laboratories performance.

	The	hypotheses	Reliability	Validity			
	The	first hypothesis	0.90	0.95			
	The	second hypothesis	0.87	0.93			
	The	third hypothesis	0.94	0.97			
	The	fourth hypothesis	0.94	0.97			
	Overall					0.97	0.98
Тa	Table 2: The frequency distribution for the respon			ondents' ans	wers about	the questions of t	he first hypothesi
	No.	Phrases	Strongly	Agree	Neutral	Disagree	Strongly
			agree				disagree
	1	There are procedures	27	28	6	1	3
		to protect samples	41.5%	43.1%	9.2%	1.5%	4.6%

|--|

2	under testing from contaminated by surrounding environment or any other samples or solutions There are procedures	25	24	6	6	4
	to monitor the general environmental situation inside the laboratory	38.5%	36.9%	9.2%	9.2%	6.2%
3	There are control procedures for the environmental condition such as humidity, radiation, dust, noise level, temperature and lighting intensity	12 18.5%	23 35.4%	18 27.7%	8 12.3%	4 6.2%
4	Analysis and testing shall be discontinued if the laboratory's environmental condition does not match the environmental condition required by the ASTM standard	8 12.3%	21 32.3%	14 21.5%	15 23.1%	7 10.8%
5	Employees perform analysis in an excellent environment in terms of lighting, ventilation, humidity and temperature	11 6.9%	36 55.4%	6 9.2%	6 9.2%	6 9.2%
6	Laboratory management provides all analysis needs of materials, devices, calibration solutions and any resources for analysis in the analysis sites	35 52.3%	24 36.9%	1	2 3.1%	3 4.6%
7	Laboratory analysis equipment is calibrated periodically and continuously by external calibration bodies	29 44.6%	<u>16</u> 24.6%	7 10.8%	8 12.3%	5
8	The validity and efficiency of analytical instruments are tested with standard samples before the analysis begins	32 49.2%	24 36.9%	6 9.2%	2 3.1%	1 1.5%

No	Phrases	Chi-	Df	Sig	Median	Interpretation
INU.		square value	DI	Sig.	Meulan	
1	There are procedures to protect samples under testing from contaminated by surrounding environment or any other samples or solutions.	54.92	4	0.000	4.00	Agree
2	There are procedures to monitor the general environmental situation inside the laboratory.	34.15	4	0.000	4.00	Agree
3	There are control procedures for the environmental condition such as humidity, radiation, dust, noise level, temperature and lighting intensity.	17.84	4	0.000	4.00	Agree
4	Analysis and testing shall be discontinued if the laboratory's environmental condition does not match the environmental condition required by the ASTM standard.	10.00	4	0.000	3.00	Neutral
5	Employees perform analysis in an excellent environment in terms of lighting, ventilation, humidity and temperature.	52.30	4	0.000	4.00	Agree
6	Laboratory management provides all analysis needs of materials, devices, calibration solutions and any resources for analysis in the analysis sites.	74.61	4	0.000	5.00	Strongly agree
7	Laboratory analysis equipment is calibrated periodically and continuously by external calibration bodies.	30.00	4	0.000	4.00	Agree
8	The validity and efficiency of analytical instruments are tested with standard samples before the analysis begins.	61.23	4	0.000	4.00	Agree

Table 3: Chi-square test results for respondents' answers about the questions of the first hypothesis

Table 4: T	The frequency	distribution fo	or the respondents'	answers about the questions of	the second hypothesis
	1 2		1	1	21

No.	Phrases	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	The document control	28	16	18	2	1
	system clearly identify the difficulty of implementing some of the procedures described in the document	43.1%	24.6%	27.7%	3.1%	1.5%
2	The application of	34	22	4	4	1
	documentation and control system helps to facilitate and understand the work	52.3%	33.8%	6.2%	6.2%	1.5%

	instructions					
3	The application of the documentation system sometimes complicates work procedures	3 4.6%	10 15.4%	19 29.2%	21 32.3%	12 18.5%
4	Controlling the procedures and instructions of the work through documentation reduces the work pressure through the clarity of responsibilities and authorities for employees	<u>39</u> 60.0%	<u>14</u> 21.5%	8 12.3%	2 3.1%	2 3.1%
5	All procedures related to laboratory activities are available, understood and clearly documented to the employees	26 40.0%	17 26.2%	11 16.9%	10 15.4%	1.5%
6	Documents are reviewed, updated and controlled periodically	34 52.3%	12 18.5%	13 20.0%	4 6.2%	2 3.1%
7	There is documentation and archiving of external source documents and procedures (such as calibration procedures, standard samples, maintenance procedures and spare parts for devices)	32 49.2%	18 27.7%	12 18.5%	2 3.1%	1.5%
8	When the document expires, it is cancelled immediately and another replacement document is issued	33 50.8%	15 23.1%	15 23.1%	2 3.1%	0 0.0%
9	The laboratory management maintains all documents related to all devices in addition to the procedures of the periodic maintenance plan	35 53.8%	12 18.5%	15 23.1%	2 3.1%	1 1.5%

