Sudan University of Science & Technology

College of Graduate Studies

Development of a Model for Inspection and Evaluation of Medical Devices

(Case Study)

تطوير نموذج لتفتيش وتقويم الأجهزة الطبية

(دراسة حالة)

A proposal Submitted in the Fulfilment for the Requirements of the M.Sc. in the Biomedical Engineering

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Dedication

To My Parents

Acknowledgpement

I offer my sincerest gratitude to my supervisors, Dr.Eltahir Mohamed Hussein giving me the opportunity to do my M.Sc., and for their excellent advice, insight, support and encouragement during the M.Sc. research studies. This thesis would not have been completed without him. Thanks especially to Dr. Alnazier Hamza who helped me patiently with his excellent knowledge. I gratefully thank to Military Inspection Crop and to General Engineer PSc. Ali El Sharif El Tahir, Inspector General for his guidance. Thank you very much to my friends Hisham Haidar and Abdoelmonien Awad whose helped me to accomplish this important goal in my personal life, and opened the door in my professional life. Thanks to engineers at the Military Hospital and the Khartoum Hospital. Last, but not least, I would like to express my deepest gratitude to my family, who always believed in me and supported me. I would have achieved for less without their continuous support. They have been my greatest mentors, and I owe all my success to them.

ABSTRACT

The objective of this research is to identify the methods to improve current inspection and evaluation strategies for medical devices in health facilities. The research aims to emphasize the effect of proposed model variables (documents, visual inspection, risk management, preventive maintenance, performance indicators, corrective maintenance, inventory management, policies and procedures and vocational performance) on the dependent variable (the development of health care). The most important objectives include, establish a metrology model to reduce medical risk and optimizing health care quality. Evaluate the work of medical devices based on the recommendations of the World Health Organization and create a system, 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 has been assessed according to designed model. The model was designed, consistent with The Joint Commission for Accreditation of Healthcare Organizations (JCAHO), Operating Guide for TOE Medical Equipment Maintenance (Headquarters Department of the Army, Washington, DC, 2006), WHO Medical device technical series (2011), Jordanian Royal Medical Services ("Auditor Guide for quality", 2007) , ISO 14971(2007) and successful practices of other countries' systems. A model was applied by interviewing the heads and biomedical engineers of the sample facilities at some departments and sections that working with medical devices in the Military Hospital (17) unit and Khartoum Hospital (8) unit, visual inspection and performance indicator for medical devices. The survey data related to the model are analyzed by the IBM SPSS statistics soft wear program version 20.0 - 2011 by using the statistical methods such

as the mean, frequencies, percentages and independent T – test. Results obtained by model reflected 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 %). The research results indicated 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 =.744 and it was greater than (0.05) . The results indicated evidence to support the null hypothesis that current inspection and evaluation activities for medical devices may have negative effect in the development of healthcare facilities.

المستخلص

الهدف من هذا البحث هو التعرف على طريقة لتحسين استراتيجيات التفتيش والتقييم الحالية للأجهزة الطبية في المرافق الصحية.وعملت الدراسة على التأكيد على تأثير المتغيرات المستقلة (المستندات ، التفتيش المرئي ، وإدارة المخاطر، ومؤشرات أداء الصيانة الوقائية والصيانة التصحيحية، وإدارة المخزون ،السياسات والإجراءات ،الأداء المهني للمهندسين وكفاءة أداء الأجهزة) على المتغير التابع (تطوير الرعاية الصحية) . ركزت الدراسة على إنشاء نظام قياس مترولوجي يحد من مخاطر الأجهزة الطبية ويودي إلى تحسين جودة تفتيش وتقييم الأجهزة الطبية بناء على توصيات منظمة الصحة العالمية وإنشاء نظام من شانه المساعدة في تقليل تكلفة إعادة التشخيص للنتائج غير الدقيقة . نظرت الدراسة للوضع الحالي للأجهزة الطبية في مستشفى السلاح الطبي و مستشفى الخرطوم بغرض تقيمها ، وفقاً للنظام المصمم . و أعدا هذا النموذج بناءا على متطلبات اعتماد منظمات الرعاية الصحية (JCAHO) و دليل تشغيل صيانة المعدات الطبية الخاص بوزارة الدفاع الأمريكية (2006) و سلسلة مراجع الأجهزة الطبية الفنية لمنظمة الصحة العالمية (2011) ودليل مدقق الجودة بالخدمات الطبية الملكية الأردنية (2007) وتطبيق إدارة المخاطر على الأجهزة الطبية للمنظمة الدولية للمواصفات (ISO 1497, 2007) . أجريت الدراسة الاستقصائية على رؤساء الأقسام ومهندسي الأجهزة الطبية في مستشفى السلاح الطبي (17 وحدة) ومستشفى الخرطوم (8 وحدات) والتفتيش المرئى و اختبارات الكفاءة للأجهزة الطبية . للإجابة عن أسئلة الدراسة والتحقق من مدى قبول الفرضيات عند مستوى دلالة (0.05) وأدخلت بيانات الدراسة على برنامج إحصائي (IBM SPSS V20.0) . وأجرى التحليل باستخدام الأساليب الإحصائية الوصفية بما في ذلك حساب المتوسط الحسابي والتكرارات والنسب المئوية لمتغيرات النموذج وأجراء فرق المتوسطين (T- test) . والنتائج 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%) بمستشفيي السلاح الطبي والخرطوم على التوالي.أوضحت نتائج البحث أنه لا يوجد هناك فروق ذات دلالة إحصائية في تفتيش و تقييم الأجهزة الطبية بمستشفيي السلاح الطبي و الخرطوم لأن قيمة فرق المتوسطين (T- test) = 0.744 وهى اكبر من مستوى الدالة (0.05) لذا نقبل الفرضية العدمية القائلة بأن أنشطة التفتيش والتقييم الحالية للأجهزة الطبية ربما لها تأثير سلبي في تطوير الرعاية الصحية.

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ABBREVIATIONS

EM Number: Equipment Management Number.

JCAHO: Joint Commission on Accreditation of Healthcare Organizations.

PM: Preventive Maintenance.

CM: Corrective Maintenance.

WHO: World Health Organization

ISO: International Organization for Standardization.

ICU: intensive care unit.

CCU: critical care unit.

NIBP: Non-Invasive Blood Pressure.

BRS: Basic Radiological system.

CT: Computer Tomography Scanner.

ECG: Electrocardiogram.

EEG: Electroencephalography.

ENT: Ear, Nose, Throat.

GH: General Hospital.

HMIS: Health Management Information System.

IEC: International Electro Commission.

OPD: Out Patient Department.

IPM: Inspection and Preventive Maintenance.

ECRI: Emergency Care Research Institute.

LIST OF APPENDICES

CHAPTER ONE

INTRODUCTION

Chapter One

Introduction

1.1 General View

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 function 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. This research aims at addressing this gap and propose methods to improve current inspection and evaluation strategies in the healthcare facilities. This research 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 and test the activities including techniques, documents, visual inspection, risk management, preventive maintenance, performance indicators, corrective maintenance, inventory management, policies and procedures and vocational performance.

1.2 Problem Statement

The absence of medical metrology system on the performance indicators and risk management of medical equipment has negative impact on healthcare.

1.3 Objectives

The objectives of this research are to:

1. establish a metrology model to reduce medical risk and optimizing health care quality.
2. evaluate the work of medical devices based on the recommendations of the World Health Organization and Compare the health facilities system with the international systems.
3. create a system, which provide cost-oriented re-diagnosis rate of non-accuracy of the results.

1.4 Hypotheses

1. H0: Current inspection and evaluation activities for medical devices may have negative effect in the development of healthcare facilities .

2. H1: Current inspection and evaluation activities for medical devices must have positive effect in the development of healthcare facilities.

1.5 Methodology

A primary purpose of the inspection is to determine whether medical device management plan with executive responsibility ensures that an adequate and effective quality system has been established (defined, documented and implemented) at the hospital. Accordingly, each inspection should begin and end with an evaluation of this subsystem. The research 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. To answer the questions of the research and verify the extent of acceptance of hypotheses level of significance (0.05), the survey data related to the scheme system will be entered into the computer program. The IBM SPSS statistics software program version 20.0 - 2011 will be used for analysis.

1.6 Limitation

The research was limited to the survey of the inspection and evaluation of medical devices in The Military Hospital and The Khartoum Hospital to find out the impact of the absence of metrology in the development of health care in time period of the year (2013) until the year (2015).

1.7 Thesis layout

This research is structured as follows chapter one includes a brief description of the design of medical devices system for inspection and evaluation model, problems found, goals, and means to accomplish these goals. Literature rreview will be appearing in this research in the cchapter two. In cchapter three, presents a general overview of medical devices and how to develop the plan of inspection and maintenance management, meanwhile these issues can be mapped into metrological model scenarios. In chapter four, a method for inspection and evaluation of medical equipment. In chapter five, describes results and discussed the results in chapter six. The conclusions of the research and recommendations are given in chapter seven.

CHAPTER TWO

LITERATURE REVIEW

Chapter Two
Literature Review

1. Performance Analysis for Medical Devices:

The objective of this study is to investigate the performance of the medical devices by analyzing the problems of the medical devices that do not meet the international standards. The data used in this study were obtained by interpreting of the performance test results of medical devices. The study includes high risk group medical devices used at the departments of operation room and intensive care in Cerrahpasa Faculty of Medicine in Istanbul University. The performance tests of total 542 medical devices were performed and the measurement results were interpreted according to the Inspection and Preventive Maintenance System (IPM) procedures which were developed by Emergency Care Research Institute (ECRI). The obtained data were analyzed and the results were given in graphics. This study showed that the controlling of the performance of the medical devices especially the high risk group medical devices in the hospital will be helpful in quality assurance studies. As a result of this, a preventive maintenance program was created. Thus, tracing the problems before they happen and stocking required spare parts were made possible. Additionally, the analysis of the medical devices according to the manufacturer helped us to decide the right during the purchasing of the new devices **(Mana Sezdi, 2013)**.

2. The Role of Metrology in Medical Devices:

Medical measurements are present in everyday life and are fundamental processes in the prevention, diagnosis and treatment of diseases. There is therefore growing interest in the role of metrological decisions and conformity assessment, notably where measurements are made to safeguard health. This paper focuses on the use of medical devices and looks to improve their metrological traceability, highlighting the specific role of metrology in the field of healthcare and the impact of legal control in the framework of the regulation of medical devices with a measuring function. A new regulatory approach for medical devices in use is proposed, in view of the fact that we are faced with increasing convergence between European policy enforcement and metrological regulations **(Ferreira, 2011**).

3. Equipment performance and radiation protection status in X-ray fluoroscopy units in Sudan:

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 tests included: beam quality, entrance surface air kerma, image quality and radiation field measurements. Staff radiation protection tools such as lead aprons and eye glasses were also visually examined to find out whether international recommendations were fulfilled and to determine the level of staff awareness. 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.

4. Implementation of Risk Management in the Medical Device Industry:

This study looks at 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. RM activities and techniques included Establishing Risk Acceptance Criteria, Hazard Identification, Human Factors/Usability, Fault Tree Analysis (FTA), Design Failure Mode and Effects Analysis (DFMEA), Process Failure Mode and Effects Analysis (PFMEA), Hazard and Operability Study (HAZOP), Hazard Analysis and Critical Control Point (HACCP), Risk Benefit Analysis, and Risk Assessment of Customer Complaint. Devices were identified by type (therapeutic, surgical/clinical tools, diagnostic, instrument disposable, implantable, etc.), development history (new, second, third or later generation device), and time since market release. Respondents were also asked to indicate the degree of change made to the device as a result of RM activities and to rate the effectiveness of associated RM activities for the device. 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 **(Dumbrique, 2010)**.

5. Reliability Analysis of Maintenance Data for Complex Medical Devices:

For decades, reliability engineering techniques have been successfully applied in many industries to improve the performance of equipment maintenance management. Numerous inspection and optimization models are developed and widely used to achieve maintenance excellence, i.e. 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 new. 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. Most research in the area of reliability engineering for medical equipment mainly considers the devices in their design or manufacturing stage and suggests some techniques to improve the reliability. To this point, best maintenance strategies for medical equipment in their operating context have not been considered. We aim to address this gap and propose methods to improve current maintenance strategies in the healthcare industry. More specifically, we first identify or propose the criteria which are important to assess the medical equipment for maintenance decisions. The model is a novel application of multi-criteria decision making methodology to prioritize medical devices in a hospital according to their criticality. The devices with high level of criticality should be included in the hospital's maintenance management program. Then, we propose a method to statistically analyze maintenance data for complex medical devices with censoring and missing information. We present a classification of failure types and establish policies for analyzing data at different levels of the device. Moreover, a new method for trend analysis of censored failure data is proposed. A novel feature of this work is that it considers dependent

failure histories which are censored by inspection intervals. Trend analysis of this type of data has not been discussed in the literature. Finally, we introduce some assumptions based on the results of the analysis, and develop several new models to find the optimal inspection interval for a system subject to hard and soft failures. Hard failures are instantaneously revealed and fixed. Soft failures are only rectified at inspections. They do not halt the system, although they reduce its performance or productivity. The models are constructed for two main cases with the assumption of periodic inspections, and periodic and opportunistic inspections, respectively. All numerical examples and case studies presented in the dissertation are adapted from the maintenance data received from a Canadian hospital **(Taghipour, 2011).**

6. A Non-Invasive Method to Control the Tube Current Calibration of Diagnostic Radiology Equipment:

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 direct measurement of the tube current is time-consuming and is not part of the non-invasive quality control programme. A technique was therefore developed where readings from a NERO system were used to control the tube current calibration of diagnostic x-ray equipment. If the tube potential and timer are accurately calibrated, it is possible to derive the consistency of the tube current calibration from the exposure measurement. 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 **(Herbst, 2012).**

CHAPTER THREE

MEDICAL EQUIPMENT MANAGEMENT PLAN

Chapter Three

Medical Equipment Management Plan

The term “medical device” covers a broad range of products, used every day throughout the Trust to support the diagnosis, treatment and care of patients. These devices have a direct impact on the quality of care and can also be a source of risks to the patients and the staff. Regular maintenance and evaluation are necessary to assure that equipment delivers the expected performance within specified parameters. The sophistication and complexity of medical equipment continues to expand. Therefore, The MEMP is designed to assure selection of appropriate medical equipment; to support the medical care processes to assure effective preparation of staff responsible for the use or maintenance and repair of equipment; and to assure continual availability of safe, effective equipment through a program of planned maintenance, timely repair, and evaluation of all events that could have an adverse impact on the safety of patients or staff. The ability to plan for this evolution and its subsequent implications has become a major challenge in most decisions of health care organizations and their related industries. Therefore, there is a need to adequately plan for and apply those management tools that optimize the deployment of medical technology and the facilities that house it. Successful management of the technology and facilities will ensure a good match between the needs and the capabilities of staff and technology, respectively. Inspection intervals are established based upon regulatory and/or manufacturer’s recommendations, known risks and hazards. Intervals can also be changed by statistical data showing that a longer interval would not adversely affect the functionality.

A preventive maintenance (PM) format, including data and documentation of quantitative and qualitative tests performed, is followed and completed for each piece of equipment inspected. These inspections are formalized and follow automated and semi-automated procedures. A label indicating the date of the inspection, the due date of the next inspection, and initials of the person performing the test is affixed on the equipment. Detailed test data are recorded in the equipment electronic and/or paper history files.

The MEMP establishes processes for managing those aspects of clinical equipment that have a potential to harm patients and staff. The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) has specific requirements for medical equipment management planning.

3.1 Written plan [8]

The department of biomedical engineering is responsible for writing and annually reviewing a written management plan describing the processes the hospital uses to manage the effective, safe, and reliable operation of medical equipment.

This plan specifically addresses managing risks of medical equipment by ensuring that equipment is appropriate for its intended use, that equipment is maintained according to strategies intended to minimize risks, that maintainers and users of medical equipment are trained and qualified, that performance according to the requirements of this policy is measured and analyzed, and that performance improvement recommendations are implemented and effective.

3.2 Selecting and acquiring medical equipment [9]

The selection process begins in the department that will use the equipment. All requests for new medical equipment must follow the capital approval policy. Its function is to ensure the hospital purchases equipment that meet the clinical need, is safe, reliable and compatible

with other systems and supplies and is cost effective when compared to alternatives. Department heads collaborate with purchasing, hospital administration and clinical engineering in the selection and acquisition of medical equipment. Department heads are responsible for identifying equipment needs, evaluating financial responsibility, and justifying equipment purchases. The purchasing director is responsible for coordinating vendor negotiations. Hospital administration coordinates and processes capital equipment requests and purchases. The capital equipment committee has ultimate responsibility for the approval of capital equipment requests. The capital equipment acquisition policy is maintained in the hospital's administration policy manual. Department heads normally initiate the selection and acquisition process by identifying and documenting their needs and submitting a Purchase Requisition with an accompanying justification letter. This justification documents a variety of issues such as a financial analysis and a determination of installation requirements. Computerized equipment receives a separate evaluation by the Information Technology department final recommendations related to medical equipment selection are developed after negotiations conducted by the purchasing department have been completed. The capital equipment committee has final approval over all new medical equipment purchases. Documentation related to the selection and acquisition process is maintained by the purchasing department. The earliest possible stage prior to purchase, clinical engineering participates in pre purchase assessments, and determinations are made based on both clinical and technical criteria the process is intended to assure that the equipment selected meets the following requirements:

1. It is appropriate for its intended use.

2. It is compatible with existing equipment interfaces and/or shared use of accessories.
3. It will not cause undue user education difficulties.
4. It meets the design requirements of IEC 601 and the safety requirements.
5. It is not under recall and doesn't have documented safety and use concerns.
6. Any special installation planning requirements can be accommodated.
7. Space requirements can be accommodated.
8. Load and phase requirements can be accommodated.
9. It meets the minimum safety standard of 3 wire AC line cord or equivalent.
10. It has appropriate warranties and the manufacturer is reliable.
11. The manufacturer provides adequate equipment support.
12. It conforms with standardization efforts when possible.

If the equipment does not meet the above specifications, it may not be ordered or an alternate choice may be submitted for approval.

3.3 Risk criteria for inventory [9]

The director of the biomedical engineering department is responsible for uses and development risk criteria for identifying, evaluating, and creating an inventory of equipment to be included in the medical equipment management plan before the equipment is used. Heads of departments where such specialized equipment is located are responsible for coordinating their departmental efforts with the clinical engineering department. An inventory of active medical equipment is maintained in the clinical engineering department. The active inventory includes the equipment handled under contracts, with adequate documentation. The inventory includes device type, manufacturer, model, serial number,

location and risk level category. The criteria are used to evaluate risks related to the function of medical equipment, physical risks related to the use of equipment, and any history of patient safety issues related to the use of the equipment. The written criteria for medical equipment include:

1. Equipment function (diagnostic, therapeutic, analytical, and life support).
2. Physical risks associated with use of the equipment (clinical application, inappropriate therapy or misdiagnosis, potential patient injury or patient death).
3. Equipment incident history (likelihood of failure).
4. Preventive maintenance requirements by manufacturer (annually, semi-annually, quarterly, monthly, or none).
5. Environmental use classification. (Non–patient areas, general care areas, labs, critical care areas, anesthetizing location).

All new equipment shall be inventoried and inspected prior to use for patient care or any other use. Based on the above criteria, the Clinical Engineering Department will ensure that the new equipment is inspected for:

1. Presence of all accessories required for proper operation.
2. Presence of Operators Manuals and Technical Service Manuals, and Schematics.
3. Proper operation of the equipment as specified in the performance specifications in the manufacturer's service literature.
4. Passage of electrical safety requirements.
5. Inclusion into, or exclusion from, the Medical Equipment Management Program.
6. Compliance on labeling of equipment, to ensure that the equipment has been "evaluated for safety and suitability for

intended use" by a nationally recognized. Testing laboratory, and /or acceptable Listings as to the safety of goods.

