# Metrological Model for Inspection and Evaluation of Medical Devices

Mahmud Omer Mohamed Ali, Eltahir Mohammed Hussein

Biomedical Engineering Dept., Sudan University of Science and Technology, Khartoum, Sudan
Email: mahmou99@yahoo.com, Altahir_33@yahoo.com

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***ABSTRACT*** **-** In this paper a metrology model is proposed for inspection and evaluation of medical devices, which provide cost-oriented re-diagnosis rate of non-accuracy of the results. This work focuses on the current situation of medical devices in military hospital and Khartoum hospital, by applying the statistical methods such as the mean, frequencies, percentages and independent T – test. Results obtained by the model reflect the state of medical devices in hospitals. However, the average percentage of standards inspection and evaluation of medical devices which reached at military hospital is (46.8%) and Khartoum hospital is (47.9 %). While, the ratio required to ensure the efficiency of medical devices scientifically more than (95%) which helps in diagnosis, treatment, monitoring of patients to provide the best healthcare services.

***Keywords:*** *Medical metrology, Inspection, Evolution, Calibration, Risk management.*

***المستخلص***– في هذه الورقة تم إنشاء نموذج قياس مترولوجى لتفتيش وتقييم الأجهزة الطبية. وهذا النموذج من شانه المساعدة في تقليل تكلفة إعادة التشخيص للنتائج غير الدقيقة.ركزت الورقة على دراسة الوضع الحالي للأجهزة الطبية في مستشفى السلاح الطبي و مستشفى الخرطوم بغرض تقيمها، وفقاً لنظام المصمم. وأجرى التحليل باستخدام الأساليب الإحصائية الوصفية بما في ذلك حساب المتوسط الحسابي و التكرارات والنسب المئوية لمتغيرات النظام وأجراء فرق المتوسطين (T– test). النتائج المتحصل عليها عكست حالة الأجهزة الطبية في المستشفيين . وذلك من خلال تحديد نسبة متوسط معايير التفتيش والتقييم على الأجهزة الطبية التي بلغت (46.8%) و (47.9%) بمستشفى السلاح الطبي والخرطوم على التوالي بينما النسبة المطلوبة لضمان كفاءة الأجهزة الطبية علمياً أكثر من () 95%.

## *INTRODUCTION*

Several researches in area of reliable engineering for medical equipment mainly consider devices in their design or manufacturing stage and suggest many techniques to improve their reliability [1]. Device evaluation helps to determine how the device functions as well as its ability to provide reliable results. Devices have been evaluated to learn how they function. It is important to know the device limitations than to know how it performs against standard specifications. All devices have limitations, and the limitations must be identified prior to adopting the devices, to reduce the risks [2]. However, hospital inspection and evaluation strategies for medical equipment have not been considered.

Medical measurements are present in everyday life and are fundamental processes in the prevention, diagnosis and treatment of diseases. Additionally, the analysis of the medical devices according to the manufacturer helped us to decide the right during the purchasing of the new devices [3].The balance of performance, risk, resources and cost to

reach to an optimal solution, however, the application of all these techniques and models to medical devices is still in a very early phase. More over hospitals, due to possessing a large number of difference devices, can benefit significantly if the optimization techniques are used properly in the equipment management processes. There is therefore growing interest in the role of metrological decisions and conformity assessment, notably where measurements are made to safeguard health [4]. This paper aims at addressing this gap and propose model to improve current inspection and evaluation strategies in the healthcare facilities. This paper is going to test the hospital inspection and evaluation management activities for medical devices. Models in each section of The Military Hospital and Khartoum Hospital will be designed to investigate the activities.

## *METHODOLOGY*

The model is designed to determine the effect of inspection and evolution of medical devices in health care of both diagnostic and therapeutic medical, according to The Joint Commission for Accreditation of Healthcare Organizations(JCAHO) [5],recommendations of the World Health Organization (WHO)[6-9],international recommendations [10-13]and successful practices of other countries' systems [14-16]. Further, The model has been designed to investigate and evaluate the activities and techniques in (25) departments and sections that working with medical devices in Military Hospital and Khartoum Hospital , including documents, visual inspection, risk management, preventive maintenance, corrective maintenance, inventory management, policies and procedures, vocational performance and performance indicator as shows in the following flowchart .