Table 5: Chi-square test results for respondents' answers about the questions of the second hypothesis

No.	Phrases	Chi- square value	Df	Sig.	Median	Interpretation
1	The document control system clearly identifies the difficulty of implementing some of the procedures described in the document.	40.30	4	0.000	4.00	Agree
2	The application of documentation and control	63.69	4	0.000	5.00	Strongly agree

	system helps to facilitate and understand the work instructions.					
3	The application of the documentation system sometimes complicates work procedures.	16.15	4	0.000	2.00	Disagree
4	Controlling the procedures and instructions of the work through documentation reduces the work pressure through the clarity of responsibilities and authorities for employees.	72.61	4	0.000	5.00	Strongly agree
5	All procedures related to laboratory activities are available, understood and clearly documented to the employees.	26.30	4	0.000	4.00	Agree
6	Documents are reviewed, updated and controlled periodically.	49.53	4	0.000	5.00	Strongly agree
7	There is documentation and archiving of external source documents and procedures (such as calibration procedures, standard samples, maintenance procedures and spare parts for devices).	50.15	4	0.000	4.00	Agree
8	When the document expires, it is canceled immediately and another replacement document is issued.	29.95	3	0.000	5.00	Strongly agree
9	The laboratory management maintains all documents related to all devices in addition to the procedures of the periodic maintenance plan.	58.00	4	0.000	5.00	Strongly agree

Table 6: The frequency distribution for the respondents' answers about the questions of the third hypothesis

No.	Phrases	Strongly	Agree	Neutral	Disagree	Strongly
		agree				disagree
1	The laboratory management	10	29	6	15	5
	maintains clear and effective policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives	15.4%	44.6%	9.2%	23.1%	7.7%
2	There is a certain procedures and	21	27	6	9	2

	effective decision making to corrective actions in cases of errors in the analysis	32.3%	41.5%	9.2%	13.8%	3.1%
3	When an error occurs in the analysis,	18	25	11	10	1
	there is a procedures lead to the root causes of the error	27.7%	38.5%	16.9%	15.4%	1.5%
4	There is a clear methodology to	19	19	19	7	1
	monitor the effectiveness of the	29.2%	29.2%	29.2%	10.8%	1.5%
	are fundamentally resolved at the planned time					
5	Laboratory management takes a	21	20	10	12	2
	series of preventive actions to ensure that there are no errors during the analysis process, through analysis and assessment of the risks that may accompany the analysis	32.3%	30.8%	15.4%	18.5%	3.1%
6	Laboratory management conducts an	23	7	14	9	2
	assessment of preventive and corrective actions to ensure their effectiveness in preventing future errors	35.4%	6.2%	1.5%	13.8%	3.1%
7	Proactive preventive procedures and	14	21	13	13	4
	measures are in place to discover opportunities for continuous improvement	21.5%	32.3%	0.0%	20.0%	6.2%

Table 7: Chi-sq	uare test results for res	spondents' answers about	the questions of th	e third hypothesis
				21

No.	Phrases	Chi-	Df	Sig.	Median	Interpretation
		square value				
1	The laboratory management maintains clear and effective policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives.	29.38	4	0.000	4.00	Agree
2	There is a certain procedures and effective decision making to corrective actions in cases of errors in the analysis.	34.30	4	0.000	4.00	Agree
3	When an error occurs in the analysis, there is a procedures lead to the root causes of the error.	25.07	4	0.000	4.00	Agree
4	There is a clear methodology to monitor the effectiveness of the corrective action to ensure that errors are fundamentally resolved at the planned time.	22.15	4	0.000	4.00	Agree
5	Laboratory management takes a series of preventive actions to ensure that there are no errors during the analysis process, through	18.76	4	0.000	4.00	Agree

	analysis and assessment of the risks that may accompany the analysis.					
6	Laboratory management conducts an assessment of preventive and corrective actions to ensure their effectiveness in preventing future errors.	19.53	4	0.000	4.00	Agree
7	Proactive preventive procedures and measures are in place to discover opportunities for continuous improvement	11.23	4	0.000	4.00	Agree