New equipment that fails electrical safety tests shall not be approved for use until the deficiencies have been corrected. Equipment is removed from the inventory when it is removed from service, although a record of its history is maintained. If equipment passes all required inspections the technician will affix an Inventory Control Number and Clinical Equipment Maintenance inspection stickers based on the PM schedules. The Technicians will fill in the appropriate information on these stickers, and place it in a visible location on the device. The clinical engineering technician who performs the inspection is responsible for ensuring the completion of the initial inspection documentation. The receiving department is responsible for delivering new equipment to the clinical engineering department when it is received onsite. Medical equipment remains assigned to the program until a minimum of three (3) years of maintenance data has been accumulated. At that time, a review of the reliability of the equipment is performed. Devices that show consistently low repair/re-calibration need are placed either on a reduced PM schedule or removed from the equipment management program.

Clinical engineering uses the inventory to monitor and control the quality of services provided and assure adequate safety performance and cost effectiveness of medical equipment.

3.4 Strategies for maintaining medical equipment [10]

The director of clinical engineering uses manufacturer recommendations, applicable codes and standards, accreditation requirements, and local or hospital experience to determine the appropriate maintenance strategy for assuring safety and maximizing equipment availability and service life clinical engineering ensures the correct operation and integrity of all medical equipment through in-coming inspections, testing, corrective

maintenance and repairs. The strategies may include predictive maintenance, reliability-centered maintenance, interval-based inspections, corrective maintenance, or metered maintenance to ensure reliable performance.

3.4.1 Incoming Inspection

Clinical engineering inspects all medical equipment (new, used, loaner and rental) for electrical safety, physical condition and performance verification upon arrival. User department managers notify the clinical engineering department upon delivery of equipment to arrange for its incoming inspection prior to use.

3.4.2 Preventive Maintenance (PM)

Medical equipment is subject to effective periodic maintenance, performed by clinical engineering, the manufacturer, or a third party. In conjunction with the evaluation of equipment for inclusion in the equipment management program, each classification of device is assigned a preventive maintenance inspection strategy and schedule. The preventive maintenance inspections for most equipment included in the equipment management program are interval-based; however some are meter-based (note, interval-based preventive maintenance inspections are still assigned to meter-based devices to ensure that the device's meter is checked). The frequency for interval-based preventive maintenance inspections is determined based upon manufacturer recommendations, risk levels, and past organizational experience. Preventive maintenance work orders are generated on a monthly basis, with expectations that the work orders be completed in a timely manner. Additional preventive maintenance work orders may be generated for those devices that have missed their previous preventive maintenance inspections (e.g. device could not be located, device was in use, etc.), or that came due for preventive maintenance off-cycle (e.g. meter-based inspections).

3.4.3 Service Contracts/Warranty

Manufacturers or a third party may cover specific medical equipment under contract. This equipment is repaired and maintained by the outside source. Upon receipt of their documentation, clinical engineering reviews it and, if acceptable, enters it into the equipment management program history.

3.4.4 Repairs

Clinical engineering staffs perform in-house repairs. All repairs are prioritized and performed in a timely manner. Manufacturers and other outside vendors conduct repairs of specific contracted devices. Each vendor provides the hospital with copies of operator and service manuals as part of the purchasing process. This information, plus hospital experience and general industry experience with the type of equipment, is used to determine inspection, testing, and maintenance needs of the equipment. To assure the continuation of patient care in the event of equipment failure, backup devices are available for most critical devices (e.g. anesthesia units, physiologic monitors, defibrillators, ventilators, infusion pumps, etc.). Backup devices may be located either within the using department, in biomedical engineering, or in Patient Equipment, depending on the criticality of reduction in downtime. These backup devices are also available for use in expanding the facility's capacity to provide patient care in the event of internal/external disasters.

3.5 Scheduled Maintenance [8]

A hospital defines intervals for inspecting, testing, and maintaining appropriate equipment on the inventory (that is, those pieces of equipment on the inventory benefiting from scheduled activities to minimize the clinical and physical risks) that are based upon criteria such as manufacturers' recommendations, risk levels, and current hospital experience. All equipment included in the program is inspected and

tested prior to its initial use and at set intervals, commonly referred to as preventive maintenance (PM). A systematic approach to scheduled maintenance of medical equipment is a means of making certain that the equipment is safe for use and can obtain maximum utilization at a reasonable cost. Equipment in the inventory benefits from scheduled activities to minimize the clinical and physical risks. Clinical engineering has established and operates a continual PM program based on risk criteria and organizational experience. Each device is assigned a risk classification based on five distinct categories:

1. Equipment function: energy delivering, patient monitoring, or patient convenience devices.
2. physical risk
3. maintenance (PM)
4. incident history, and
5. environment use

Each item of equipment will be assigned numerical scores for equipment function, physical risk, maintenance requirements and incident history according to the following:

1. Equipment Function

Equipment function will be evaluated on a scale from 1 to 10 as shown in table 3.1.

Table 3 .1: Equipment Function Evaluated [8]

Category	Score	Type	Definition	Examples
Therapeutic (devices that apply some form of energy)	10	Life Support; Radiation Therapy	devices used to support life; devices used for radiation therapy	Defibrillator, Ventilator, Pacemaker, infant Incubator
	9	Surgical And Intensive Care	devices therapeutic in nature, but alone don't support life	Electrosurgical Unit, laser
	8	Physical Therapy And Treatment	devices intended to treat a patient's ailment	Dialysis Machine, Infusion pump, Traction unit, Diathermy
Diagnostic (devices used to diagnose patient ailments)	7	Surgical &Critical Care Monitoring; Radiology Systems	monitors & modules used in the surgical or critical care environment; radiology systems	EEG Machine, Non Invasive Blood Pressure Monitor, X-ray Generator
	6	Additional Physiological Monitoring And Diagnostics	devices not routinely used in critical care environment	Adult Scale, Tympanic Thermometer, Ultrasound Unit
Analytical (devices primarily used outside the patient care area that provide Information to assist in the Diagnosis of Patient.)	5	Analytical Laboratory	devices used in the clinical laboratory to perform diagnostic testing of specimens	Blood Gas Analyzer, Clinical Chemistry Analyzer, Cell Counter
	4	Devices Used To Prepare Specimens For Analysis	shaker, centrifuge, incubator, microtome	Computer, Ticket Printer, QC System
	3	Computer And Related	devices used to record, print, gather, or distribute data	Computer, ticket Printer, qc system
Miscellaneous	2	Computer, Ticket Printer, Qc System	devices related to patient care, but not directly used	X-ray view box, Sterilizer, chair lift
	1	Non-Patient Related; Test Equipment	devices unrelated to patient care	ECG simulator, Office equipment, Kitchen equipment, Ups

2. Physical Risk Associated With Clinical Application

Physical risk will be evaluated on a scale from 1 to 5 as shown in table 3.2.

Table 3.2: Physical Risk Evaluated [8]

Category	Score	Definition	Examples
Patient death	5	Failure of the device could result in the death of a patient	Defibrillator, ventilator ,pacemaker, infant incubator
Patient or Operator injury	4	Failure not likely to cause death but may result in injuries	Hypo/hyperthermia unit, laser, electrosurgical unit
Inappropriate Therapy or Misdiagnosis	3	Failure could result in misdiagnosis or improper therapy	ECG machine, blood gas analyzer, centrifuge
Minimal risk	2	Failure not likely to cause any adverse outcome with the patient or affect safety of patients or staff	Gel warmer, heat sealer, suction pump
No Significant Risk	1	Failure will not cause an adverse outcome with the patient or affect patient or staff safety	Exam light, computer terminal, video printer

3. Maintenance Requirements

Maintenance requirements will be evaluated on a scale from 1 to 5 as show in table 3.3.

Table 3.3: Maintenance Requirements Evaluated [8]

Category	Score	Definition	Examples
Extensive	5	Devices that are predominantly mechanical, pneumatic, or fluidic in nature (needed routine calibration and part replacement required)	Dialysis machine, ventilator, anesthesia machine, x-ray table
Above average	4	Devices that have mechanical, pneumatic, or fluidic components, but are primarily electronic in nature	Infant incubator, blood warmer, laser, portable x-ray system
Average	3	Devices that need only performance verification and safety testing, primarily electronic in nature (performance verification and safety testing)	Defibrillator, infusion pump, electrosurgical unit, traction unit
Below average	2	Devices that require less extensive testing of performance	Lab microscope, scales, general medical device
Minimal	1	Devices that may require only visual inspection	Exam light, computer terminal, video camera

4. Equipment Incident History

Any information available regarding service history that can be considered when evaluating the device type to determine an Equipment Management (EM) will be evaluated as shown in table 3.4.

Table 3.4: Equipment Incident Evaluated [10]

Category	Score	Definition
Significant	+2	Average equipment failures more than one every 6 months
Moderate	+1	Average equipment failures one every 6–9 months
Average	0	Average equipment failures one every 9–18 months
Minimal	-1	Average equipment failures one every 18–30 months
Insignificant	-2	Average equipment failures less than one in the past 30 months

EM number equation = Function + Application + Maintenance + History.

All devices with a total EM number of 12 or more will be included in the programme and scheduled for inspections and preventive maintenance. During the acceptance testing, any new device will be included in the programme if the device has been previously evaluated and classified for inclusion. If the device has not been previously evaluated, a new device classification will be created. It will be evaluated according to the outlined procedure to produce an EM number and will be included in the programme if appropriate. If included, a performance assurance inspection and preventive maintenance procedure will be written for the new device. The maintenance requirement values are also used to determine the interval between each inspection and maintenance procedure for each device type all devices classified as extensive (characteristic value of 4 or 5) are given a preventive maintenance interval of six months. Devices with average or minimal requirements (values of 3, 2 or 1) are scheduled for preventive maintenance annually.

Devices with an EM number of 15 or above will be scheduled for inspection at least every six months.

Devices with an EM number of 19 or 20 will be given an inspection interval of four months. All patient care-related equipment including therapeutic, monitoring, diagnostic or analytical equipment not included in the programme, because it did not receive an EM number of 12 or above, may still be included in the hospital's biomedical equipment inventory and be covered on a repair-only basis.

3.6 Medical Equipment Hazard Notices and Recalls [8]

A hospital identifies and implements processes for monitoring and acting on equipment hazard notices and recalls, and clinical engineering actively participates in the handling of the medical device recalls. All product safety alerts, hazard notices and recalls will be directed to the

clinical engineers. The purchasing department receives and distributes the alerts and recalls to staff. When notice of an equipment hazard or recall is received by clinical engineering, the director will ensure that the equipment inventory database is reviewed to determine if any equipment is affected and evaluate the severity of the risk.

If there are no devices of the type identified in the alert or recall, the Director will:

1. Initial the alert or recall and return to Purchasing.
2. Notify Purchasing that no equipment of that type exists in the hospital.
3. Make an appropriate entry in the Alerts records database.

If there is equipment in the inventory which has been identified in the alert or recall, the Director will:

1. Notify the Purchasing Department of the alert or recall.
2. Notify the Department Manager of the alert or recall.
3. Locate the equipment.
4. Take the recommended steps described in the alert.
5. Make an appropriate entry in the Alerts database.
6. Document the actions on a work order in the equipment database. for the particular medical equipment.
7. Notify the department manager of the action taken.
8. Notify the Purchasing department of the action taken.

The director of clinical engineering will provide the environment of care committee with a summary of the findings on a regular basis and actions taken to comply with the product alert or recall.

3.7 Monitoring and Reporting Incidents [8]

The safe medical device Act of 1990 requires that all hospitals to report incidents to the device manufacturer when the facility determines a device has, or may have, caused or contributed to the death or serious injury of an individual.

3.8 Emergency Procedures [8]

A hospital identifies and implements processes for emergency procedures that address the following.

1. What to do in the event of equipment disruption or failure.
2. When and how to perform emergency clinical interventions when medical Equipment fails.
3. Availability of backup equipment

In the case of equipment failure during use, backup equipment is available in most cases. Two areas where specific backup plans have been specified are respiratory and perfusion.

a. Respiratory

In case of a ventilator failure, staff is instructed to manually ventilate the patient and call for a replacement ventilator.

b. Perfusion

In the event of a pump failure, two emergency backup modalities exist, operation on battery and manual operation. The procedures for both of these are outlined in the Emergency Management policy.

4. How to Obtain Repair Services

In the event of equipment failure, repair services can be obtained by contacting biomedical engineering medical equipment, which meets criteria as critical to patient safety, has emergency procedures established for implementation in the event of the occurrence of an equipment malfunction or failure. Equipment considered critical to patient safety Includes life support, life sustaining or other critical

equipment whose malfunction or failure may result in an adverse patient outcome.

3.9 Inventory of Medical Equipment [8]

A hospital documents a current, accurate, and separate inventory of all equipment identified in the medical equipment management plan, regardless of ownership. The clinical engineering department maintains record of all equipment identified in the plan regardless if it is owned or rented/leased equipment. It also ensures preventative maintenance records are maintained for equipment whether it is serviced by our own biomedical engineers or by outside vendors. Clinical engineering maintains all this data via the computerized medical equipment tracking system, or manually with repair documentation completed by outside vendors in binders. The director of clinical engineering ensures that all equipment included in the PM inventory is maintained as required by the set PM schedule.

3.10 Testing Before Initial Use [9]

All clinical equipment coming into the hospital is tested before initial use and appropriately added to an inventory. These tests, evaluations and inventories are documented. Clinical Engineering has developed a policy and procedures for the performance testing of any medical equipment to be complete either by clinical engineering staff, or by the manufacturer's representatives with a member of the clinical engineering department witnessing the completion of all necessary acceptance and electrical safety checks before any equipment is use for patient care or treatment. All clinical equipment falling under the responsibility of the clinical engineering department is covered by this policy, regardless of ownership, and must pass the incoming inspection before it will be allowed into the hospital. Examples of ownership categories are:

1. Rental/leased equipment.
2. Physician - owned equipment.
3. Donated / loaned equipment.
4. Hospital - owned equipment.

3.11 Maintenance of Life support Equipment [8]

Documents maintenance of equipment used for life support that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan clinical engineering has developed preventive maintenance procedures for all critical medical devices in the hospital. The preventive maintenance procedures are developed using the manufacturer's preventive maintenance recommendations, NFPA standards and ANSI standards.

Medical equipment used for life support receives the highest priority to ensure that 100 % of this type of equipment is located and appropriate inspections and maintenance is performed on schedule. All repairs are prioritized and performed in a timely manner. To assure the continuation of patient care in the event of equipment failure, backup devices are available for most critical devices (e.g., anesthesia units, physiologic monitors, defibrillators, ventilators, infusion pumps, etc.).

It must be continually reviewing equipment’s preventative maintenance records to ensure that inspection frequency match the equipment criticality or history of incidents. And look to schedule multi-year capital planning programs to replace older equipment over several years.

3.12 Maintenance of Non-life Support Equipment [8]

The hospital documents maintenance of non-life support equipment is completed according to scheduled frequency. Non-Life Support PM compliance is to be greater than 90%. If the quarterly rate of completion falls below 90%, the manager of the MEMP will also present an analysis to determine what the cause of the problem is and make

recommendations for addressing it. The preventative maintenance procedures for these types of equipment are developed based on manufacturer's recommendations and any incident history data.

3.13 Sterilizer Performance Testing [9]

Uses various steam sterilizers, and documents performance testing of all Sterilizers used. Performance testing is completed with each sterilization batch using a test strip and/or other procedures. These test's results are reviewed by central processing and other user departments' staff which log all this data in record books for each sterilizer. The facilities management department also conducts a quarterly inspection of sterilizers to ensure they are operating properly and the results of the annual inspections are reported quarterly by clinical engineering.

3.14 Renal Dialysis Water Testing [8]

Biomedical engineer is responsible for maintenance of dialysis equipment used. The program of maintenance includes regular cleaning and disinfection of all dialysis equipment and testing for compliance with biological and chemical standards for the dialysis water supply. Water and power technologies performs regular maintenance and testing of the dialysis water supply. Dialysis department staff performs daily tests for purity of the water used for dialysis and out of range results are documented as patient safety incidents and reported to the risk manager for evaluation and action. Any event resulting in a patient injury or death will be treated as a sentinel event.

3.15 Orientation and Training of Clinical Engineering [8]

The Human Resources department conducts a general orientation twice a month. All staff members must complete the general orientation during the first thirty days of employment. Clinical Engineering staff is hired with at least an associate degree in clinical or electrical engineering and

basic equipment repair skills either from previous work experience or from formal education programs. All staff get a department specific training session with regards the medical equipment management plan. In addition, clinical engineering staff members also receive a department-specific orientation, which includes activities related to inspection, testing and maintenance, repair of equipment and patient and staff equipment safety issues. The goal of the department orientation program is to provide new staff members with current information regarding area-specific issues and departmental responsibilities. The medical equipment-training program addresses the following:

1. The capabilities, limitations and special applications of equipment.
2. Basic operating and safety procedures for equipment use.
3. Emergency procedures in the event of equipment failure.
4. Information and skills necessary to perform assigned maintenance responsibilities.
5. Processes for reporting medical equipment management problems, such as failures and user errors.
6. Personal safety including use of protective equipment.

Clinical equipment technicians are trained on the maintenance of new equipment either by the manufacturer or by other, more experienced technicians within the department. Equipment with low probability of failure and/or low risk level may not necessarily require formal training.

New equipment to be repaired or maintained by clinical engineering is not placed in service until the vendor trains the clinical engineering staff on how to perform basic repairs. Moreover, repair manuals are required for new equipment and appropriate manufacturers technical support information is provided to the clinical engineering and user departments, as appropriate. The competency of staff is evaluated by the Supervisor as part of the annual appraisal process. If the supervisor believes that a

technician is not able to repair a specific type of equipment, he is immediately taken off that assignment until he is sufficiently retrained and demonstrates competency in repairing that equipment. All staff members of the clinical engineering department are required to participate in a mandatory continuing education and training program, and in-service training conducted regularly.

3.16 Orientation and Education of Medical Equipment Users [9]

All staff that use medical equipment are trained in the use of such equipment prior to actual use on patients. The nursing in-service department is responsible for the training, evaluating competency, and retraining of nursing personnel utilizing equipment. Other non-nursing personnel are trained on equipment use when and if necessary.

3.17 Annual Evaluation [9]

Once each calendar year, the director of clinical engineering drafts an evaluation of the MEMP. The draft addresses the scope, objectives, performance and effectiveness of the plan. The draft includes the information on the following:

1. Equipment inventory.
2. Management of the PM program.
3. Equipment repairs (turn-around time, call back within one month)
4. Equipment failure, incidents reports, user errors.
5. Current level of performance.
6. Performance improvement plan of Clinical Engineering Department.

The annual evaluation uses a variety of information sources including incident report summaries, meeting minutes, the EOC committee reports, and other summaries of activities. The draft evaluation provides a balanced summary of the MEMP performance over the preceding 12 months. Strengths are noted and deficiencies are evaluated to set goals

for the next year or longer-term future. The draft evaluation is distributed to the EOC committee distribution list for review and comment, and comments are incorporated. The final evaluation is then presented to the EOC committee for approval. The chair of the EOC committee presents a summary of the evaluation to the executive VP for hospital operations.