### *Model Designation*

Model designed and modified from The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) [5], Operating Guide for TOE Medical Equipment Maintenance, NO. MED 750-2 (Headquarters Department of the Army, Washington, DC, 2006) [17], WHO medical device technical series, June 2011[6- 9], Jordanian Royal Medical Services "Auditor Guide for quality", (2007) [18] and ISO 14971, 2nd Ed., 2007, Medical devices: Application of risk management to medical devices [19]. The above mentioned resources are the main tool used in similar studies, this concept shown in Figure 1.

### *Data Collection*

The designed model was applied by interviewing the heads and biomedical engineers of the sample facilities in the Military Hospital and Khartoum Hospital, visual inspection for medical devices and Performance indicator of the devices will be evaluated according to manufacturer's specifications by testing equipment (as shows in Table1) with high accuracy and international references, and these data will be used to record the output readings taken during the inspection of the Performance of medical devices.

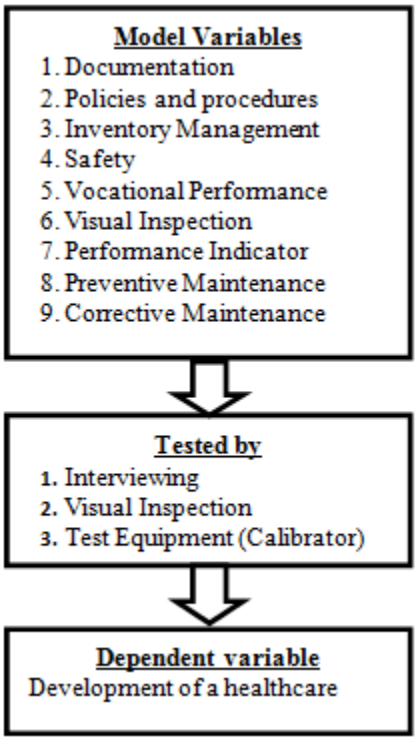


**Figure 1: proposed model flowchart**

The following test equipment (calibrator) can be used to test samples (10 samples) of medical devices to measure the performance indicators as it's mentioned in the Table (1).Data from the sections and departments of sample facilities was

collected as follows: The health care facilities sample of Military Hospital (17 sample facilities) the engineering workshop, operation theatres, Surgery, Children's, Obstetrics and Gynecology, ICU, CCU, ENT, laboratory, Orthopedic, Urology, Ophthalmology, Outpatient, Physical Therapy, dental unit and Radiology department. The health care facilities sample of Khartoum Hospital (8 sample facilities) the engineering workshop, operation theatres, Emergency, Children's, ICU, laboratory, Wards and Radiology department.

***DATA ANALYSIS***

The survey data related to the model are analyzed by the IBM SPSS statistics soft wear program version 20.0 - August 2011 by using the statistical methods such as the mean, frequencies, percentages and independent t – test. The arithmetic mean and the standard deviation are calculated to describe the characteristics of the proposed model variables. It includes dependent variable it is the development of health services and the independent variable, which measured through nine variables: documentation, policies and procedures, inventory management, safety, performance vocational, visual inspection, preventive maintenance, corrective maintenance and performance indicator. Performance indicator is measured by tests a random sample (10 equipment) as the following: patient monitor, electric shock, electrocardiograph, general x - ray, dental x -ray, incubator, dialysis machine and non-invasive blood pressure by using calibration devices (refer to Table 1).

***RESULTS***

***A. Model***

The Joint Commission for Accreditation of Healthcare Organizations has specific requirements for medical equipment management planning. However, the proposed model satisfied with JCAHO standard requirements. The model will review medical equipment management plan, maintenance policy, inspection and review the records and periodical maintenance in Military Hospital and Khartoum Hospital. This process to ensure the validity and accuracy of devices. Standard operation procedures knowledge and log books will be checked. The research will investigate quality control and performance indicators by test a device function. Furthermore, risk management procedures of medical equipment, good storage and inventory management will be checked up. Tables 2 to10 show the metrological model designed by the researcher to inspect and evaluate medical devices.

***Document Model***

To check instructions and measurement, regulation for documentations.

***Policies and Procedures Model***

In this model, policies and procedures relating to equipment and devices will be reviewed to focus on management of medical devices and equipment.