Table 8: The frequency distribution for the respondents' answers about the questions of the fourth hypothesis

No.	Phrases	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	Laboratory management	25	22	13	3	2
	provides all conditions that lead to accurate and reliable results	38.5%	33.8%	20.0%	4.6%	3.1%
2	The laboratory management	19	22	13	8	3
	monitors and controls the working conditions and provide suitable environment for the employees, samples and devices	29.2%	33.8%	20.0%	12.3%	4.6%
3	Every individual working in	29	18	12	3	3
	the lab knows his / her duties (responsibilities and authorities) by obtaining a copy of the job description	44.6%	27.7%	18.5%	4.6%	4.6%
4	The job description clearly	29	12	15	5	4
	describes the responsibilities and authorities powers	44.6%	18.5%	23.1%	7.7%	6.2%
5	There is a procedure in the	10	11	11	18	15
	laboratory to determine the training needs of all employees	15.4%	16.9%	16.9%	27.7%	23.1%
6	The laboratory has a clear	9	10	16	14	16
	training plan to raise the technical capabilities of workers	13.8%	15.4%	24.6%	21.5%	24.6%
7	The laboratory management	9	20	7	12	17
	supports the training program and the development of personal skills of the laboratories and provide them to staff	13.8%	30.8%	10.8%	18.5%	26.2%
8	Laboratory management	28	14	16	4	3
	determines mechanisms to evaluate factors that affect the validity of the results, for example, calibration of	43.1%	21.5%	24.6%	6.2%	4.6%

	instruments, the samples, the experience of the analyst person, the environmental conditions (etc.)					
9	The laboratory management	32	19	13	1	0
	controls all data related to	49.2%	29.2%	20.0%	1.5%	0.0%
	the analysis (results-					
	calibration data- and others)					
10	Instruments are calibrated on	19	22	18	5	1
	both (Software and	29.2%	33.8%	27.7%	7.7%	1.5%
	Hardware) and completely					
	isolated so that the settings					
	are not changed by					
	unauthorized person the one					

Table 9: Chi-square test results for respondents' answers about the questions of the fourth hypothesis

No.	Phrases	Chi-	Df	Sig.	Median	Interpretation
		value				
1	Laboratory management provides all conditions that lead to accurate and reliable results.	34.30	4	0.000	4.00	Agree
2	The laboratory management monitors and controls the working conditions and provide suitable environment for the employees, samples and devices.	18.61	4	0.000	4.00	Agree
3	Every individual working in the lab knows his / her duties (responsibilities and authorities) by obtaining a copy of the job description.	37.07	4	0.000	4.00	Agree
4	The job description clearly describes the responsibilities and authorities powers.	31.23	4	0.000	4.00	Agree
5	There is a procedure in the laboratory to determine the training needs of all employees.	23.53	4	0.000	2.00	Disagree
6	The laboratory has a clear training plan to raise the technical capabilities of workers.	23.38	4	0.000	3.00	Neutral
7	The laboratory management supports the training program and the development of personal skills of the laboratories and provide them to staff.	28.18	4	0.000	3.00	Neutral
8	Laboratory management determines mechanisms to evaluate factors that affect the validity of the results, for example, calibration of instruments, the samples, the experience of the analyst person, the environmental conditions (etc.)	32.00	4	0.000	4.00	Agree

9	The laboratory management controls all data related to the analysis (results - calibration data - and others).	30.69	3	0.000	4.00	Agree
10	Instruments are calibrated on both (Software and Hardware) and completely isolated so that the settings are not changed by unauthorized person the one.	26.92	4	0.000	4.00	Agree

 Table 10: Result of first hypothesis (There is a relationship between the work accommodation and environmental condition and laboratories performance at Khartoum Refinery Company)

No.	Chi-square	Df	Sig.	Median	Scale	Statistical significant
65	15.67	3.0	0.000	4.00	Agree	Significant

Table 11: Result of the second hypothesis (There is a relationship between the implementation of documented controlled information system and laboratories performance at Khartoum Refinery Company)

No.	Chi-square	Df	Sig.	Median	Scale	Statistical significant
65	39.84	4	0.000	4.00	Agree	Significant

 Table 12: Result of the third hypothesis) There is a relationship between the continuous improvement and laboratories performance at Khartoum Refinery Company)

No.	Chi-square	Df	Sig.	Median	Scale	Statistical significant
65	19.53	4	0.000	4.00	Agree	Significant

 Table 13: Result of the fourth hypothesis (There is a relationship between meeting the technical requirements of ISO/IEC 17025:2005 and laboratories performance)