3.18 Performance Monitoring [8]

The director of clinical engineering manages performance monitoring for the MEMP. At least once per calendar year, clinical engineering recommends goals to the EOC and one or more indicators that can be used to objectively measure the performance of the MEMP. Clinical Engineering also recommends appropriate data sources, data collection methods, data collection intervals, analysis techniques, and report formats for the indicators. These recommendations are based on information and data that have been collected and discussed by the EOC committee during the preceding year. As a rule, the indicators are recommended with a view towards monitoring important elements of the MEMP and providing a general sense of whether it is functioning effectively. The indicators are not intended to monitor all aspects of the plan. Clinical Engineering incorporates the goals and indicators into the annual evaluations of the MEMP. The EOC committee discusses the goals and indicators and modifies them as needed before approving them. Once indicators have been approved, clinical engineering collects and analyzes data and periodically reports to the EOC committee. The frequency of reporting varies depending on the indicators selected. However, data is reported at least once a year as part of the annual evaluation of the MEMP. If warranted (e.g., when conditions change), clinical engineering may change indicators during the calendar year, as long as the EOC committee approves the changes. At the time this plan

was written, the clinical engineering department was implementing the following performance indicators and standards:

1. Preventive maintenance of life support equipment. Target 100% - A measure of compliance. Clinical Engineering completes scheduled preventive maintenance of life support equipment (defibrillators, ventilators, heart-lung bypass machines, and pacemakers).
2. Preventive maintenance by of all equipment. Target >95% - A measure of compliance. Clinical Engineering completes scheduled preventive maintenance of all medical equipment (including life support equipment).
3. Preventive maintenance by Radiology of all Radiology equipment. Target >95% - A measure of compliance. SIEMENS completes scheduled preventive maintenance of all radiological medical equipment.
4. Operator / User Errors. Target <2% - A measure of training program effectiveness. Medical equipment users don't request repairs / service because they don't know how to use equipment.
5. Patient Incidents. Target 0 - A measure of plan effectiveness. Medical equipment does not malfunction when it is being used on patients.
6. Safe Medical Devices Act reporting. Target 100% - A measure of compliance. Risk Management reports patient incidents involving medical equipment in compliance with the Safe Medical Devices Act.
7. Renal dialysis water. Target 100% - A measure of compliance. The hospital maintains proper documentation of chemical and biological testing of water used in renal dialysis.
8. Preventive maintenance of sterilizers – Target >95%. A measure of compliance. Facilities Management completes scheduled preventive maintenance of sterilizers per hospital policy.

The clinical engineering department shall monitor performance improvement indicators/standards, equipment management effectiveness indicators/standards, corrective maintenance indicators/standards, and performance regarding actual or potential risks through the following activities:

a. Participating in hospital-wide environmental rounds, including clinical engineering department environmental rounds, which are conducted monthly in patient care areas.
b. Collecting and analyzing data on all services provided by clinical engineering department on a monthly basis.

CHAPTER FOUR

METHODOLOGY

(THE PROPOSED MODEL)

Chapter Four

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 recommendations of the World Health Organization (WHO) [10 - 13] ,The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) [14],international recommendations[15 -18] and successful practices of other countries' systems[8,9,19,20]. 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 Fig No (4.1).

4.1 Model Designation

A model designed and modified from Operating Guide for TOE Medical Equipment Maintenance, NO. MED 750-2 (Headquarters Department of the Army, Washington, DC, 2006) [21],Jordanian Royal Medical Services "Auditor Guide for quality", (2007) [22] , ISO 14971, 2nd Ed., 2007, Medical devices: Application of risk management to medical devices [23] ,WHO medical device technical series, June 2011[10- 13] and The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) [14]. The above mentioned resources are the main tool used in similar studies this concept shown in Figure 4.1.

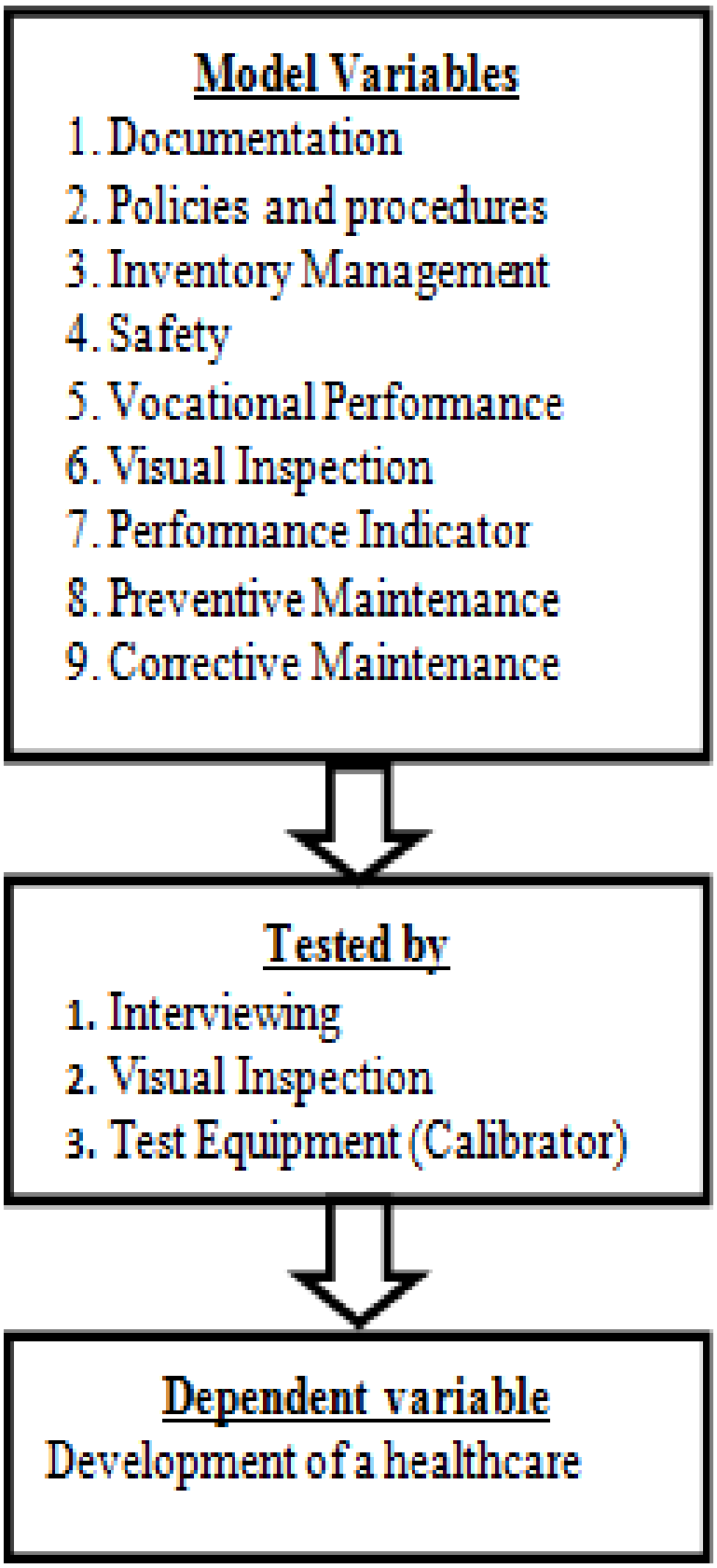

Figure 4.1: Proposed Model Flowchart

4.2 Model

The ability to investigate and evaluate the activities of medical equipment and its subsequent implications has become a major challenge in most decisions of health care organizations and their related industries. Therefore, there is a need to adequately implemented and apply those management tools that optimize the deployment of medical technology and the facilities that house it.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. The Joint Commission for Accreditation of Healthcare Organizations has specific requirements for medical equipment management planning. However, the proposed model compliance with JCAHO standard to describe how model meet JCAHO requirements as shown in the following tables (4.1 - 4.8).

1. Document Model

To check instructions and measurement, regulation for documentations.

Table 4.1: Proposed Model Documentation.

Metrological Model For Inspection And Evaluation Of Medical Devices			
Name of the facility:		**Unit:**	
Inspector:		**Date:**	
Documentation			
NO	**Item**	**JCAHO**	**Proposed Model**
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 No 4.1 represents the proposed model documentation cover all requirements for management plan in JCAHO standard see Appendix B.

2. 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.

Table 4.2: 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**	**JCAHO**	**Proposed Model**
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 No 4.2 represents the proposed model policies and procedures cover all requirements for procedures in JCAHO standard see Appendix B.

3. 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.

Table 4.3: Proposed Model Inventory Management

Metrological Model For Inspection And Evaluation Of Medical Devices			
Name of the facility:		**Unit:**	
Inspector:		**Date:**	
Inventory Management			
NO	**Item**	**JCAHO**	**Proposed Model**
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		

4. Safety Model

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

Table 4.4: Proposed Model Safety

Metrological Model For Inspection And Evaluation Of Medical Devices			
Name of the facility:		**Unit:**	
Inspector:		**Date:**	
Safety			
NO	**Item**	**JCAHO**	**Proposed Model**
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		

5. Performance Vocational Model

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

Table 4.5: Proposed Model Performance Vocational

Metrological Model For Inspection And Evaluation Of Medical Devices			
Name of the facility:		**Unit:**	
Inspector:		**Date:**	
Performance Vocational			
NO	**Item**	**JCAHO**	**Proposed Model**
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 No 4.5 represents the proposed model performance vocational cover all requirements for Training in JCAHO standard see Appendix B.

6. Visual Inspection Model

A checklist will be applied to determine the conditions of all items such as the shown in table (4.6).

Table 5.6: Proposed Model Visual Inspection

Metrological Model For Inspection And Evaluation Of Medical Devices			
Name of the facility:		**Unit:**	
Inspector:		**Date:**	
Visual inspection			
NO	**Item**	**JCAHO**	**Proposed Model**
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		

7. Preventive Maintenance Model

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

Table 4.7: Proposed Model Preventive Maintenance

Metrological Model For Inspection And Evaluation Of Medical Devices			
Name of the facility:		**Unit:**	
Inspector:		**Date:**	
Preventive maintenance			
NO	Item	**JCAHO**	**Proposed Model**
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		

8. Corrective Maintenance Model

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

Table 4.8: Proposed Model Corrective Maintenance

Metrological Model For Inspection And Evaluation Of Medical Devices			
Name of the facility:		**Unit:**	
Inspector:		**Date:**	
Corrective maintenance			
NO	Item	**JCAHO**	**Proposed Model**
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		

4.3 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 table 4.9) 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. 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 (4.9).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.

Table 4.9: 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

4.4 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 4.9). The research using 3 point liker scale techniques to assessing a case of medical devices throughout the calculated mean and then determines the attitude by the average weighted values which ranges between not existing (1) and existing (3) as shown in table No (4.10).

Table 4.10: Values of Weighted Average

Weighted mean	Attitude
From 1.00 to 1.06	Not Existing
From 1.07 to 2.33	Incomplete
From 2.34 to 3.00	Existing

CHAPTER FIVE

RESULTS

Chapter Five

Results

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 as following tables (5.1 - 5.19).

5.1 Proposed Model Documentation Output

The results obtained are shown in the following tables (5.1, 5.2).

5.1.1 Documents in Military Hospital (case1)

The Table 5.1: Documentation in Case 1.

Documentation	Frequency			Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)			
Documentation of maintenance service.	0	0	17 (100)	2.0000	.00000	incomplete
Documentation of PM(books/logs/forms)	1 (5.9)	16(94.1)	0	1.1176	.48507	not existing
Documentation of calibration	0	15(88.2)	2(11.8)	1.1176	.33211	not existing
Archiving of medical devices documents	15(88.2)	1 (5.9)	1(5.9)	2.8235	.52859	existing
reporting incidents	0	16(94.1)	1(5.9)	1.0588	.24254	not existing
Certificate of conformity	1(5.9)	16(94.1)	0	1.1176	.48507	not existing
List of spare parts and disposables	0	15(88.2)	2(11.8)	1.1176	.33211	not existing
medical equipment Inventory list	8(47.1)	0	9(52.9)	2.4706	.51450	existing
Daily Record to check medical devices	16(94.1)	1 (5.9)	0	2.8824	.48507	existing
Record of Equipment out of service	1(5.9)	14(82.4)	2(11.8)	1.2353	.56230	not existing
List of devices that need to be repaired	4(23.5)	11(64.7)	2(11.8)	1.5882	.87026	not existing
list of Inventory storage devices	1 (5.9)	16(94.1)	0	1.1176	.48507	not existing
Requests for equipment maintenance	16(94.1)	0	1 (5.9)	2.9412	.24254	Existing
Record of risk management	0	17 (100)	0	1.0000	.00000	not existing
Documentation for training	5 (29.4)	11(64.7)	1 (5.9)	1.6471	.93148	not existing
Documentation of inspections and testing	0	16(94.1)	1 (5.9)	1.0588	.24254	not existing
Annual effectiveness report	17(100)	0	0	3.0000	.00000	Existing

Table No 5.1 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, documents in Military Hospital case1 showed the following results: the archiving of medical devices documents, the medical equipment inventory list, daily record to check medical devices, requests for equipment maintenance and annual effectiveness report indicated existing attitude. The documentation of PM (books/logs/forms), documentation of calibration, reporting incidents, certificate of conformity, list of spare parts and disposables, record of equipment out of service, list of devices that need to be repaired, list of inventory storage devices, record of risk management, documentation for training and documentation of inspections and testing specified as not existing. The documentation of maintenance service showed as in completed attitude.

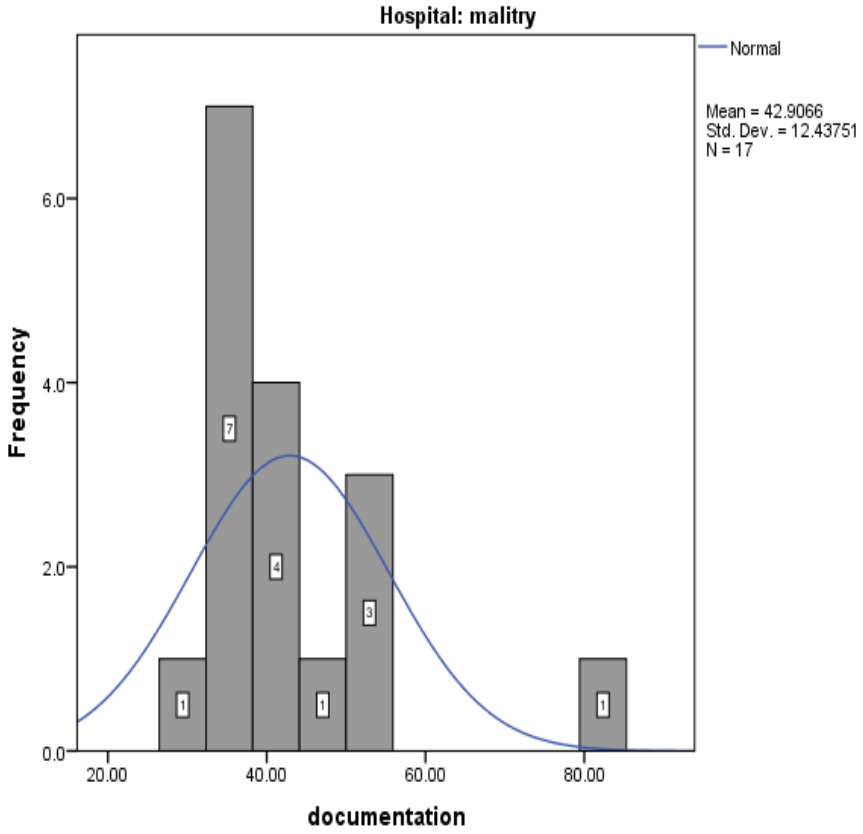

Figure 5.1: Histograms With Normal Distribution Curve for Documents in Military Hospital Each Histogram Displays The Frequency of Documentation Occurs within The Sample.

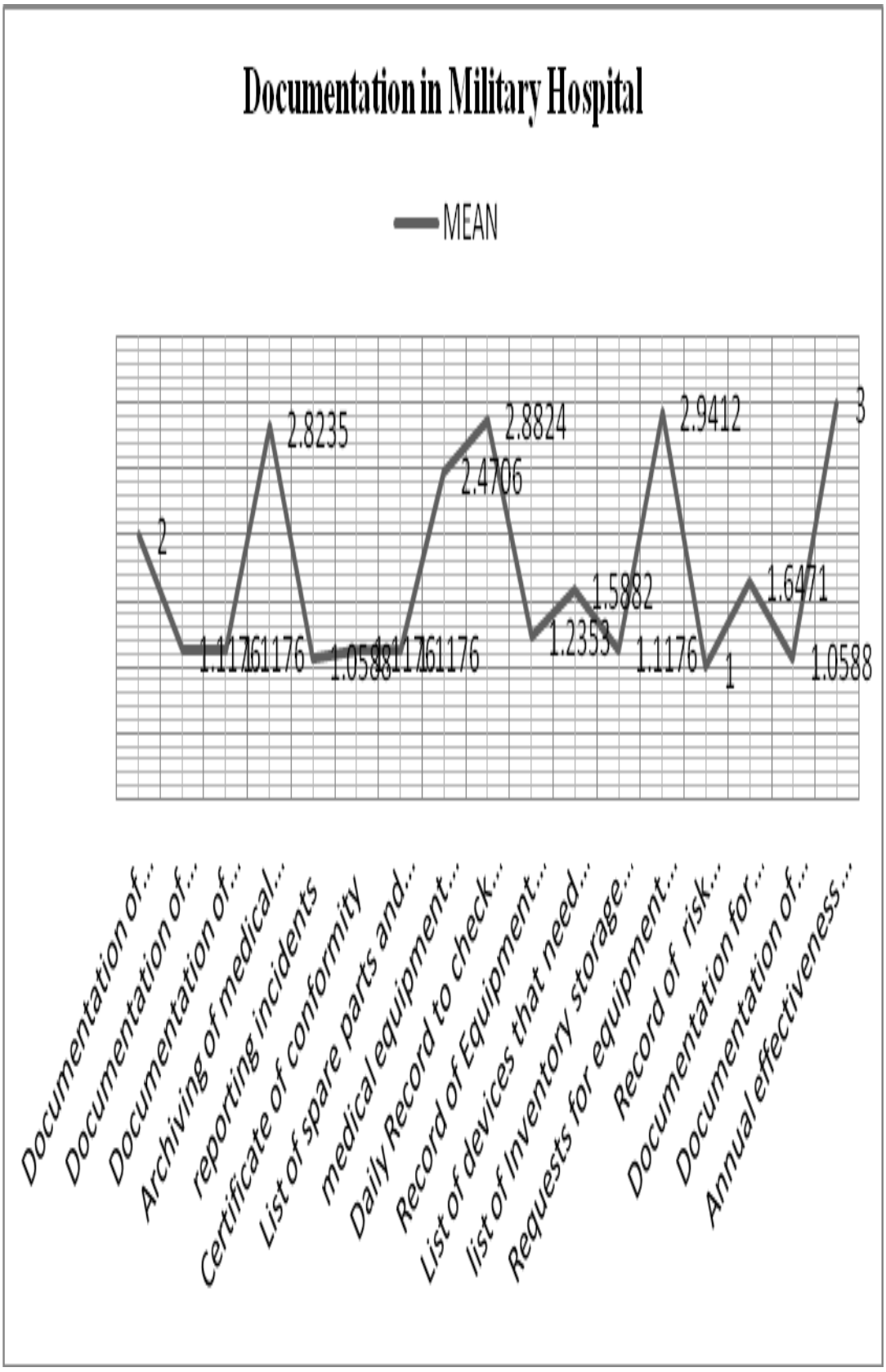

Figure 5.2: Arithmetic Mean for Documents in Military Hospital.

5.1.2 Documents in Khartoum Hospital (case2)

The Table 5.2: Documentation in Case 2.