***Inventory Management Model***

The inventory of equipment and medical devices will be reviewed to reflect type, quantity, operational situation, accessories, consumables, spare parts and the degree of risk of equipment and devices.

***Safety Model***

To review the plans of management including the risks of medical devices equipment and services throughout the facility.

***Performance Vocational Model***

In this model activities of biomedical engineers and method of identifying training needs will be studied and checked.

***Visual Inspection Model***

A checklist will be applied to determine the conditions of all items such as Table 7.

***Preventive Maintenance Model***

In this model, the basic principles will be reviewed including policies, procedures and manufacture recommendation.

***Corrective Maintenance Model***

Will be studied to check the documentation of maintenance, contract services and availability of spare part; etc.

***B. Tested Model***

The results are obtained from applying the model to 25 departments and sections that

working with different medical devices in the military hospital and Khartoum hospital are showed in Tables (10 – 12).

***Statistical Description of Model Variables***

Table No 10 shows the descriptive statistics for Military Hospital and Khartoum Hospital of the variables being tested.

***Overall Mean***

Table No 11 shows the descriptive statistics for the average Percentage of Standards inspection and evaluation of medical devices for Military Hospital and Khartoum Hospital. The average Percentage of Standards inspection and evaluation of medical devices which reached at military hospital is (46.8%) and Khartoum hospital is (47.9 %) as shows in Table (11). While, the ratio required .to ensure the efficiency of medical devices scientifically more than (95%).

***Independent T – Test***

Table No 12 represents the results of the independent-test. The result found that there were No significance differences between the Assessments of medical equipment of Military Hospital and Khartoum Hospital because the P. value of independent T – test = (0.744) and it was greater than (0.05).

***Performance Indicator***

Decide the unit under test pass or fail according to manufacturer′s specifications and/or international recommendation. The Performance Indicator Test Results of some medical devices on a random sample (10 equipment) does not represent the whole of society, was the result of tests fail (30 %) of the sample.

***Results Obtained Comparing With Others Results***

The number of fluoroscopy and fluoroscopically guided procedures has been substantially growing in developing countries at the same time advanced and sophisticated equipment are used in some hospitals. However, radiation protection requirements are not necessarily well adopted. In this study nine fluoroscopy X-ray units in Sudan were examined for compliance with international standards. The measured peak tube voltage deviation exceeded the recommended tolerance level in 30 % of the measurements.

The results of patient doses measurements exceeded the recommended reference dose levels in 43 % of the measurements; however Image quality and radiation field generally fulfilled the requirements for most units. The study revealed that a considerable number of fluoroscopy units were not performing according to the international standards and highlights the need of optimization of radiation protection [20].

The implementation and effectiveness of risk management (RM) activities in the medical device industry. An online survey was distributed to medical device professionals who were asked to identify RM-related activities performed during the device life cycle. Survey results indicated that RM's impact and level of effectiveness on a medical device are dependent primarily on the device type and life-cycle stage (i.e., pre-market versus post-market). There is also some impact of development history and the time since the device was released to market [21].

The correct calibration of the tube current of diagnostic X ray equipment is important to ensure optimal image quality. This decreases the number of retakes which will reduce the radiation dose to the patient and the radiation worker.. The exposure of 27 x ray machines was measured using a 65 cm focus-detector distance at 80 KV.

Previous tests on the different machines showed that the calibration of the timer and tube potential was correct within 5%. The half value layer (HVL) for each machine was determined at 80 kV. The range of HVL values was from 2.44 to 3.62 mm Al at 80 kV and the corresponding exposure from 0.06 to 0.19 mGy (mA.s) -1 (95% confidence level). If the exposure is not within these limits with a correct tube potential and timer calibration, it will be indicative of a faulty tube current

value. A non-invasive method was developed to control the tube current calibration of diagnostic x ray machines and this study showed that it could be implemented successfully [22].

## *CONCLUSION*

This paper aims at identify the models to improve current inspection and evaluation strategies for medical devices in healthcare facilities. The results are obtained from applying the model to 25 departments and sections that working with different medical devices in the Military Hospital and Khartoum Hospital. The average Percentage of Standards inspection and evaluation of medical devices which reached at Military Hospital is (46.8%) and Khartoum hospital is (47.9 %). While, the ratio required to ensure the efficiency of medical devices scientifically more than (95%). the results of the independent T-test found that there were No significance differences between the Assessments of medical equipment of Military Hospital and Khartoum Hospital because the P. value of Independent T – test =(0.744) and it was greater than (0.05) .