No.	Chi-square	Df	Sig.	Pearson's R	Scale	Statistical significant
65	61.46	9	0.000	0.75	Agree	Significant

5. Discussion

The present study showed that the most frequency distribution for the respondents' answers about the questions of the first hypothesis was 35 (52.3%) for strongly agree for the statement (Laboratory management provides all analysis needs of materials, devices, calibration solutions and any resources for analysis in the analysis sites), in general, means that most of the respondents have strongly agreed with all what mentioned about the first hypothesis, but do not mean that all the respondents in the sample have agreed with the questions because there were some respondents who were disagreed with the questions, besides, there were some respondents who were do not realize or do not see a relationship between the work accommodation and environmental condition and laboratories performance. Regarding the first hypothesis, the results showed that the value of the Chi-square test (15.67) by significant value (0.000) it is less than the probability value (0.05); this means that there was a relationship between the work

accommodation and environmental condition and laboratories performance at Khartoum Refinery Company. The results reflected that the most frequency distribution for the respondents' answers about the questions of the second hypothesis were 39 (60.0%) for strongly agree for the statement (Controlling the procedures and instructions of the work through documentation reduces the work pressure through the clarity of responsibilities and authorities for employees), in general, means that most of the respondents have strongly agreed with all what mentioned about the second hypothesis, but do not mean that all the respondents in the sample have agreed with the questions because there were some respondents who were disagreed with the questions, besides, there were some respondents who were do not realize or do not see a relationship between the implementation of documented controlled information system and laboratories performance at Khartoum Refinery Company. The results of second hypothesis showed that the

value of the Chi-square test (39.84) by significant value (0.000) it is less than the probability value (0.05), this means that there was a relationship between the implementation of documented controlled information system and laboratories performance at Khartoum Refinery Company. The present study showed that the most frequency distribution for the respondents' answers about the questions of the third hypothesis were 29 (44.6%) for agree for the statement (The laboratory management maintains clear and effective policy and plan for continuous improvement and upgrading of performance in the central laboratory through quality policy and objectives), means that most of the respondents have agreed with all what mentioned about the third hypothesis, but do not mean that all the respondents in the sample have agreed with the questions because there were some respondents who were strongly disagreed with the questions, besides, there were some respondents who were do not realize or do not see a relationship between the continuous improvement and laboratories performance at Khartoum Refinery Company. The results of third hypothesis showed that the value of the Chi-square test (19.53) by significant value (0.000) it is less than the probability value (0.05), this means that there was a relationship between the continuous improvement and laboratories performance at Khartoum Refinery Company. The present study illustrated that the most frequency distribution for the respondents' answers about the questions of the fourth hypothesis were 32 (49.2%) for strongly agree for the statement (The laboratory management controls all data related to the analysis (resultscalibration data- and others)), means that most of the respondents have strongly agreed with all what mentioned about the fourth hypothesis, but do not mean that all the respondents in the sample have agreed with the questions because there were some respondents who were disagreed

6. Conclusion

The study concluded that implementation of ISO/IEC17025:2005 have impact on work accommodation and environmental condition inside the laboratories, implementation of documented controlled information system, the continuous improvement and meeting the technical requirements of ISO/IEC 17025:2005 in the central laboratory at Khartoum Refinery Company.

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with the questions, besides, there were some respondents who were do not realize or do not see a relationship between meeting the technical requirements of ISO/IEC 17025:2005 and laboratories performance. The results of fourth hypothesis showed that the value of the Chi-square test (61.46) by significant value (0.000) it is less than the probability value (0.05) and Pearson's R (0.75), this means that there was a relationship between meeting the technical requirements of ISO/IEC 17025:2005 and laboratories performance. The findings from the present study were in disagreement with findings obtained by Fadul (2014) [5] who found that the services provided by national public health laboratory (NPHL) was low quality; there was no clear management system with unknown responsibilities inside NPHL, but the findings of the present study were in agreement with the findings of Hamza (2015) [6] who found that the awareness and perception of top managers of ISO helped them in the process of evaluation and measuring the system as well achieving intended results, work environment inside the laboratory was suitable and helped in correct testing results and provided implementing ISO system enhanced the performance and the quality of the laboratory. Also, the results obtained from the present study were in agreement with results obtained by Mohamed (2016) [7] who found that the effect of the ISO 17025 was clearly visible; the systems have been improved to the best. The findings of the present study were in agreement with the findings of Ahmed (2018) [8] who found that there was a positive relationship between implementing of ISO/IEC17025 standard and improvement of work environment and with findings of Abbas (2018) [9] who found that the working accommodation and environment inside DNA laboratory is suitable and helps in correct testing results.

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