Documentation	Frequency			Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)			
Documentation of maintenance service.	1(12.5)	2(25.0)	5(62.5)	1.8750	.64087	incomplete
Documentation of PM(books/logs/forms)	1(12.5)	0	7(87.5)	2.1250	.35355	incomplete
Documentation of calibration	0	8(100)	0	1.0000	.00000	not existing
Archiving of medical devices documents	1(12.5)	1(12.5)	6(75.0)	2.0000	.53452	incomplete
reporting incidents	0	7(87.5)	1(12.5)	1.1250	.35355	not existing
Certificate of conformity	0	7(87.5)	1(12.5)	1.1250	.35355	not existing
List of spare parts and disposables	0	5(62.5)	3(37.5)	1.3750	.51755	not existing
medical equipment Inventory list	6(75.0)	0	2(25.0)	2.7500	.46291	existing
Daily Record to check medical devices	2(25.0)	2(25.0)	4(50.0)	2.0000	.75593	incomplete
Record of Equipment out of service	0	4(50.0)	4(50.0)	1.5000	.53452	not existing
List of devices that need to be repaired	0	6(75.0)	2(25.0)	1.2500	.46291	not existing
list of Inventory storage devices	0	5(62.5)	3(37.5)	1.3750	.51755	not existing
Requests for equipment maintenance	3(37.5)	1(12.5)	4(50.0)	2.2500	.70711	incomplete
Record of risk management	0	8(100)	0	1.0000	.00000	not existing
Documentation for training	0	3(37.5)	5(62.5)	1.6250	.51755	not existing
Documentation of inspections and testing	0	7(87.5)	1(12.5)	1.1250	.35355	not existing
Annual effectiveness report	1(12.5)	1(12.5)	6(75.0)	2.0000	.53452	incomplete

Table No 5.2 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, documents in Khartoum Hospital case2 showed the following results: the medical equipment inventory list showed as existing attitude. The documentation of calibration, reporting incidents, certificate of conformity, list of spare parts and disposables, record of equipment out of service, list of devices that need to be repaired, list of inventory storage devices, record of risk management, documentation for training and documentation of inspections and testing specified as not existing. The documentation of maintenance service, documentation of PM (books/logs/forms), archiving of medical devices documents, daily record to check medical devices, requests for equipment maintenance and annual effectiveness report indicated in completed attitude.

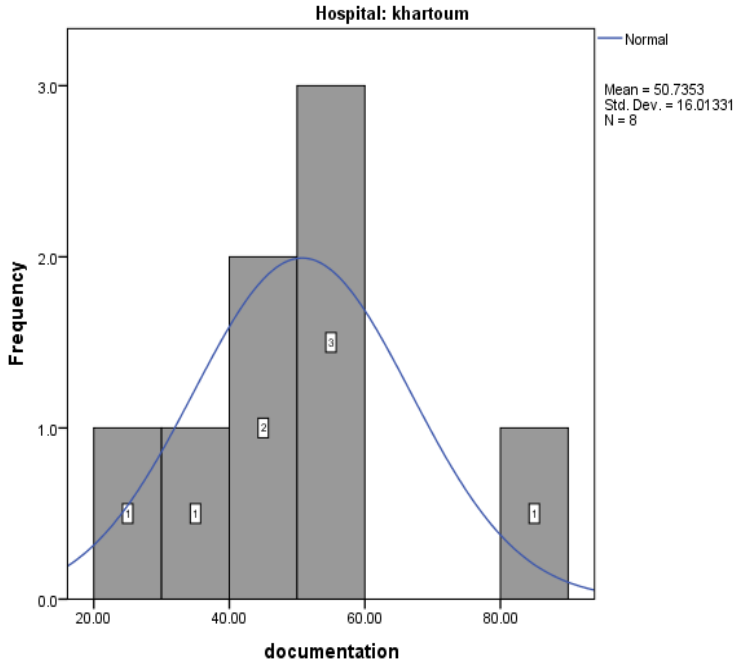

Figure 5.3: Histograms with Normal Distribution Curve for Documents in Khartoum Hospital Each Histogram Displays The Frequency of Documentation Occurs within The Sample.

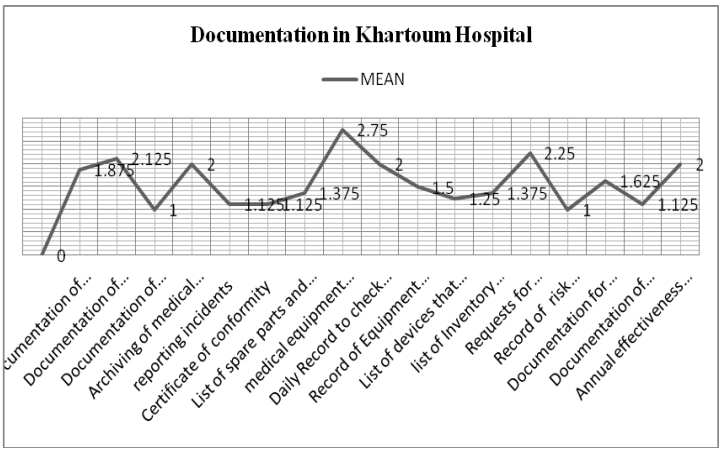

Figure 5.4: Arithmetic Mean for Documents in Khartoum Hospital.

5.2 Proposed Model Policies And Procedures Output

The results obtained are shown in the following tables (5.3, 5.4).

5.2.1 Policies and Procedures in Military Hospital (case1)

The Table 5.3: Policies and Procedures in Case1.

Policies and Procedures	Frequency			Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)			
Equipment management manual	0	17(100)	0	1.0000	.00000	not existing
Policy to create a file for devices	0	2(11.8)	15(88.2)	1.8824	.33211	incomplete
Policies for preventive maintenance	0	15(88.2)	2(11.8)	1.1176	.33211	not existing
Policy to develop and improve the work of devices	0	17(100)	0	1.0000	.00000	not existing
Monitoring of performance indicators	0	17(100)	0	1.0000	.00000	not existing
reporting system	0	0	17(100)	2.0000	.00000	incomplete
Policies for corrective maintenance	0	17(100)	0	1.0000	.00000	not existing
Policies for the Structure and staff	0	1(5.9)	16(94.1)	1.9412	.24254	incomplete
Policies to train operators	0	16(94.1)	1(5.9)	1.0588	.24254	not existing
Policies to train engineers	0	1(5.9)	15(88.2)	1.8824	.33211	incomplete

Table No5.3 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight Policies and procedures in Military Hospital case1 showed the following results: The equipment management manual, policies for preventive maintenance, policy to develop and improve the work of devices, policies for corrective maintenance and policies to train operators specified as not existing attitude. The policy to create a file for devices, reporting system, policies for the structure and staff and policies to train engineers showed as in completed attitude.

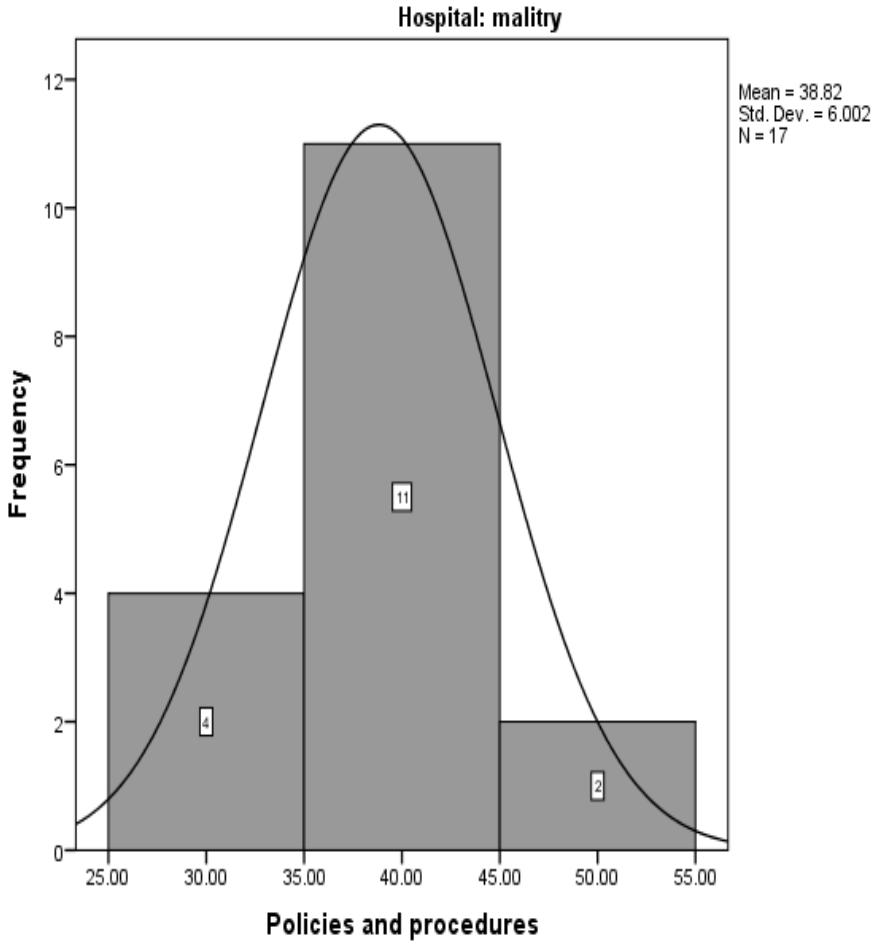

Figure 5.5: Histograms with Normal Distribution Curve for Policies and Procedures in Military Hospital Each Histogram Displays The Frequency of Policies and Procedures Occurs within The Sample.

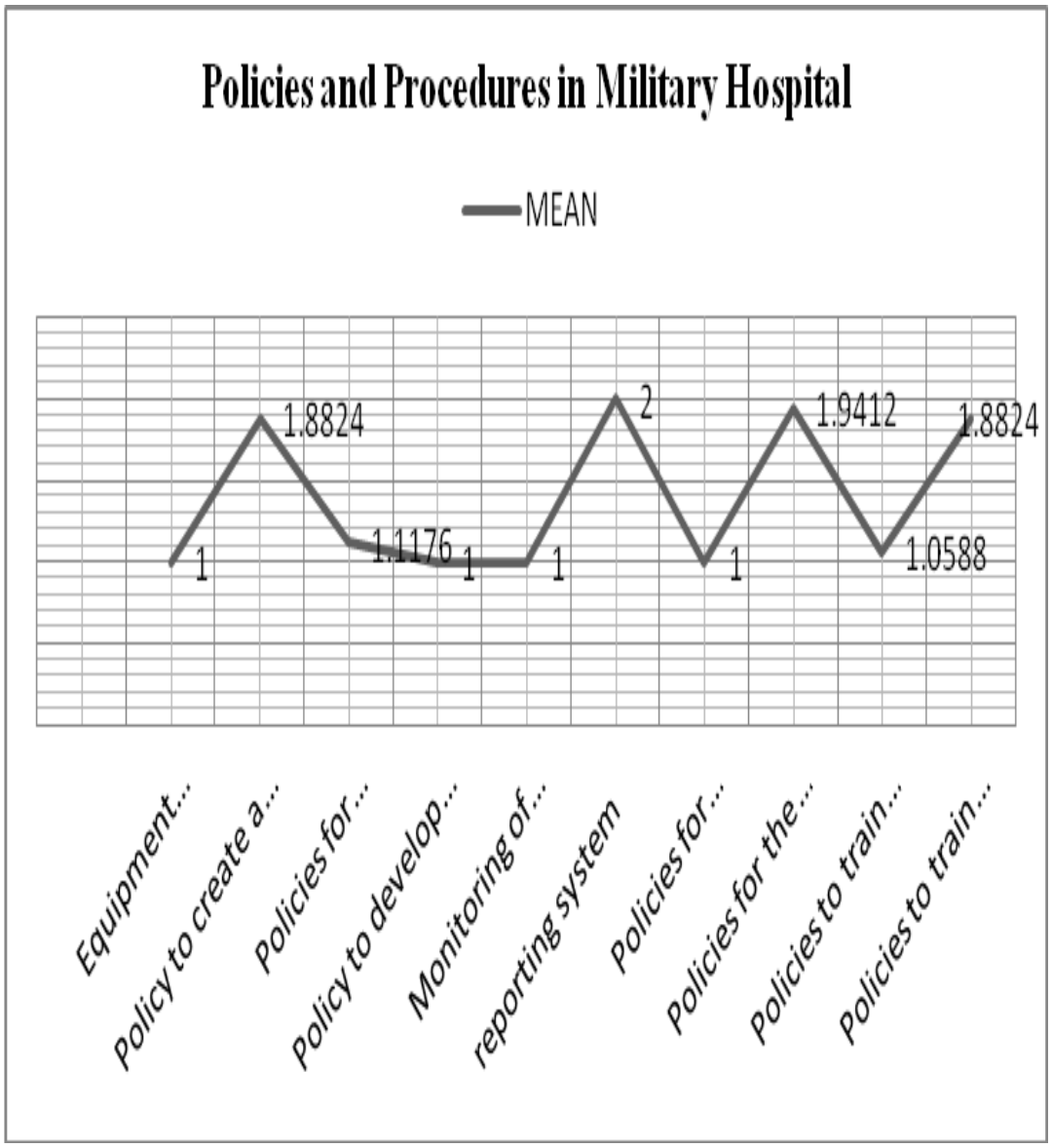

Figure 5.6: Arithmetic Mean for Policies and Procedures in Military Hospital.

5.2.2 Policies and Procedures in Khartoum Hospital (case2)

The Table 5.4: Policies and Procedures in Case2.

Policies and Procedures	Frequency			Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)			
Equipment management manual	0	8(100)	0	1.0000	.00000	not existing
Policy to create a file for devices	0	4(50)	4(50)	1.5000	.53452	not existing
Policies for preventive maintenance	0	8(100)	0	1.0000	.00000	not existing
Policy to develop and improve the work of devices	0	8(100)	0	1.0000	.00000	not existing
Monitoring of performance indicators	0	7(87.5)	1(12.5)	1.1250	.35355	not existing
reporting system	0	3(37.5)	5(62.5)	1.6250	.51755	not existing
Policies for corrective maintenance	0	8(100)	0	1.0000	.00000	not existing
Policies for the Structure and staff	0	8(100)	0	1.0000	.00000	not existing
Policies to train operators	0	8(100)	0	1.0000	.00000	not existing
Policies to train engineers	0	8(100)	0	1.0000	.00000	not existing

Table No 5.4 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight Policies and procedures in Khartoum Hospital case2 showed the following results: The equipment management manual, policy to create a file for devices, policies for preventive maintenance, policy to develop and improve the work of devices, monitoring of performance indicators, reporting system,

policies for corrective maintenance, Policies for the Structure and staff, Policies to train operators and Policies to train engineers indicated existing attitude.

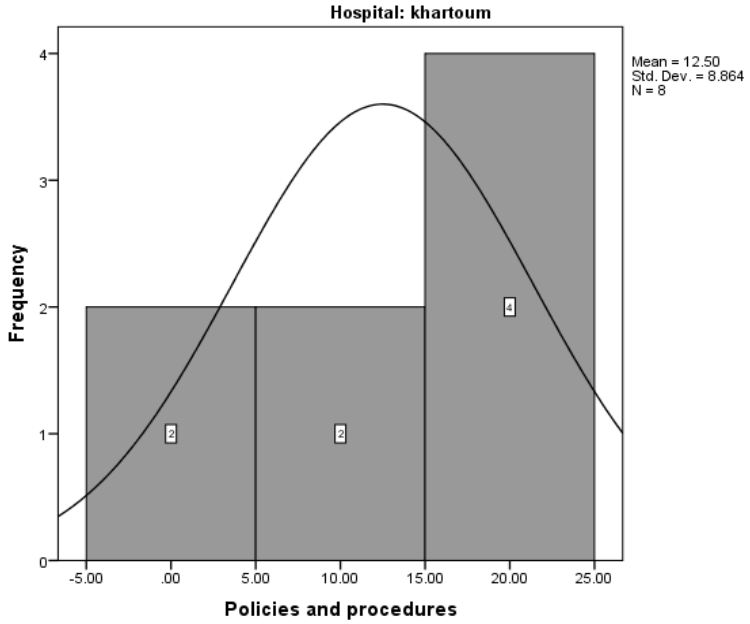

Figure 5.7: Histograms with Normal Distribution Curve for Policies and Procedures in Khartoum Hospital Each Histogram Displays The Frequency of Policies and Procedures Occurs Within The Sample.

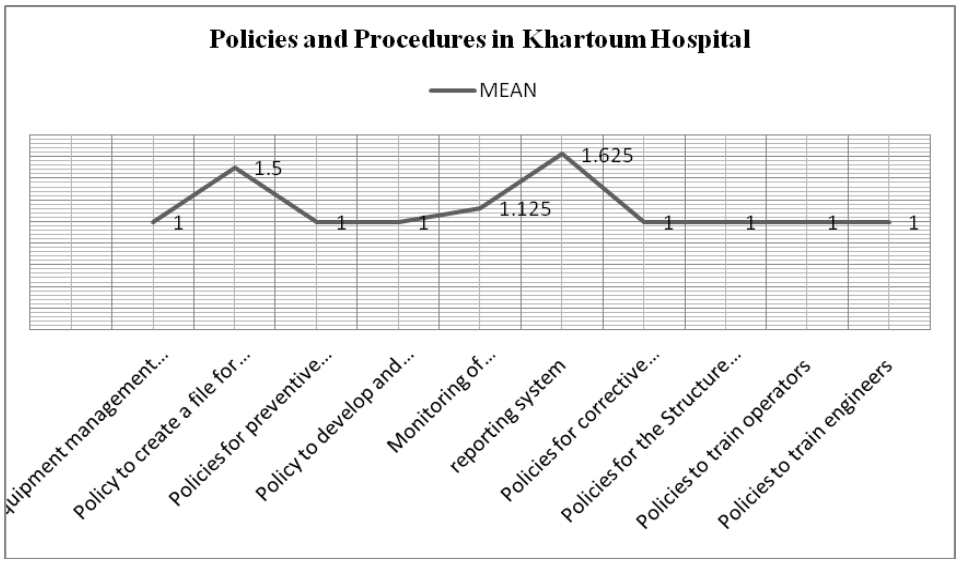

Figure 5.8: Arithmetic Mean for Policies and Procedures in Khartoum Hospital

5.3 Proposed Model Inventory Management Output

The results obtained are shown in the following tables (5.5, 5.6).

5.3.1 Inventory Management in Military Hospital (case1)

The Table 5.5: Inventory Management in Case1.

Inventory Management	Frequency				Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Conducting clinical trials	0	1(5.9)	0	16(94.1)	1.0000	.00000	not existing
Availability of spare parts and consumables	1(5.9)	0	1(5.9)	15(88.2)	2.5000	.70711	existing
Checking risks	1(5.9)	1(5.9)	0	15(88.2)	2.0000	1.41421	incomplete
Checking and saving documents	0	0	1(5.9)	16(94.1)	2.0000	.00000	incomplete
Entering information into the database	2(11.8)	0	0	15(88.2)	3.0000	.00000	existing
Checking store inventory devices by scheduling	1(5.9)	0	0	16(94.1)	3.0000	.00000	existing
Intervals PM for the stored equipment	0	1(5.9)	0	16(94.1)	1.0000	.00000	not existing
plan of distributing devices and spare parts	0	0	1(5.9)	16(94.1)	2.0000	.00000	incomplete
Labeling safety signs	1(5.9)	1(5.9)	0	15(88.2)	2.0000	1.41421	incomplete
Checking temperature in storage	1(5.9)	1(5.9)	0	15(88.2)	2.0000	1.41421	incomplete
Checking humidity in storage	1(5.9)	1(5.9)	0	15(88.2)	2.0000	1.41421	incomplete
appropriate distance between the device and the surfaces	0	2(11.8)	0	15(88.2)	1.0000	.00000	not existing
Storage of devices by classification	0	1(5.9)	0	16(94.1)	1.0000	.00000	not existing

Table No 5.5 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, Inventory Management in Military Hospital case1 showed the following results: The availability of spare parts and consumables, entering information into the database and checking store inventory devices by scheduling indicated existing attitude. The conducting clinical trials, intervals PM for the stored equipment, checking humidity in storage, appropriate distance between the device and the surfaces and storage of devices by classification specified as not existing. The checking risks, checking and saving documents, plan of distributing devices and spare parts, labeling safety signs, checking temperature in storage and checking humidity in storage showed as incompleted attitude.