The Performance Indicator Test Results of some medical devices on a random sample (10 equipment) does not represent the whole of society, was the result of tests fail (30 %) of the sample.This result showed the potential to cause medical devices risks to the patient, users and the economy. The foremost important aspect of this study is to figure out the ability of the proposed model variables techniques to assess the case of medical devices throughout the device's lifecycle.

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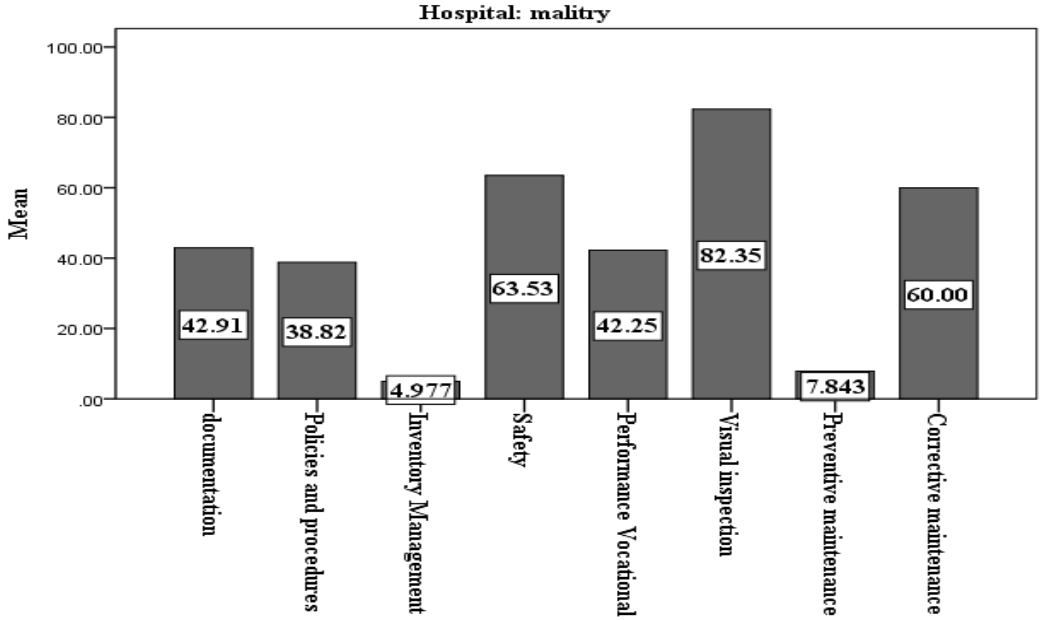


**Figure 2: Histograms with Mean Score Percentage for Military Hospital Each Histogram Displays The Score Percentage of Model Variables.**