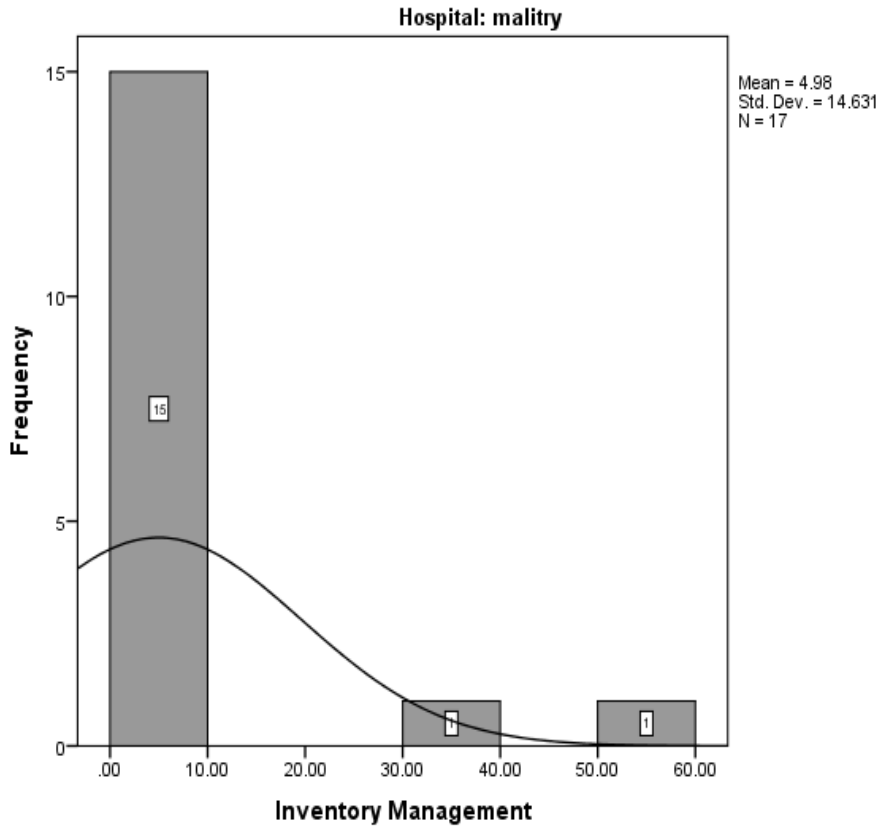

Figure 5.9: Histograms With Normal Distribution Curve for Inventory Management in Military Hospital Each Histogram Displays The Frequency of Inventory Management Occurs Within The Sample.

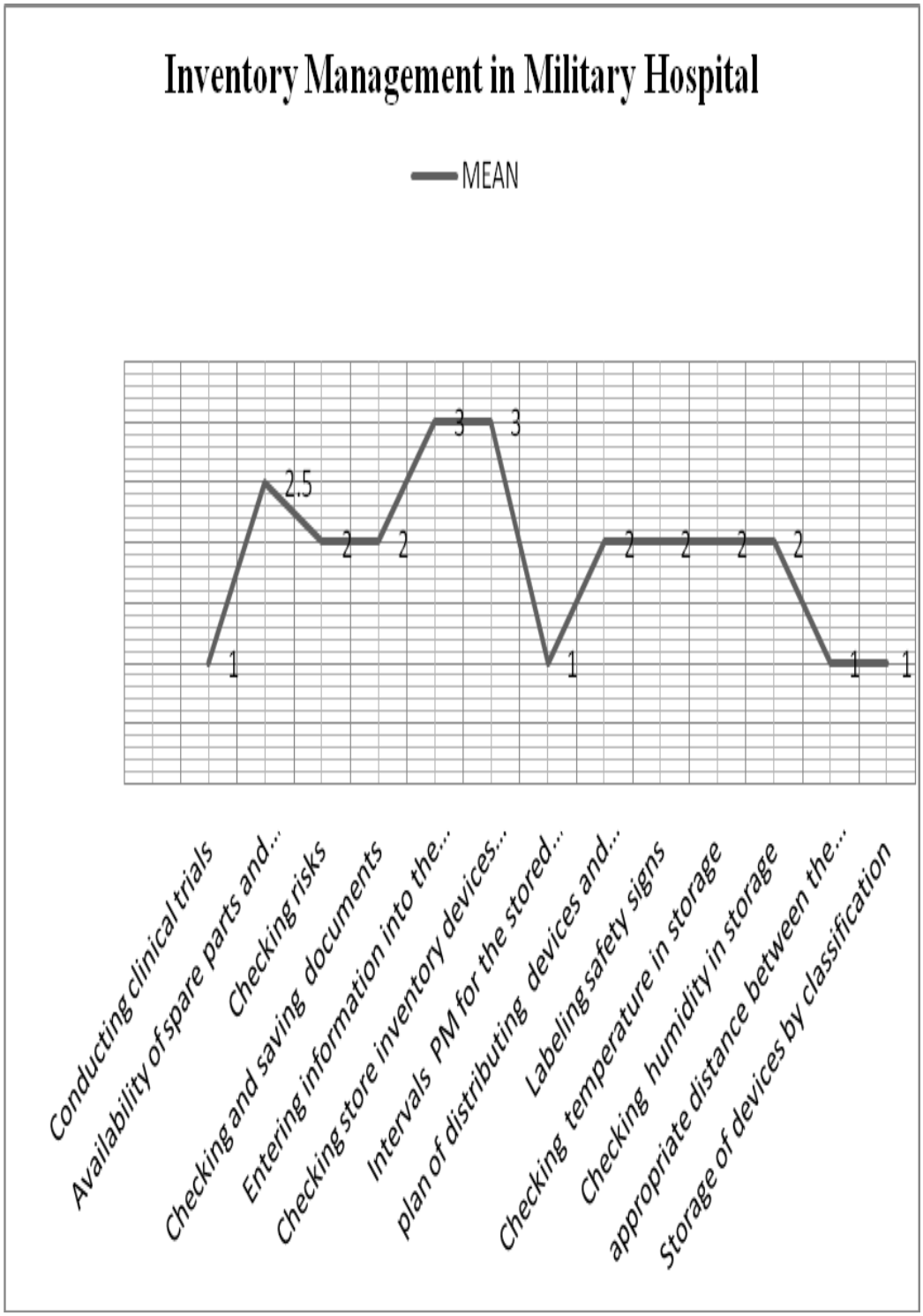

Figure 5.10: Arithmetic Mean for Inventory Management in Military Hospital.

5.3.2 Inventory Management in Khartoum Hospital (case2)

The Table 5.6: Inventory Management in Case 2.

Inventory Management	Frequency				Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Conducting clinical trials	0	5(62.5)	1(12.5)	2(25)	1.1667	.40825	not existing
Availability of spare parts and consumables	0	1(12.5)	5(62.5)	2(25)	1.8333	.40825	incomplete
Checking risks	0	4(50)	2(25)	2(25)	1.3333	.51640	not existing
Checking and saving documents	2(25)	0	4(50)	2(25)	2.3333	.51640	incomplete
Entering information into the database	0	6(75)	0	2(25)	1.0000	.00000	not existing
Checking store inventory devices by scheduling	0	6(75)	0	2(25)	1.0000	.00000	not existing
Intervals PM for the stored equipment	0	6(75)	0	2(25)	1.0000	.00000	not existing
plan of distributing devices and spare parts	0	4(50)	2(25)	2(25)	1.3333	.51640	not existing
Labeling safety signs	0	6(75)	0	2(25)	1.0000	.00000	not existing
Checking temperature in storage	1(12.5)	5(62.5)	0	2(25)	1.3333	.81650	not existing
Checking humidity in storage	0	6(75)	0	2(25)	1.0000	.00000	not existing
appropriate distance between the device and the surfaces	1(12.5)	5(62.5)	0	2(25)	1.3333	.81650	not existing
Storage of devices by classification	0	6(75)	0	2(25)	1.0000	.00000	not existing

Table No 5.6 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, Inventory Management in Khartoum Hospital case2 showed the following results: The conducting clinical trials, checking risks, entering information into the database ,storage of devices by classification , intervals PM for the stored equipment , plan of distributing devices and spare parts labeling safety signs ,checking temperature in storage ,checking humidity in

storage**,** appropriate distance between the device and the surfaces **,**checking store inventory devices by scheduling indicated not existing attitude. The availability of spare parts and consumables and checking and saving documents specified as incompleted attitude.

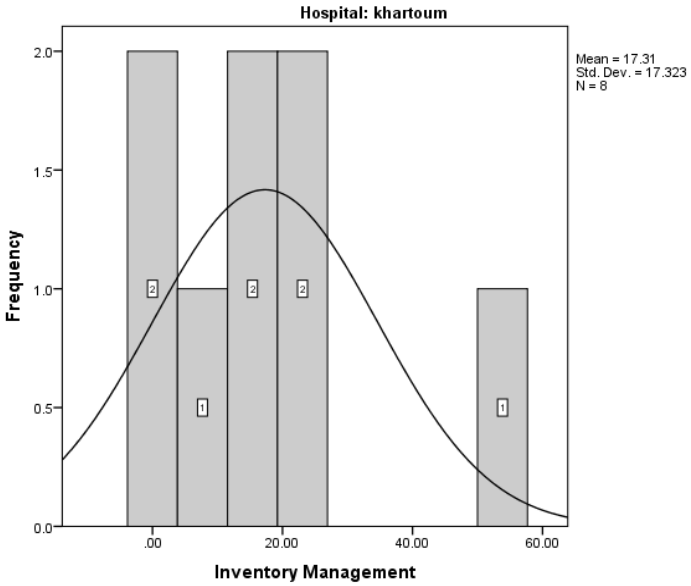

Figure 5.11: Histograms with Normal Distribution Curve for Inventory Management in Khartoum Hospital Each Histogram Displays The Frequency of Inventory Management Occurs within The Sample.

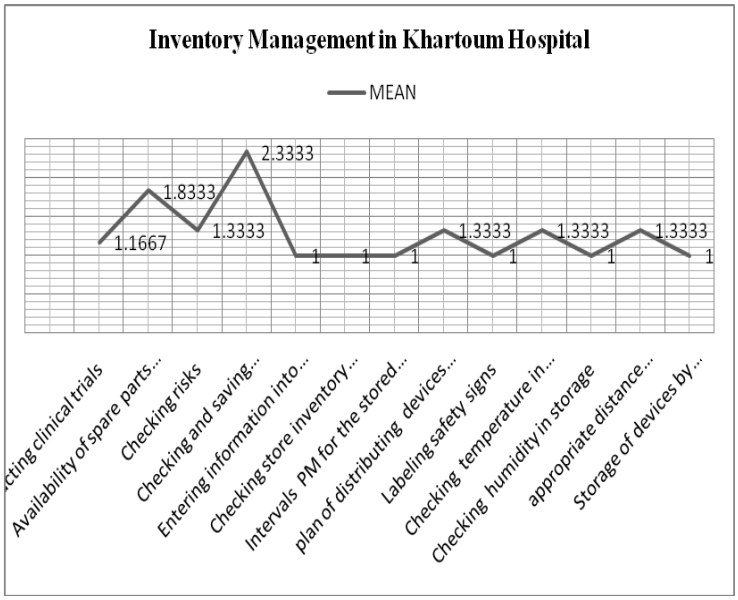

Figure 5.12: Arithmetic Mean for Inventory Management in Khartoum Hospital

5.4 Proposed Model Safety Output

The results obtained are shown in the following tables (5.7, 5.8).

5.4.1 Safety in Military Hospital (case1)

The Table 5.7: Safety in Case 1.

Safety	Frequency				Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Electrical safety standard 3 wire AC line cord or equivalent	0	0	17(100)	0	2.0000	.00000	incomplete
Safety electrical wiring	16(94.1)	0	1(5.9)	0	2.9412	.24254	existing
Fire system	15(88.2)	2(11.8)	0	0	2.7647	.66421	existing
Use gloves during maintenance	16(94.1)	0	1(5.9)	0	2.9412	.24254	existing
Electrical Earthing systems	10(58.8)	7(41.2)	0	0	2.1765	1.01460	incomplete
Electric generator (ATS)	15(88.2)	2(11.8)	0	0	2.7647	.66421	existing
Electrical safety testing	0	17(100)	0	0	1.0000	.00000	not existing
Environmental safety testing	0	17(100)	0	0	1.0000	.00000	not existing
The warning signs	1(5.9)	15(88.2)	1(5.9)	0	1.1765	.52859	not existing
Cleaning and disinfection devices	15(88.2)	2(11.8)	0	0	2.7647	.66421	existing

Table No5.7 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, Safety in Military Hospital case1 showed the following results: The safety electrical wiring, fire system, use gloves during maintenance and cleaning and disinfection devices showed as existing attitude. The electrical safety testing, environmental safety testing and the warning signs specified as

not existing attitude. The electrical safety standard 3 wire AC line cord or equivalent and electrical ear thing systems indicated incomplete attitude.

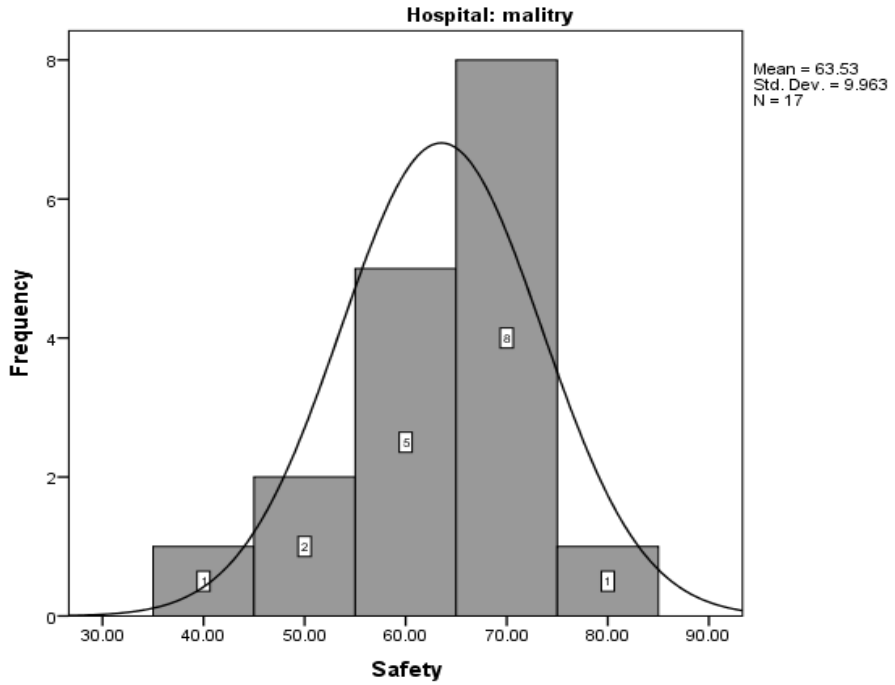

Figure 5.13: Histograms with Normal Distribution Curve for Safety in Military Hospital Each Histogram Displays The Frequency of Safety in Military Occurs within The Sample.

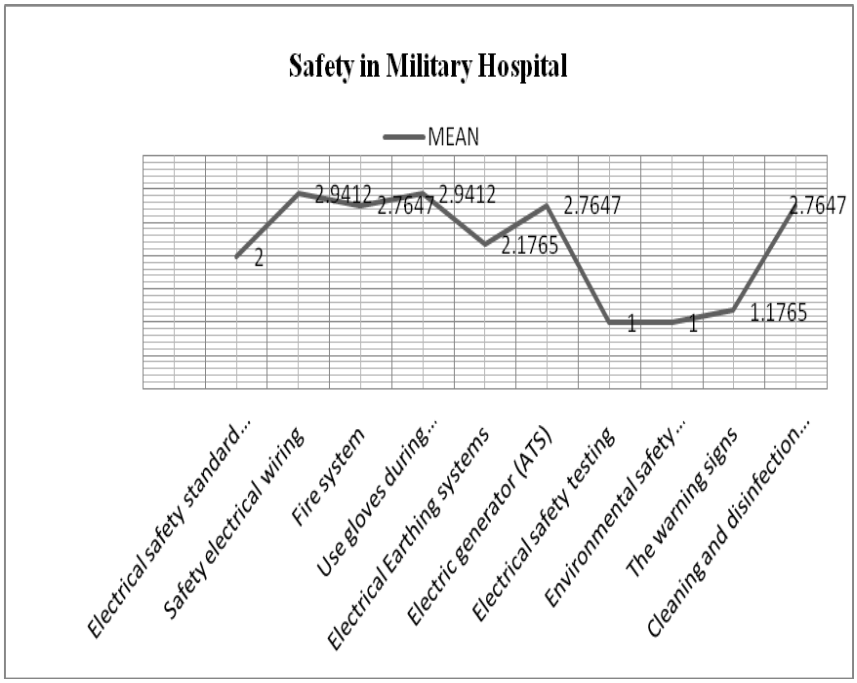

Figure 5.14: Arithmetic Mean for Safety in Military Hospital.

5.4.2 Safety in Khartoum Hospital(case2)

The Table 5.8: Safety in Case 2.

Safety	Frequency				Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Electrical safety standard 3 wire AC line cord or equivalent	2(25)	0	6(75)	0	2.2500	.46291	incomplete
Safety electrical wiring	3(37.5)	0	5(62.5)	0	2.3750	.51755	existing
Fire system	5(62.5)	1(12.5)	2(25)	0	2.5000	.75593	existing
Use gloves during maintenance	3(37.5)	1(12.5)	4(50)	0	2.2500	.70711	incomplete
Electrical Earthing systems	0	6	2(25)	0	1.2500	.46291	not existing
Electric generator (ATS)	6(75)	1(12.5)	1(12.5)	0	2.6250	.74402	existing
Electrical safety testing	0	8(100)	0	0	1.0000	.00000	not existing
Environmental safety testing	0	8(100)	0	0	1.0000	.00000	not existing
The warning signs	0	5(62.5)	3(37.5)	0	1.3750	.51755	not existing
Cleaning and disinfection devices	1(12.5)	2(25)	5(62.5)	0	1.8750	.64087	incomplete

Table No 5.8 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, Safety in Khartoum Hospital case2 showed the following results: The safety electrical wiring, Fire system and electric generator (ATS) indicated existing attitude. The electrical earthing systems, electrical safety testing, environmental safety testing and the warning signs showed as not

existing attitude. The electrical safety standard 3 wire AC line cord or equivalent ,use gloves during maintenance and cleaning and disinfection devices specified as incomplete attitude.

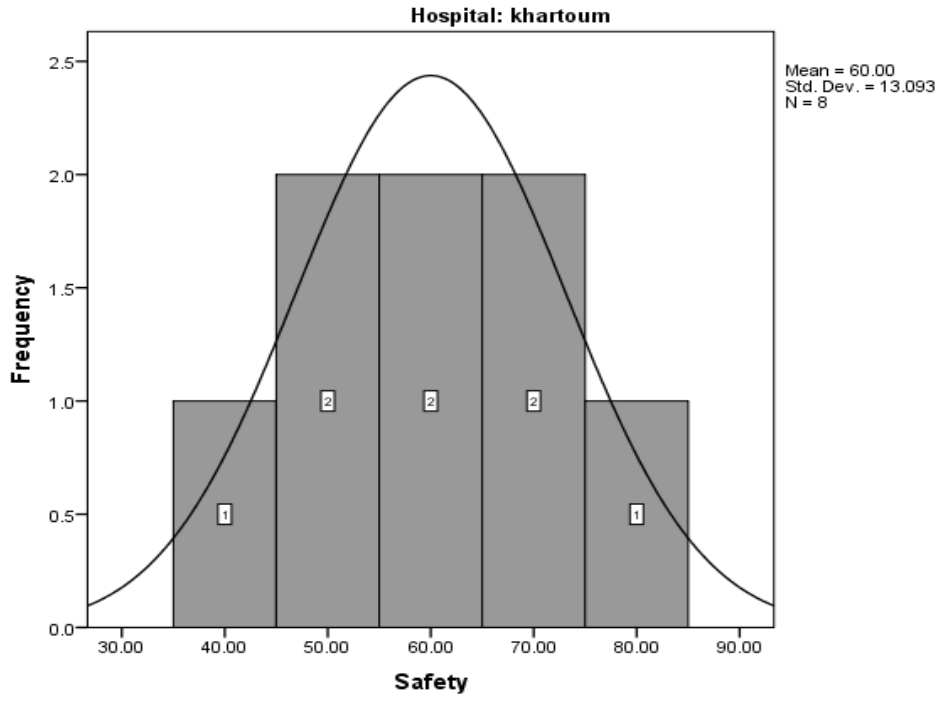

Figure 5.15: Histograms with Normal Distribution Curve for Safety in Khartoum Hospital Each Histogram Displays The Frequency of Safety Occurs Within The Sample.

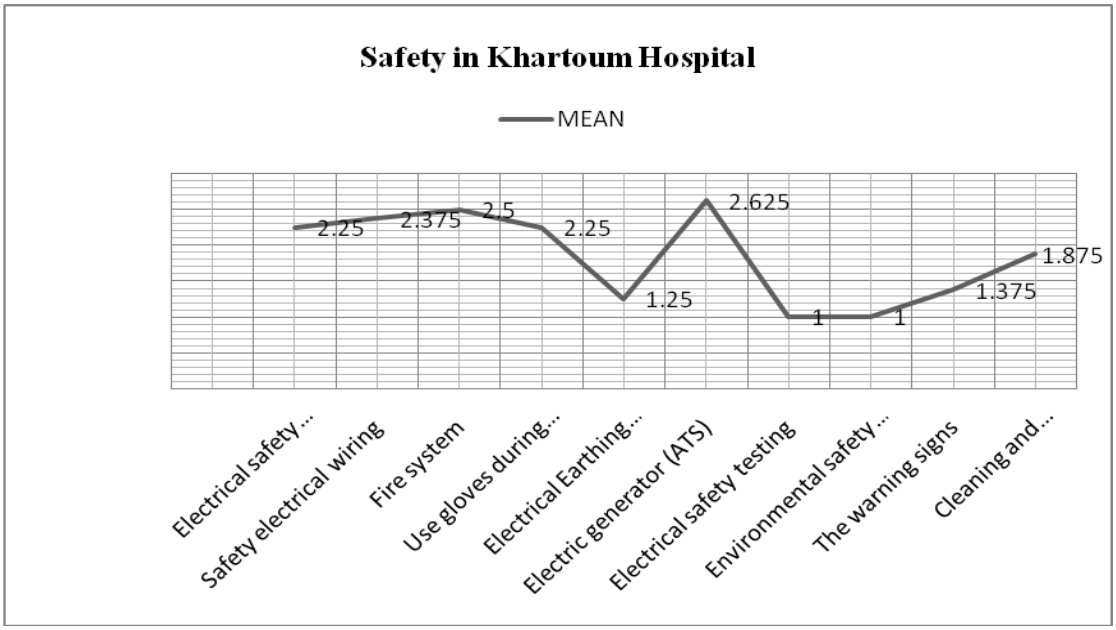

Figure 5.16: Arithmetic Mean for Safety in Khartoum Hospital.

5.5 Proposed Model Performance Vocational Output

The results obtained are shown in the following tables (5.9, 5.10).

5.5.1 Performance Vocational in Military Hospital (case1)

The Table 5.9: Performance Vocational in Case 1.

Performance Vocational	Frequency				Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Service and maintenance of medical equipment	16(94.1)	0	1(5.9)	0	2.9412	.24254	existing
Development and implementation of Medical equipment management plan	0	17(100)	0	0	1.0000	.00000	not existing
Management operating and maintenance manuals	5(29.4)	7(41.2)	5(29.4)	0	1.8824	.85749	incomplete
Management of maintenance contracts	1(5.9)	1(5.9)	3(17.6)	12(70.6)	2.0000	.70711	incomplete
Development and implementation of replacement programs	1(5.9)	16(94.1)	0	0	1.1176	.48507	not existing
Knowledge of international standards and recent recommendations	0	12(70.6)	5(29.4)	0	1.2941	.46967	not existing
The ability to investigate incidents of medical devices	17(100)	0	0	0	3.0000	.00000	existing
Participate in the purchase and sale of devices	1(5.9)	16(94.1)	0	0	1.1176	.48507	not existing
Receiving and inspection new devices	10(58.8)	1(5.9)	1(5.9)	5(29.4)	2.7500	.62158	existing
Coordinating training on the operation of medical devices	3(17.6)	13(76.5)	1(5.9)	0	1.4118	.79521	not existing
Continuous Training	6(35.3)	8(47.1)	3(17.6)	0	1.8824	.92752	incomplete

Table No 5.9 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, Performance Vocational in Military Hospital case1 showed the following results: The service and maintenance of medical equipment, the ability to investigate incidents of medical devices and receiving and inspection new devices indicated existing attitude. The development and implementation of Medical equipment management plan, development and implementation of replacement programs, knowledge of international standards and recent recommendations, participate in the purchase and sale of devices and Coordinating training on the operation of medical devices showed as not existing attitude. The management operating and maintenance manuals, management of maintenance contracts and continuous Training specified as incomplete attitude.

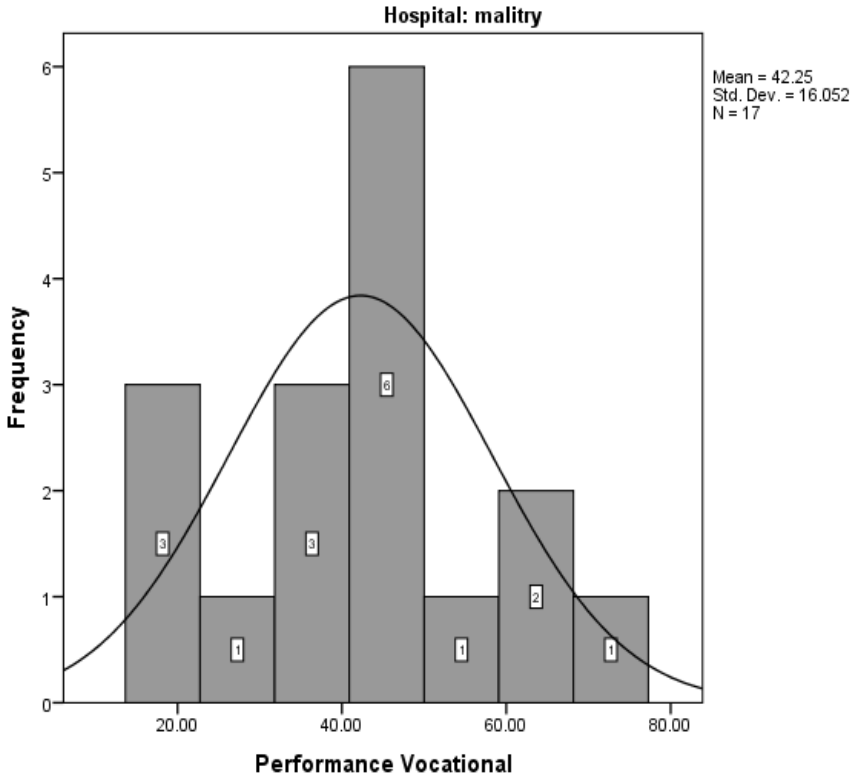

Figure 5.17: Histograms with Normal Distribution Curve for Performance Vocational in Military Hospital Each Histogram Displays The Frequency of Performance Vocational Occurs within The Sample.

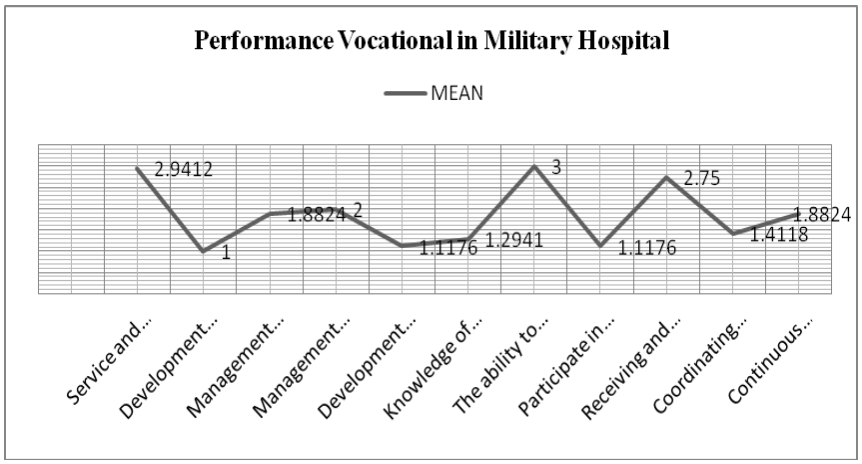

Figure 5.18: Arithmetic Mean for Performance Vocational in Military Hospital.

5.5.2 Performance Vocational in Khartoum Hospital (case2)

The Table 5.10: Performance Vocational in Case 2.

Performance Vocational	Frequency				MEAN	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Service and maintenance of medical equipment	4(50)	0	4(50)	0	2.5000	.53452	existing
Development and implementation of Medical equipment management plan	0	8(100)	0	0	1.0000	.00000	not existing
Management operating and maintenance manuals	3(37.5)	0	5(62.5)	0	2.3750	.51755	existing
Management of maintenance contracts	1(12.5)	0	1(12.5)	6(75)	2.5000	.70711	existing
Development and implementation of replacement programs	0	1(12.5)	7(87.5)	0	1.8750	.35355	incomplete
Knowledge of international standards and recent recommendations	0	5(62.5)	3(37.5)	0	1.3750	.51755	not existing
The ability to investigate incidents of medical devices	2(25)	0	5(62.5)	1(12.5)	2.2857	.48795	incomplete
Participate in the purchase and sale of devices	3(37.5)	2(25)	3(37.5)	0	2.1250	.83452	incomplete
Receiving and inspection new devices	7(87.5)	0	1(12.5)	0	2.8750	.35355	existing
Coordinating training on the operation of medical devices	1(12.5)	2(25)	5(62.5)	0	1.8750	.64087	incomplete
Continuous Training	0	6(75)	2(25)	0	1.2500	.46291	not existing

This table represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, Performance Vocational in Khartoum Hospital case2 showed the following results: The service and maintenance of medical equipment, management operating and maintenance manuals, management of maintenance contracts and receiving and inspection new devices specified as existing attitude. The development and implementation of medical equipment management plan, knowledge of international standards and recent recommendations and the continuous training indicated not existing attitude. The development and implementation of replacement programs, the ability to investigate incidents of medical devices, participate in the purchase and sale of devices and coordinating training on the operation of medical devices showed as incomplete attitude.

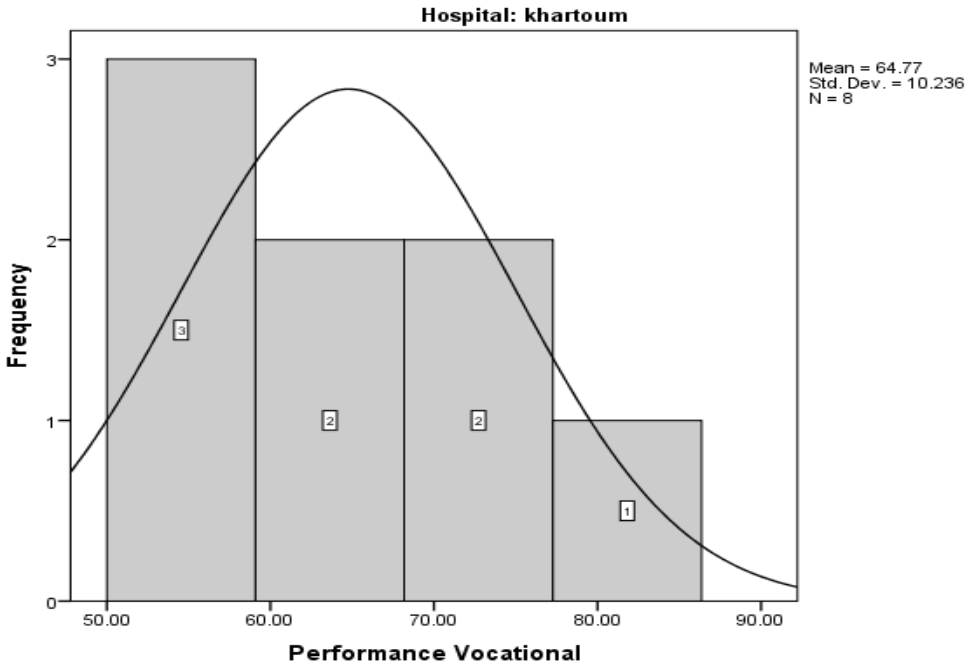

Figure 5.19: Histograms with Normal Distribution Curve for Performance Vocational in Khartoum Hospital Each Histogram Displays The Frequency of Performance Vocational Occurs within The Sample.

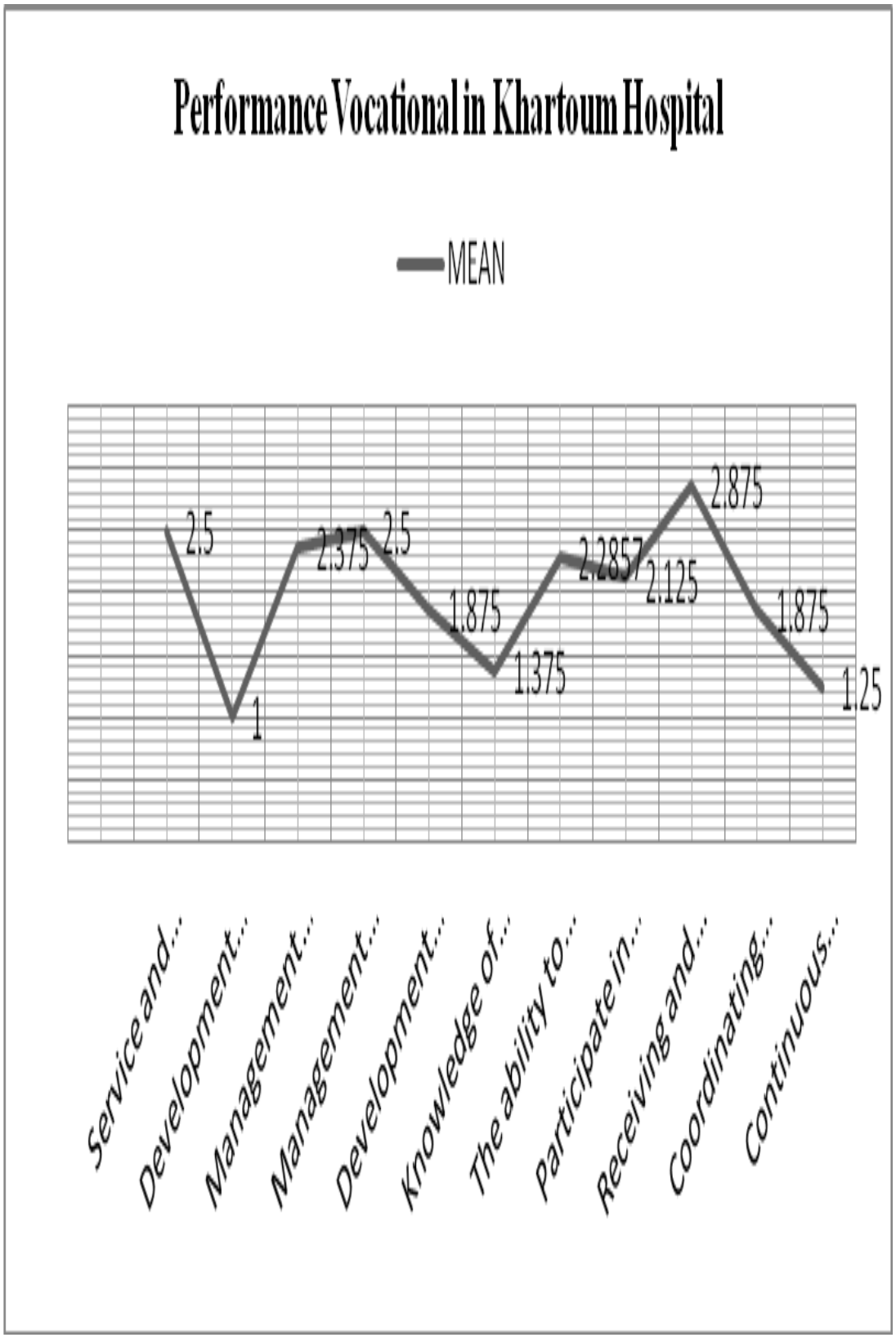

Figure 5.20: Arithmetic Mean for Performance Vocational in Khartoum Hospital.

5.6 Proposed Model Visual Inspection Output

The results obtained are shown in the following tables (5.11, 5.12).

5.6.1 Visual Inspection in Military Hospital (case1)

The Table 5.11: Visual Inspection in Case 1.

Visual inspection	Frequency				Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Presence of all accessories required for proper operation	15(88.2)	0	1(5.9)	1(5.9)	2.9375	.25000	existing
standard operating procedure (SOP)	1(5.9)	10(58.8)	5(29.4)	1(5.9)	2.0625	2.46221	incomplete
Proper operation of the equipment as specified in the manufacturer's service literature.	1(5.9)	1(5.9)	14(82.4)	1(5.9)	2.0000	.36515	incomplete
Electrical connectors(jacks, receptacles, or plugs)	17(100)	0	0	0	3.0000	.00000	existing
Alarms	16(94.1)	0	0	1(5.9)	3.0000	.00000	existing
Circuit Breaker/Fuse	16(94.1)	0	0	1(5.9)	3.0000	.00000	existing
Controls/Switches	16(94.1)	0	0	1(5.9)	3.0000	.00000	existing
Indicators/Displays	16(94.1)	0	0	1(5.9)	3.0000	.00000	existing
Audible Signals	16(94.1)	0	0	1(5.9)	3.0000	.00000	existing
Battery/Charger	16(94.1)	0	0	1(5.9)	3.0000	.00000	existing
Availability and validity of consumables	14(82.4)	0	2(11.8)	1(5.9)	2.8750	.34157	existing
Equipment cards	11(64.7)	5(29.4)	1(5.9)	0	2.3529	.93148	existing
Connecting the device to the grounding system	9(52.9)	8(47.1)	0	0	2.0588	1.02899	incomplete
Calibration stickers	0	17(100)	0	0	1.0000	.00000	not existing
Suitable environment for equipment	16(94.1)	0	1(5.9)	0	2.9412	.24254	existing
Freeing device internally and externally from rust and corrosion, liquids and dust	15(88.2)	0	2(11.8)	0	2.8824	.33211	existing
Doors , knobs and the other of the moving parts are working well	15(88.2)	1(5.9)	0	1(5.9)	2.8750	.50000	existing
checking the Component holders, clips, and receptacles	15(88.2)	1(5.9)	0	1(5.9)	2.8750	.50000	existing
Checking the Nuts, bolts, screws, and other hardware	15(88.2)	1(5.9)	0	1(5.9)	2.8750	.50000	existing

Table No 5.11 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, performance vocational in Military Hospital case1 showed the following results: The presence of all accessories required for proper operation, electrical connectors (jacks, receptacles, or plugs), alarms, circuit breaker/fuse, controls/switches, indicators/displays, audible signals, battery/charger availability and validity of consumables, equipment cards, suitable environment for equipment ,checking the Nuts, bolts, screws, and other hardware ,doors , knobs and the other of the moving parts are working well ,checking the component holders, clips, and receptacles and freeing device internally and externally from rust and corrosion, liquids and dust indicated existing attitude. The calibration stickers specified as not existing attitude. The standard operating procedure (SOP), proper operation of the equipment as specified in the manufacturer's service literature and connecting the device to the grounding system showed as incomplete attitude.