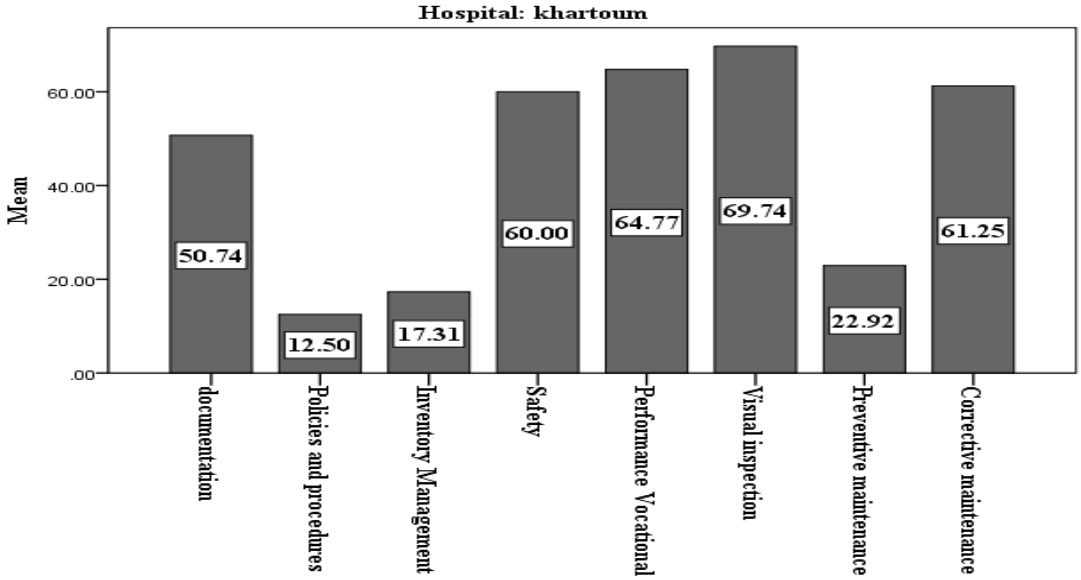


**Figure 3: Histograms with Mean Score Percentage for Khartoum Hospital Each Histogram Displays The Score Percentage of Model Variables.**

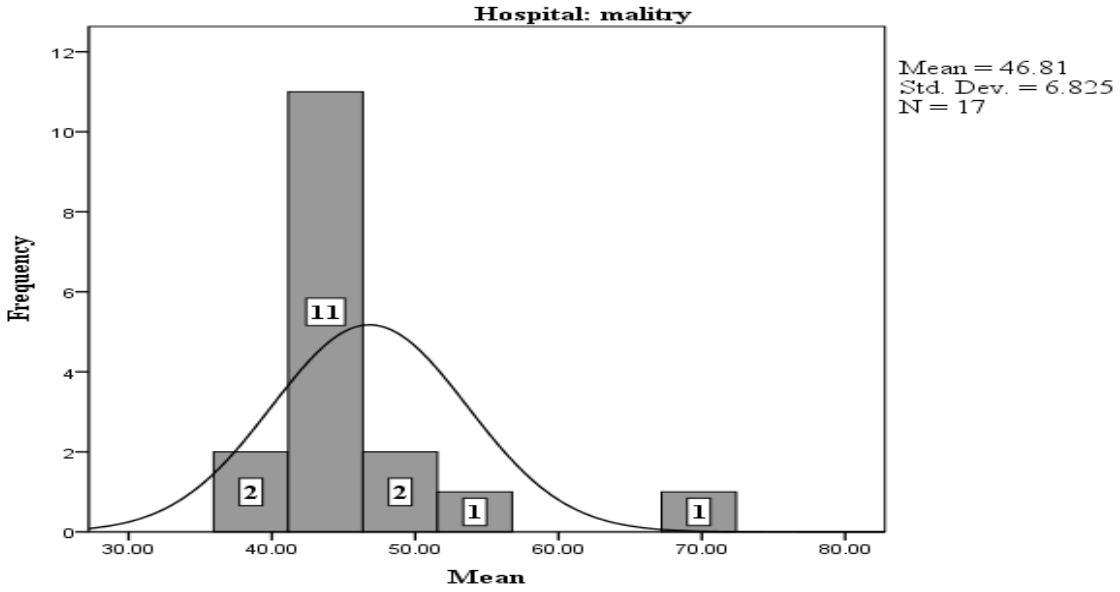


**Figure 4: Histograms with Normal Distribution Curve for The Descriptive Statistics of Mean in Military Hospital Each Histogram Displays The Frequency of Mean Occurs within The Sample.**