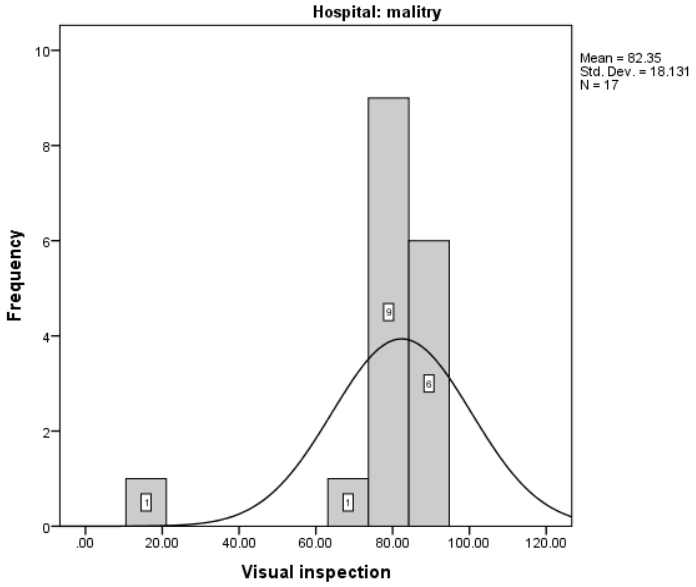

Figure 5.21: Histograms with Normal Distribution Curve for Visual Inspection in Military Hospital Each Histogram Displays The Frequency of Visual Inspection Occurs within The Sample.

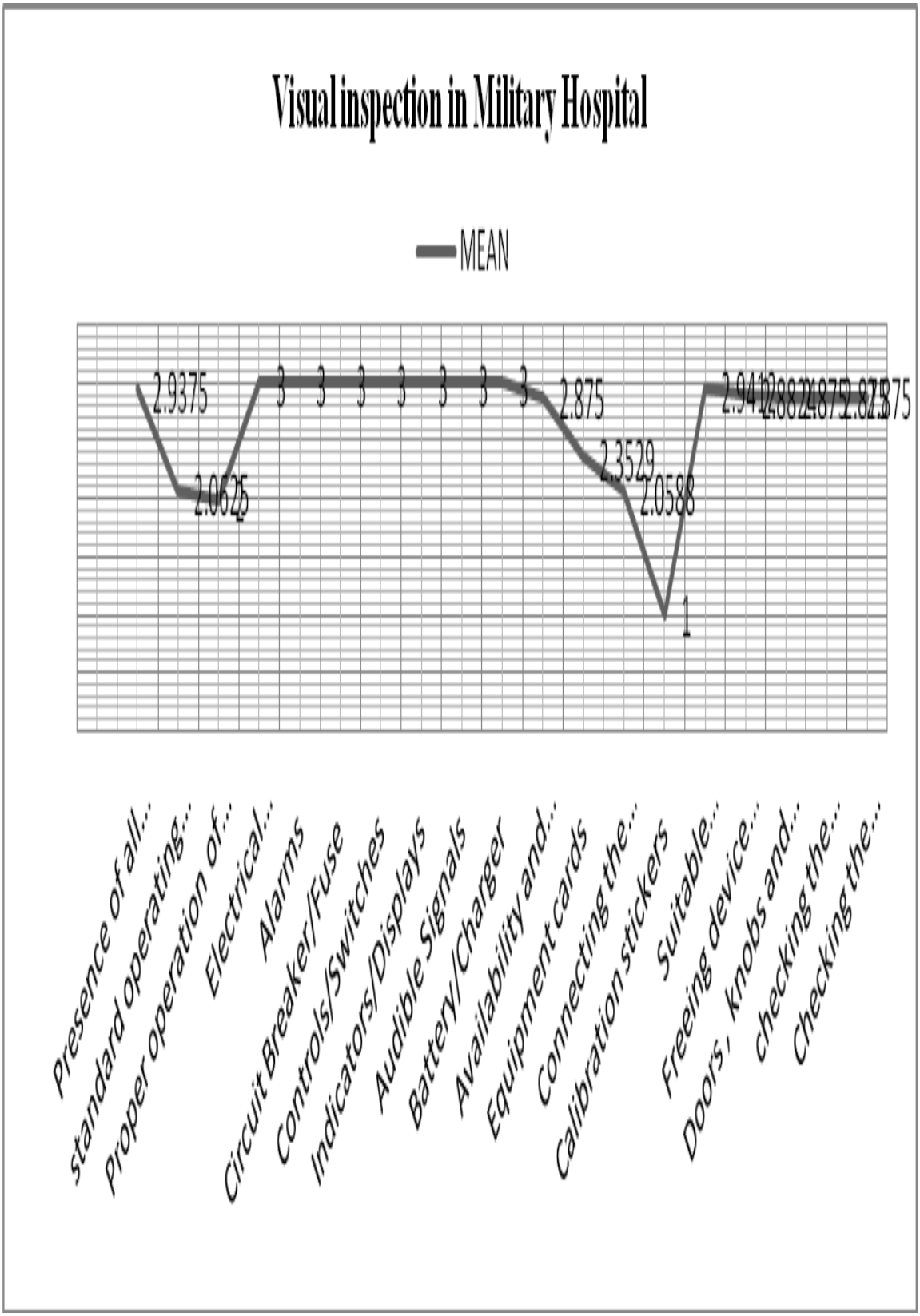

Figure 5.22: Arithmetic Mean for Visual Inspection in Military Hospital.

5.6.2 Visual Inspection in Khartoum Hospital (case2)

The Table 5.12: Visual Inspection in Case 2.

Visual Inspection	Frequency				Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Presence of all accessories required for proper operation	4(50)	0	3(37.5)	1(12.5)	2.5714	.53452	existing
standard operating procedure (SOP)	0	5(62.5)	2(25)	1(12.5)	1.2857	.48795	not existing
Proper operation of the equipment as specified in the manufacturer's service literature.	0	0	7(87.5)	0	2.0000	.00000	incomplete
Electrical connectors(jacks, receptacles, or plugs)	2(25)	0	6(75)	0	2.2500	.46291	incomplete
Alarms	6(75)	0	0	2(25)	3.0000	.00000	existing
Circuit Breaker/Fuse	6(75)	0	1(12.5)	0	2.8571	.37796	existing
Controls/Switches	4(50)	0	3(37.5)	1(12.5)	2.5714	.53452	existing
Indicators/Displays	5(62.5)	0	2(25)	1(12.5)	2.7143	.48795	existing
Audible Signals	6(75)	0	0	2(25)	3.0000	.00000	existing
Battery/Charger	4	0	2(25)	2(25)	2.6667	.51640	existing
Availability and validity of consumables	1(12.5)	0	6(75)	1(12.5)	2.1429	.37796	incomplete
Equipment cards	0	7(87.5)	1(12.5)	0	1.1250	.35355	not existing
Connecting the device to the grounding system	0	6(75)	2(25)	0	1.2500	.46291	not existing
Calibration stickers	1(12.5)	7(87.5)	0	0	1.2500	.70711	not existing
Suitable environment for equipment	4(50)	0	4(50)	0	2.5000	.53452	existing
Freeing device internally and externally from rust and corrosion, liquids and dust	2(25)	3(37.5)	2(25)	1(12.5)	1.8571	.89974	incomplete
Doors , knobs and the other of the moving parts are working well	4(50)	0	3(37.5)	1(12.5)	2.5714	.53452	existing
checking the Component holders, clips, and receptacles	1(12.5)	1(12.5)	5(62.5)	1(12.5)	2.0000	.57735	incomplete
Checking the Nuts, bolts, screws, and other hardware	2(25)	0	5(62.5)	1(12.5)	2.2857	.48795	incomplete

Table No 5.12 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, Visual inspection in Khartoum Hospital case2 showed the following results: The presence of all accessories required for proper operation, alarms, circuit breaker / fuse, controls/ switches, indicators/displays, audible signals, battery/charger, suitable environment for equipment and doors, knobs and the other of the moving parts are working well specified as existing attitude. The standard operating procedure (SOP), equipment cards, connecting the device to the grounding system and calibration stickers showed as not existing attitude. The proper operation of the equipment as specified in the manufacturer's service literature, electrical connectors (jacks, receptacles, or plugs), availability and validity of consumables, freeing device internally and externally from rust and corrosion, liquids and dust indicated incomplete attitude.

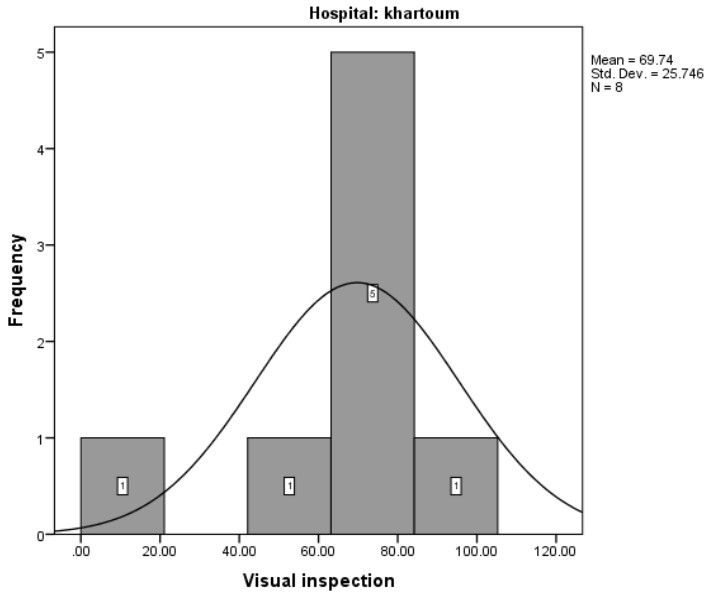

Figure 5.23: Histograms with Normal Distribution Curve for Visual Inspection in Khartoum Hospital Each Histogram Displays The Frequency of Visual Inspection Occurs within The Sample.

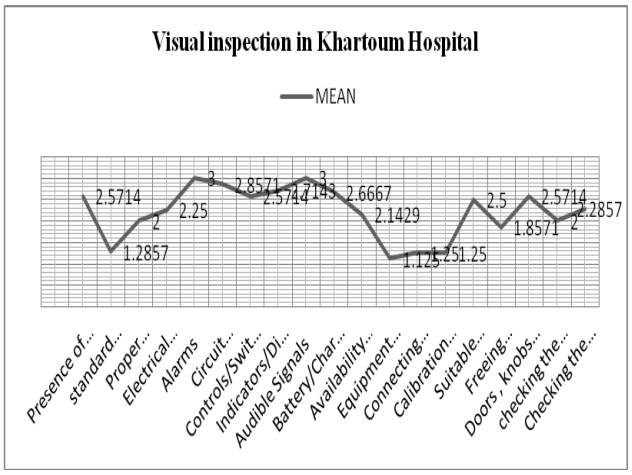

Figure 5.24: Arithmetic Mean for Visual Inspection in Khartoum Hospital.

5.7 Proposed Model Preventive Maintenance Output

The results obtained are shown in the following tables (5.13, 5.14).

5.7.1 Preventive Maintenance in Military Hospital (case1)

The Table 5.13: Preventive Maintenance in Case 1.

Preventive Maintenance	Frequency				Mean	Std. Deviation	Attitude
	Existing	Not existing	Incomplete	Missing			
Schedule illustrating dates of periodic maintenance	1(5.9)	16(94.1)	0	0	1.1176	.48507	not existing
Providing the necessary consumables for periodic preventive maintenance	1(5.9%)	14(82.4%)	2(11.8%)	0	1.2353	.56230	not existing
Making the card or file for follow-up	2(11.8%)	14(82.4%)	1(5.9%)	0	1.2941	.68599	not existing
PM procedures	0	17(100)	0	0	1.0000	.00000	not existing
inspections and testing of medical equipment	1(5.9)	16(94.1)	0	0	1.1176	.48507	not existing
calibration of equipment	0	17(100)	0	0	1.0000	.00000	not existing

Table No 5.13 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, Preventive maintenance in Military Hospital case1 showed the following results: The schedule illustrating dates of periodic maintenance, providing the necessary consumables for periodic preventive maintenance, making the card or file for follow-up, PM procedures, inspections and testing of medical equipment and calibration of equipment indicated not existing attitude.

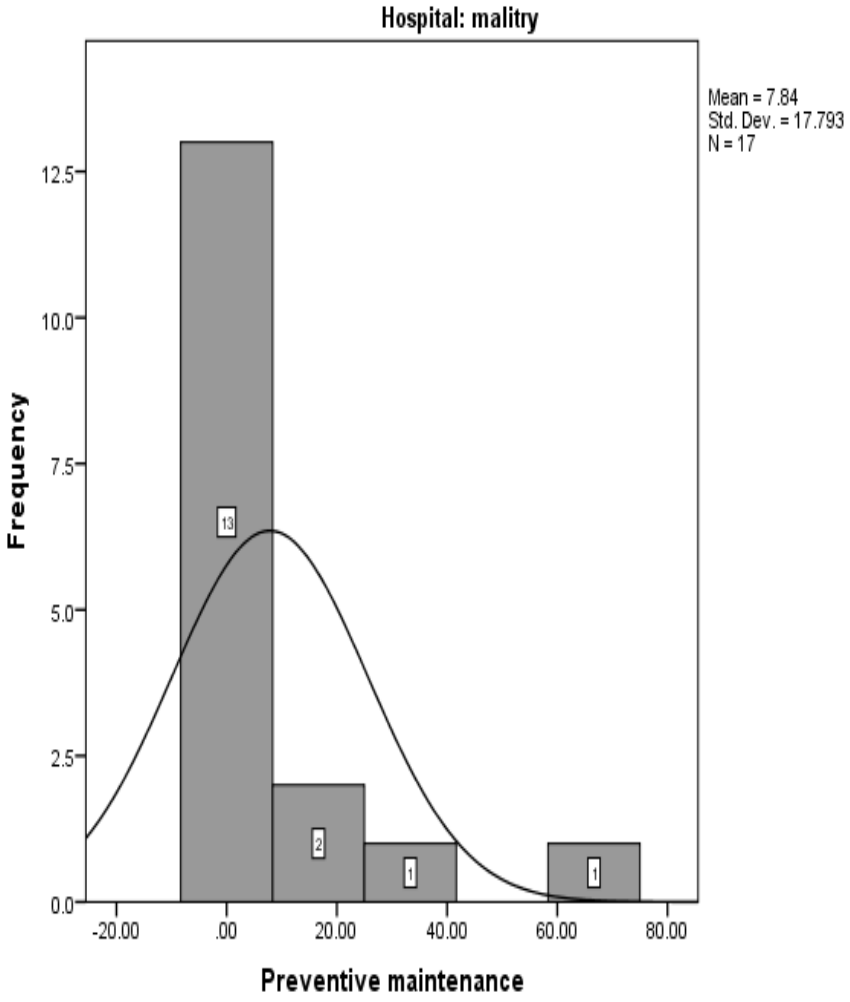

Figure 5.25: Histograms with Normal Distribution Curve for Preventive Maintenance in Military Hospital Each Histogram Displays The Frequency of Preventive Maintenance Occurs within The Sample.

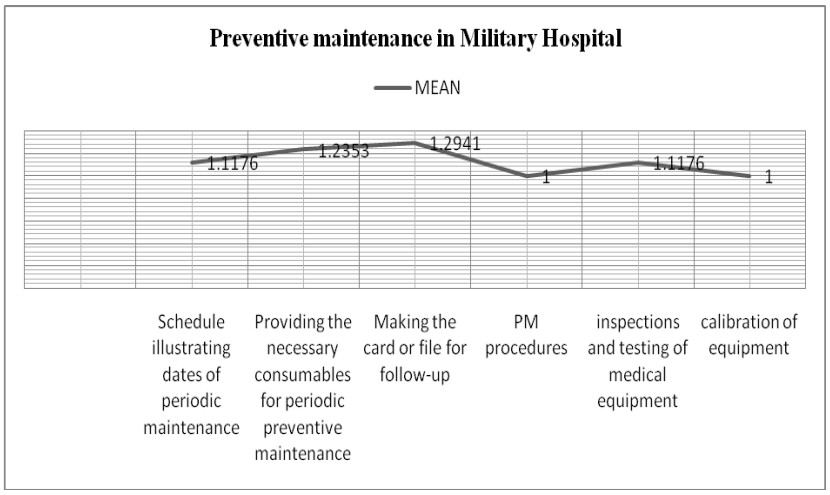

Figure 5.26: Arithmetic Mean for Preventive Maintenance in Military Hospital.

5.7.2 Preventive Maintenance in Khartoum Hospital (case2)

The Table 5.14: Preventive Maintenance in Case 2.

Preventive Maintenance	Frequency				Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Schedule illustrating dates of periodic maintenance	0	7(87.5)	1(12.5)	0	1.1250	.35355	not existing
Providing the necessary consumables for periodic preventive maintenance	0	5(62.5)	3(37.5)	0	1.3750	.51755	not existing
Making the card or file for follow-up	1(12.5)	2(25)	5(62.5)	0	1.8750	.64087	incomplete
PM procedures	0	8(100)	0	0	1.0000	.00000	not existing
inspections and testing of medical equipment	0	7(87.5)	1(12.5)	0	1.1250	.35355	not existing
calibration of equipment	0	8(100)	0	0	1.0000	.00000	not existing

Table No 5.14 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, preventive maintenance in Khartoum Hospital case2 showed the following results: The schedule illustrating dates of periodic maintenance, providing the necessary consumables for periodic preventive maintenance, PM procedures, inspections and testing of medical equipment and calibration of equipment indicated not existing attitude. The making the card or file for follow-up showed as incomplete attitude.

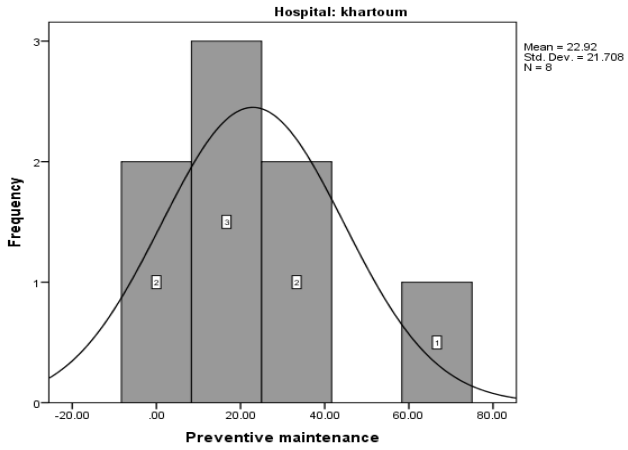

Figure 5.27: Histograms with Normal Distribution Curve for Preventive Maintenance in Khartoum Hospital Each Histogram Displays The Frequency of Preventive Maintenance Occurs within The Sample.

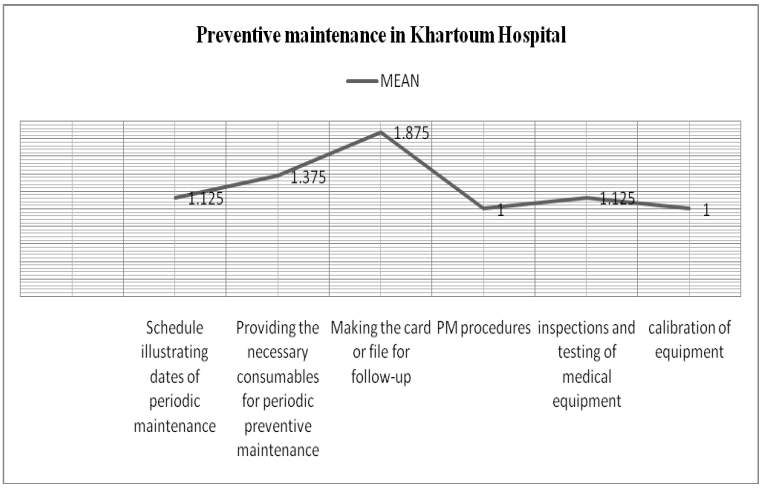

Figure 5.28: Arithmetic Mean for Preventive Maintenance in Khartoum Hospital.