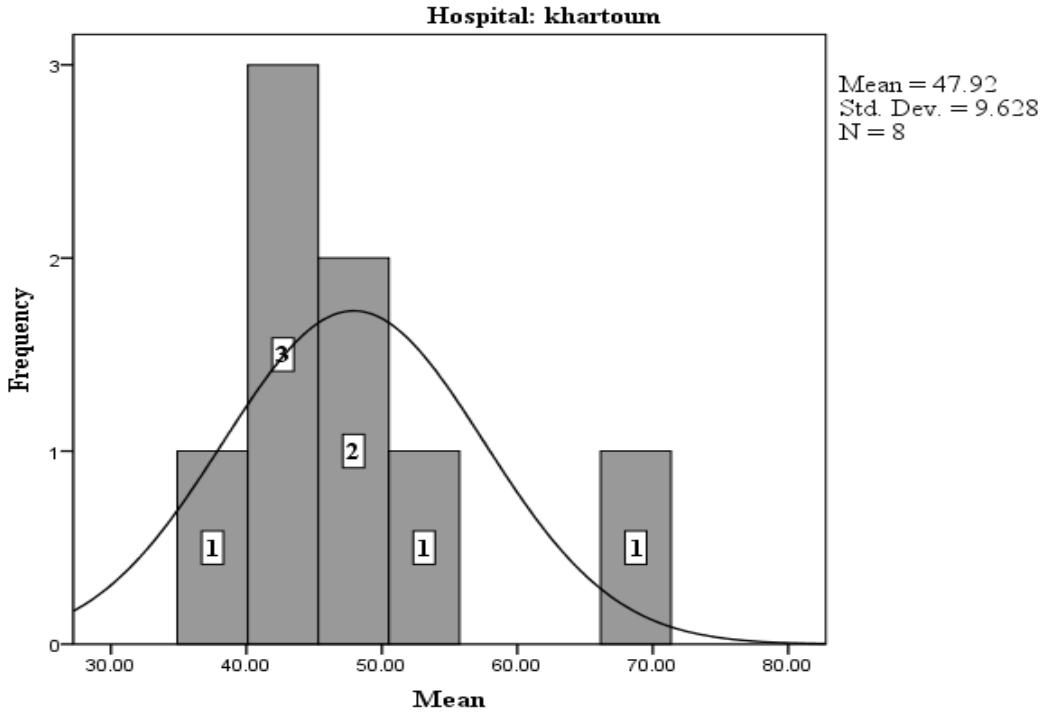


**Figure 5: Histograms with Normal Distribution Curve for The Descriptive Statistics of Mean in Khartoum Hospital Each Histogram Displays The Frequency of Mean Occurs within The Sample**

**Table.1: calibrator and sample of medical devices**

| No | Calibrator | Device | parameter | range | Accuracy |
|---|---|---|---|---|---|
| 1 | CUFFLINK | Sphygmomanometer | Accuracy Of Blood Pressure | 0.00 – 500 mmHg | ± 1 % |
| 2 | IMPULSE 4000 | ECG | Hart Rate | 12- lead | ±1% |
| | | | Filter | | |
| | | | Cables | | |
| | | | Battery | | |
| 4 | CUFFLINK | Patient Monitor | ECG | 12- lead | ±1% |
| | INDEX 2 XLFE | | $SPO_2$ | 35-100% | 100 - 75% ±1% |
| | IMPULSE 4000 | | Blood Pressure | 0.00 – 500 mmHg | 1 ±% |
| 5 | TNT 12000 WD | General X-ray | KV | 0 -150 KV | ±2% |
| | | Dental X-ray | Dose | 0.5mR – 999R | ±5% |
| 6 | PRT AND THERMOCOUPLE INDICATOR | Incubator | Temperature | -200 to 2315°C | ±0.01°C |
| 7 | HEM DIALYSIS | Dialysis | Conductivity | 0 -199.9 mS/cm | ±3% |
| | | | Temperature | 0 - 100°C | ± 0.07 |

**Table 2: Proposed model documentation.**

| **Metrological Model For Inspection And Evaluation Of Medical Devices** | | | | |
|---|---|---|---|---|
| **Name of the facility:** | | **Unit:** | | |
| **Inspector:** | | **Date:** | | |
| **Documentation** | | | | |
| NO | Item | EXISTING | INCOMPLETE | NOT EXISTING |
| 1 | Documentation of maintenance service | | | |
| 2 | Documentation of PM(books/logs/forms) | | | |
| 3 | Documentation of calibration | | | |
| 4 | Archiving of medical devices documents | | | |
| 5 | reporting incidents | | | |
| 6 | Certificate of conformity | | | |
| 7 | List of spare parts and disposables | | | |
| 8 | medical equipment Inventory list | | | |
| 9 | Daily Record to check medical devices | | | |
| 10 | Record of Equipment out of service | | | |
| 11 | List of devices that need to be repaired | | | |
| 12 | list of Inventory storage devices | | | |
| 13 | Requests for equipment maintenance | | | |
| 14 | Record of risk management | | | |
| 15 | Documentation for training. | | | |
| 16 | Documentation of inspections and testing | | | |
| 17 | Annual effectiveness report | | | |

**Table 3: Proposed model policies and procedures.**

| Metrological Model For Inspection And Evaluation Of Medical Devices | | | | |
|---|---|---|---|---|
| **Name of the facility:** | | **Unit:** | | |
| **Inspector:** | | **Date:** | | |
| **Policies and procedures** | | | | |
| NO | Item | EXISTING | INCOMPLETE | NOT EXISTING |
| 1 | Equipment management manual | | | |
| 2 | Policy to create a file for devices | | | |
| 3 | Policies for preventive maintenance | | | |
| 4 | Policy to develop and improve the work of devices | | | |
| 5 | Monitoring of performance indicators | | | |
| 6 | Reporting system | | | |
| 7 | Policies for corrective maintenance | | | |
| 8 | Policies for the Structure and staff | | | |
| 9 | Policies to train operators | | | |
| 10 | Policies to train engineers | | | |

**Table 4: Proposed model inventory management**

| Metrological Model For Inspection And Evaluation Of Medical Devices | | | | |
|---|---|---|---|---|
| **Name of the facility:** | | **Unit:** | | |
| **Inspector:** | | **Date:** | | |
| **Inventory Management** | | | | |
| NO | Item | EXISTING | INCOMPLETE | NOT EXISTING |
| 1 | Conducting clinical trials | | | |
| 2 | Availability of spare parts and consumables | | | |
| 3 | Checking risks | | | |
| 4 | Checking and saving documents | | | |
| 5 | Entering information into the database | | | |
| 6 | Checking store inventory devices by scheduling | | | |
| 7 | Intervals PM of the stored equipment | | | |
| 8 | plan of distributing devices and spare parts | | | |
| 9 | Labeling safety signs | | | |
| 10 | Checking temperature in storage | | | |
| 11 | Checking humidity in storage | | | |
| 12 | Appropriate distance between the device and the surfaces | | | |
| 13 | Storage of devices by classification | | | |

**Table 5: Proposed model safety**

| Metrological Model For Inspection And Evaluation Of Medical Devices | | | | |
|---|---|---|---|---|
| **Name of the facility:** | | **Unit:** | | |
| **Inspector:** | | **Date:** | | |
| **Safety** | | | | |
| NO | Item | EXISTING | INCOMPLETE | NOT EXISTING |
| 1 | Electrical safety standard 3 wire AC line cord or equivalent. | | | |
| 2 | Safety electrical wiring | | | |
| 3 | Fire system | | | |
| 4 | Use gloves during maintenance | | | |
| 5 | Electrical earthing systems | | | |
| 6 | Electric generator (ATS) | | | |
| 7 | Electrical safety testing | | | |
| 8 | Environmental safety testing | | | |
| 9 | The warning signs | | | |
| 10 | Cleaning and disinfection devices | | | |

**Table 6: Proposed model performance vocational**

| Metrological Model For Inspection And Evaluation Of Medical Devices | | | | |
|---|---|---|---|---|
| **Name of the facility:** | | **Unit:** | | |
| **Inspector:** | | **Date:** | | |
| **Performance Vocational** | | | | |
| NO | Item | EXISTING | INCOMPLETE | NOT EXISTING |
| 1 | Service and maintenance of medical equipment | | | |
| 2 | Development and implementation of medical equipment management plan | | | |
| 3 | Management operating and maintenance manuals | | | |
| 4 | Management of maintenance contracts | | | |
| 5 | Development and implementation of replacement programs | | | |
| 6 | Knowledge of international standards or recent recommendations | | | |
| 7 | The ability to investigate incidents of medical devices | | | |
| 8 | Participate in the purchase and sale of devices | | | |
| 9 | Receiving and inspection new devices | | | |
| 10 | Coordinating training on the operation of medical devices | | | |
| 11 | Continuous Training | | | |

**Table 7: Proposed model visual inspection**

| Metrological Model For Inspection And Evaluation Of Medical Devices | | | | |
|---|---|---|---|---|
| Name of the facility: | | Unit: | | |
| Inspector: | | Date: | | |
| Visual inspection | | | | |
| NO | Item | EXISTING | INCOMPLETE | NOT EXISTING |
| 1 | Presence of all accessories required for proper operation. | | | |
| 2 | Standard operating procedure (SOP) | | | |
| 3 | Proper operation of the equipment as specified in the manufacturer's service literature. | | | |
| 4 | Electrical connectors(jacks, receptacles, or plugs) | | | |
| 5 | Alarms | | | |
| 6 | Circuit Breaker/Fuse | | | |
| 7 | Controls/Switches | | | |
| 8 | Indicators/Displays | | | |
| 9 | Audible Signals | | | |
| 10 | Battery/Charger | | | |
| 11 | Availability and validity of consumables | | | |
| 12 | Equipment cards | | | |
| 13 | Connecting the device to the grounding system | | | |
| 14 | Calibration stickers | | | |
| 15 | Suitable environment for equipment | | | |
| 16 | Freeing device internally and externally from rust and corrosion, liquids and dust | | | |
| 17 | Doors , knobs and the other of the moving parts are working well | | | |
| 18 | Checking the Component holders, clips, and receptacles | | | |
| 19 | Checking the Nuts, bolts, screws, and other hardware | | | |

**Table 8: Proposed Model Preventive Maintenance**

| **Metrological Model For Inspection And Evaluation Of Medical Devices** | | | | |
|---|---|---|---|---|
| **Name of the facility:** | | **Unit:** | | |
| **Inspector:** | | **Date:** | | |
| **Preventive maintenance** | | | | |
| NO | Item | EXISTING | INCOMPLETE | NOT EXISTING |
| 1 | Schedule illustrating dates of periodic maintenance | | | |
| 2 | Providing the necessary consumables for periodic preventive maintenance | | | |
| 3 | Making the card or file for follow-up | | | |
| 4 | PM procedures | | | |
| 5 | Inspections and testing of medical equipment | | | |
| 6 | Calibration of equipment | | | |

**Table 9: Proposed Model Corrective Maintenance**

| Metrological Model For Inspection And Evaluation Of Medical Devices | | | | |
|---|---|---|---|---|
| **Name of the facility:** | | **Unit:** | | |
| **Inspector:** | | **Date:** | | |
| **Corrective maintenance** | | | | |
| NO | Item | EXISTING | INCOMPLETE | NOT EXISTING |
| 1 | Failure/user error summary reports | | | |
| 2 | Ordering engineers for maintenance | | | |
| 3 | Repairing devices in the warranty period | | | |
| 4 | maintenance contracts | | | |
| 5 | delivery system for Equipment which has been repaired | | | |
| 6 | Availability of spare parts | | | |
| 7 | Corrective maintenance procedures | | | |
| 8 | Service manual | | | |
| 9 | Availability of maintenance tools | | | |
| 10 | Calibration after maintenance | | | |

**The Table 10: Descriptive Statistics between Cases**

| Hospital | Variables | N. of Unit | Mean (%) | Std. Deviation (%) |
|---|---|---|---|---|
| Military | documentation | 17 | 42.9066 | 12.43751 |
| | policies | 17 | 38.8235 | 6.00245 |
| | Inventory | 17 | 4.9774 | 14.63086 |
| | Safety | 17 | 63.5294 | 9.96317 |
| | Performance | 17 | 42.2460 | 16.05169 |
| | inspection | 17 | 82.3529 | 18.13129 |
| | pm | 17 | 7.8431 | 17.79283 |
| | cm | 17 | 60.0000 | 13.22876 |
| Khartoum | documentation | 8 | 50.7353 | 16.01331 |
| | policies | 8 | 12.5000 | 8.86405 |
| | Inventory | 8 | 17.3077 | 17.32295 |
| | Safety | 8 | 60.0000 | 13.09307 |
| | Performance | 8 | 64.7727 | 10.23629 |

**The Table 11: Overall Means for Military Hospital and Khartoum Hospital**

| Hospital | N. of Unit | Mean (%) | Std. Deviation (%) | Std. Error Mean (%) |
|---|---|---|---|---|
| military | 17 | 46.8137 | 6.82541 | 1.65540 |
| Khartoum | 8 | 47.9167 | 9.62787 | 3.40397 |

**The Table 12: Independent T – test**

| | | Levene's Test for Equality of Variances | | t-test for Equality of Means | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | F | Sig. | t | df | Sig. (2-tailed) | Mean Difference | Std. Error Difference | 95% Confidence Interval of the Difference | |
| | | | | | | | | | Lower | Upper |
| OVERALL | Equal variances assumed | 1.306 | .265 | -.330 | 23 | .744 | -1.103 | 3.34 | -8.009 | 5.803 |
| | Equal variances not assumed | | | -.291 | 10.45 | .776 | -1.103 | 3.9 | -9.49 | 7.3 |