5.8 Proposed Model Corrective Maintenance Output

The results obtained are shown in the following tables (5.15, 5.16).

5.8.1 Corrective Maintenance in Military Hospital (case1)

The Table 5.15: Corrective Maintenance in Case 1.

Corrective Maintenance	Frequency				Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Failure/user error summary reports	16(94.1)	0	1(5.9)	0	2.9412	.24254	existing
Ordering engineers for maintenance	17(100)	0	0	0	3.0000	.00000	existing
Repairing devices in the warranty period	5(29.4)	3(17.6)	3(17.6)	6(35.3)	2.1818	.87386	incomplete
maintenance contracts	2(11.8)	1(5.9)	4(23.5)	10(58.8)	2.1429	.69007	incomplete
delivery system for Equipment which has been repaired	17(100)	0	0	0	3.0000	.00000	existing
Availability of spare parts	10(58.8)	4(23.5)	3(17.6)	0	2.3529	.86177	existing
Corrective maintenance procedures	0	17(100)	0	0	1.0000	.00000	not existing
Service manual	2(11.8)	8(47.1)	7(41.2)	0	1.6471	.70189	not existing
Availability of maintenance tools	12(70.6)	2(11.8)	3(17.6)		2.5882	.71229	existing
Calibration after maintenance	0	17(100)	0	0	1.0000	.00000	not existing

Table No 5.15 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, corrective maintenance in Military Hospital case1 showed the following results: The failure/user error summary reports, ordering engineers for maintenance, delivery system for Equipment which has been repaired, availability of spare parts and availability of maintenance tools specified as existing attitude.

The corrective maintenance procedures, service manual and calibration after maintenance showed as not existing attitude. The repairing devices in the warranty period and maintenance contracts indicated incomplete attitude.

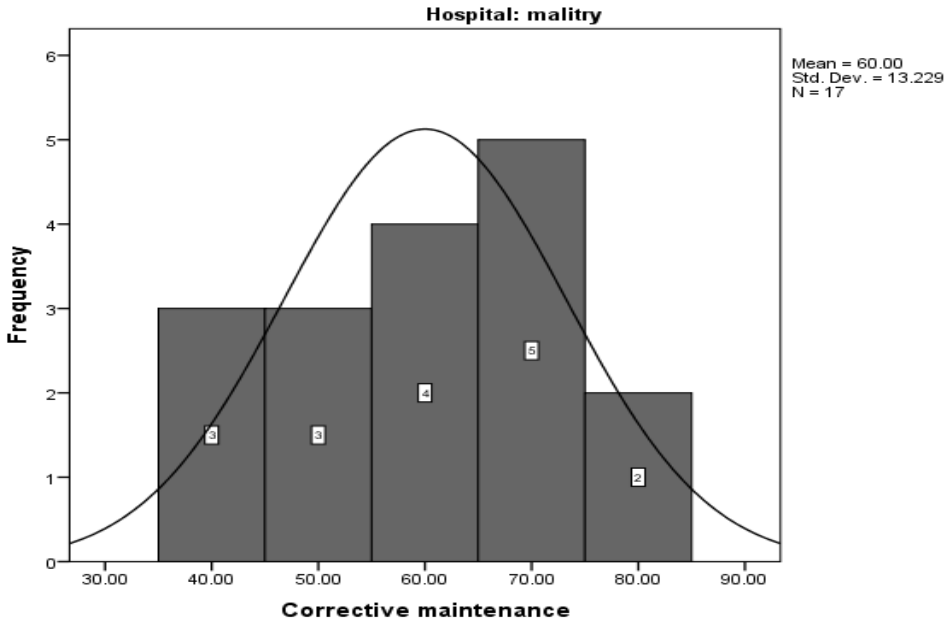

Figure 5.29: Histograms with Normal Distribution Curve For Corrective Maintenance in Military Hospital Each Histogram Displays The Frequency of Corrective Maintenance Occurs within The Sample.

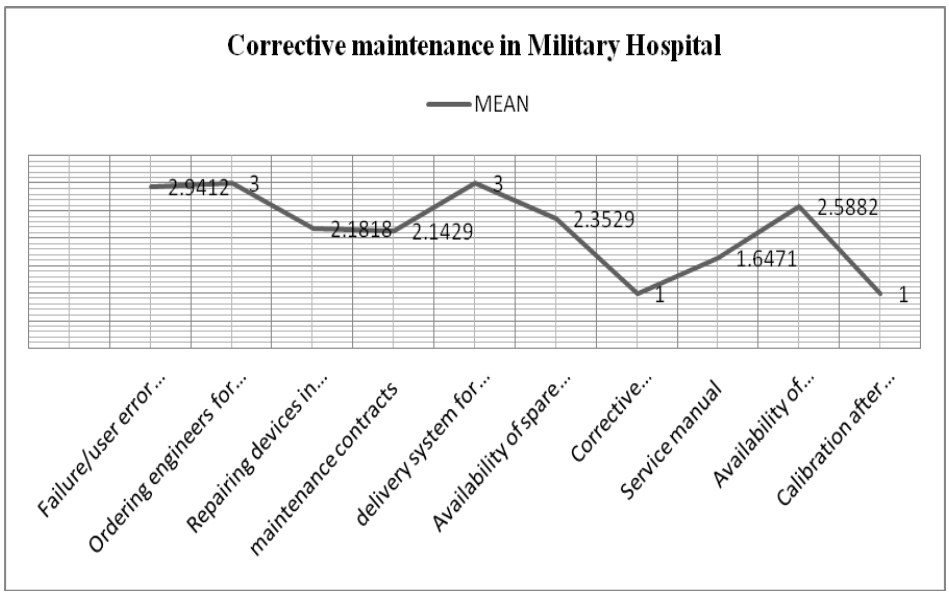

Figure 5.30: Arithmetic Mean for Corrective Maintenance in Military Hospital.

5.8.2 Corrective Maintenance in Khartoum Hospital (case2)

The Table 5.16: Corrective Maintenance in Case 2.

Corrective Maintenance	Frequency				Mean	Std. Deviation	Attitude
	Existing (%)	Not existing (%)	Incomplete (%)	Missing (%)			
Failure/user error summary reports	3(37.5)	0	5(62.5)	0	2.3750	.51755	existing
Ordering engineers for maintenance	3(62.5)	0	5(62.5)	0	2.3750	.51755	existing
Repairing devices in the warranty period	3(62.5)	0	4(50)	1(12.5)	2.4286	.53452	existing
maintenance contracts	1(12.5)	0	2(25)	5(62.5)	2.3333	.57735	incomplete
delivery system for Equipment which has been repaired	3(62.5)	1(12.5)	4(50)	0	2.2500	.70711	incomplete
Availability of spare parts	0	6(75)	2(25)	0	1.2500	.46291	not existing
Corrective maintenance procedures	0	8(100)	0	0	1.0000	.00000	not existing
Service manual	1(12.5)	1(12.5)	6(75)	0	2.0000	.53452	incomplete
Availability of maintenance tools	4(50)	1(12.5)	3(62.5)	0	2.3750	.74402	existing
Calibration after maintenance	0	8(100)	0	0	1.0000	.00000	not existing

Table No 5.16 represents the descriptive statistics for the variable being tested. This shows the specific results for each variable that you entered into the analysis. According to the mean weight, Preventive maintenance in Khartoum Hospital case2 showed the following results: The failure/user error summary reports, ordering engineers for maintenance, repairing devices in the warranty period and availability of maintenance tools specified as existing attitude. The availability of spare parts, corrective maintenance procedures and calibration after maintenance showed as not existing attitude. The maintenance contracts, delivery system for Equipment which has been repaired and corrective maintenance procedures indicated incomplete attitude.

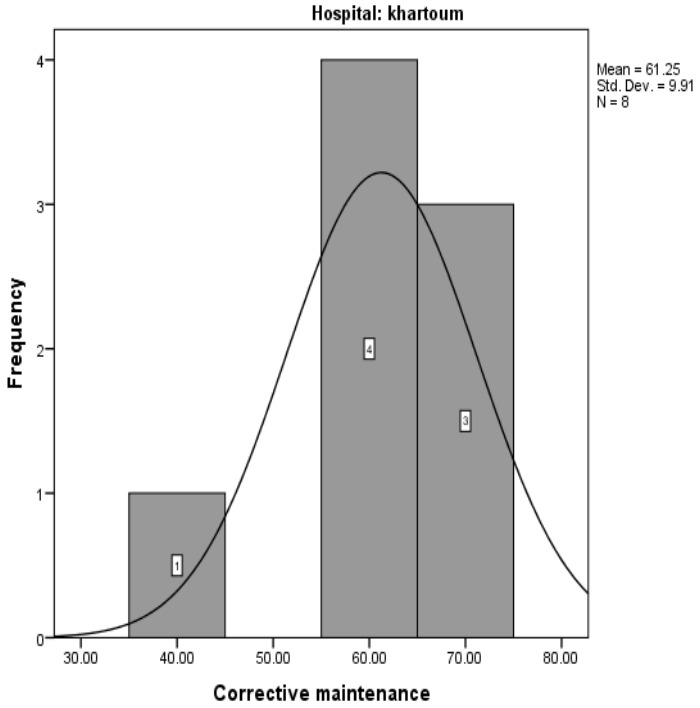

Figure 5.31: Histograms with Normal Distribution Curve for Corrective Maintenance in Khartoum Hospital Each Histogram Displays The Frequency of Corrective Maintenance Occurs within The Sample.

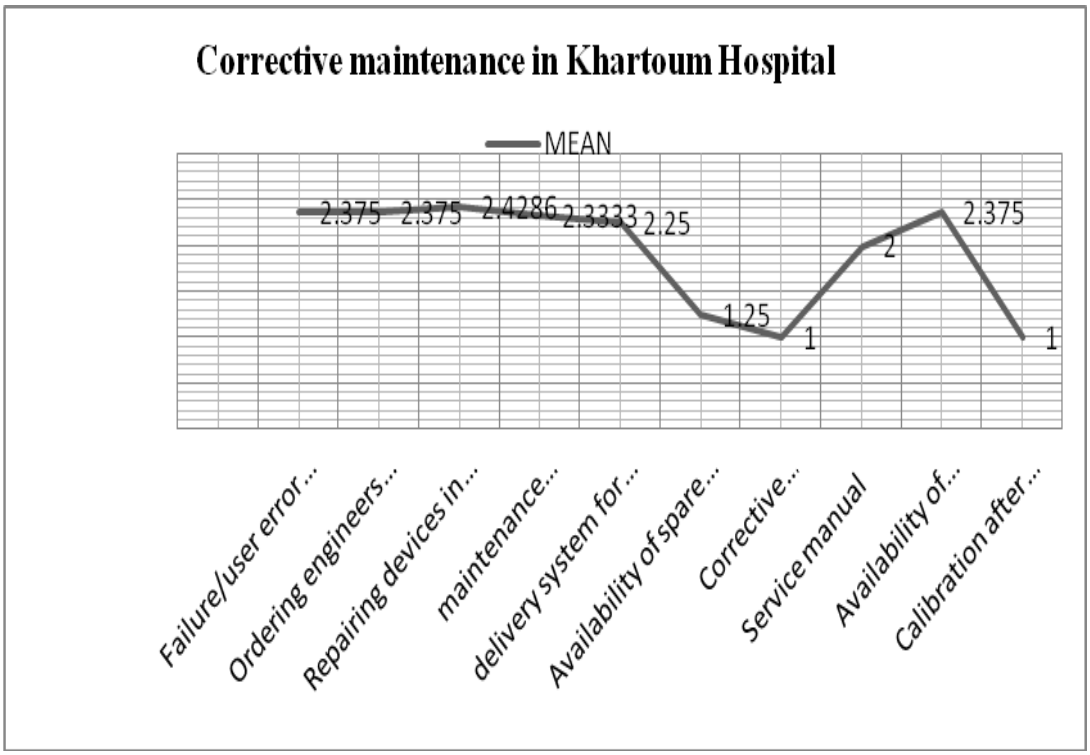

Figure 5.32: Arithmetic Mean for Corrective Maintenance in Khartoum Hospital.

5.9 Statistical Description of the Model Variables

Table No 5.17 shows the descriptive statistics for Military Hospital and Khartoum Hospital of the variables being tested.

The Table 5.17: 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
	inspection	8	69.7368	25.74570
	Pm	8	22.9167	21.70784
	Cm	8	61.2500	9.91031

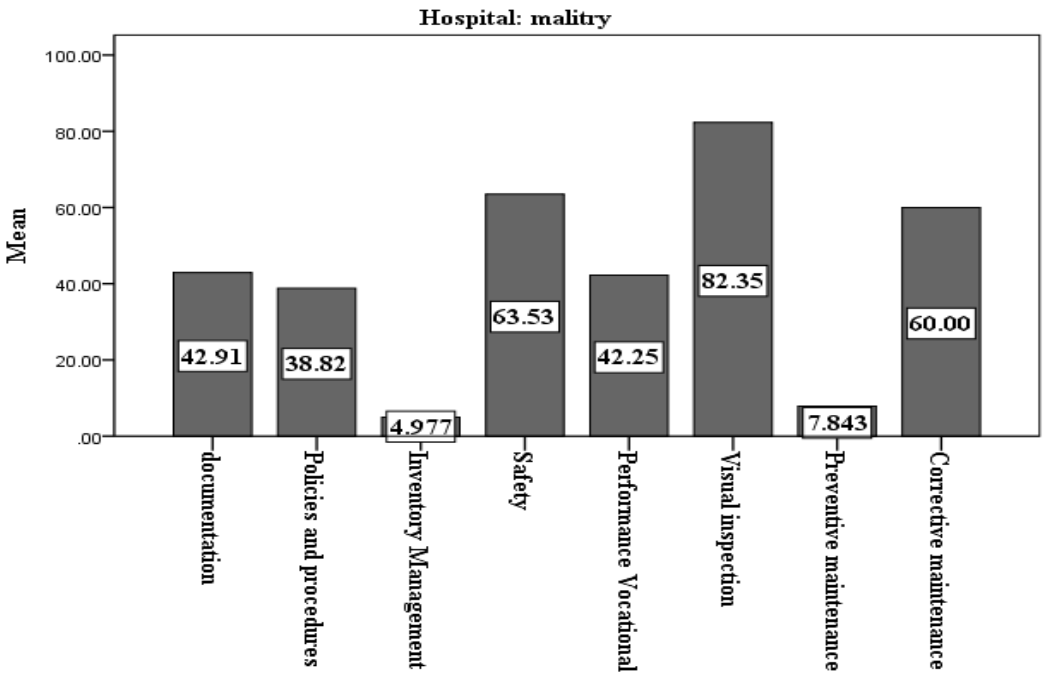

Figure 5.33: Histograms with Mean Score Percentage for Military Hospital Each Histogram Displays The Score Percentage of Model Variables.

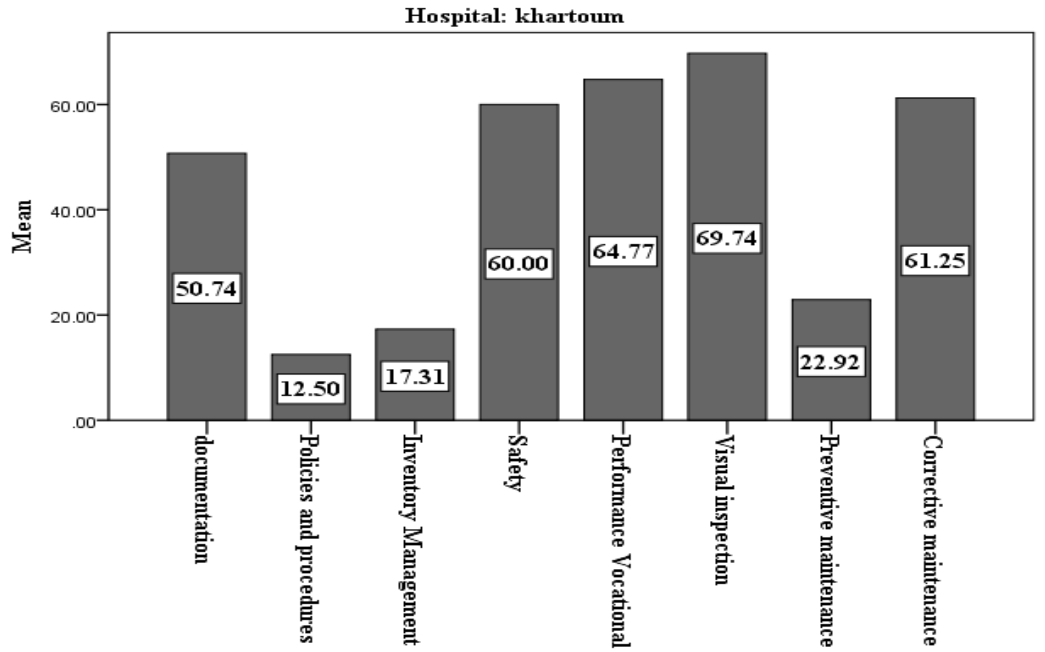

Figure 5.34: Histograms with Mean Score Percentage for Khartoum Hospital Each Histogram Displays The Score Percentage of Model Variables.

5.10 Overall Mean

The Table 5.18: 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

Table No 5.18 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 %).

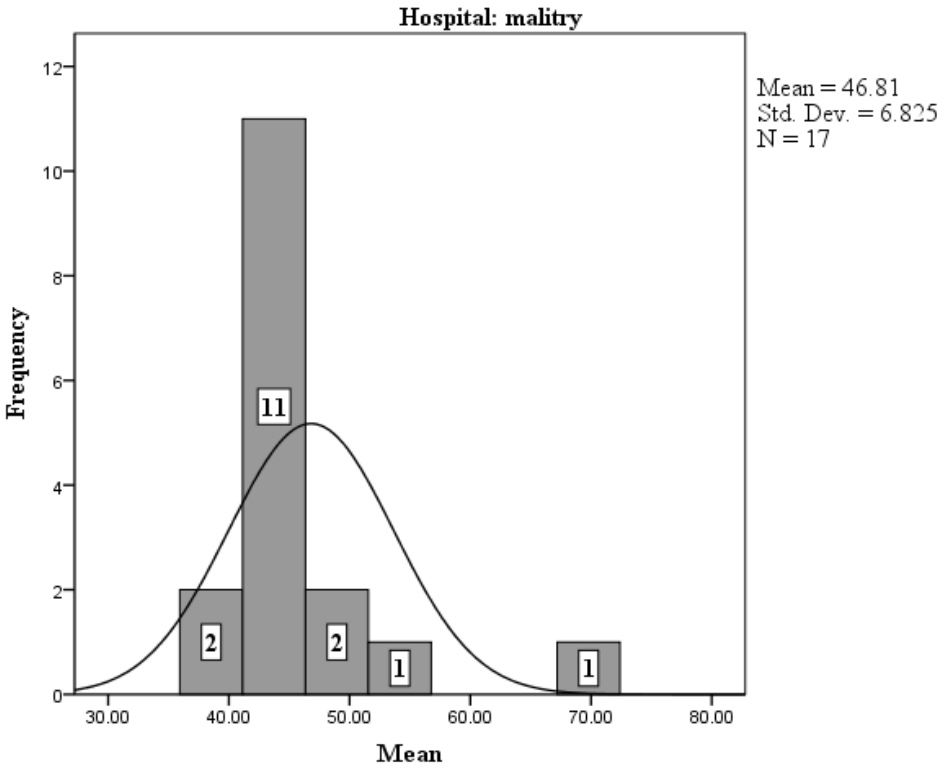

Figure 5.35: Histograms with Normal Distribution Curve for The Descriptive Statistics of Mean in Military Hospital Each Histogram Displays The Frequency of Mean Occurs within The Sample.

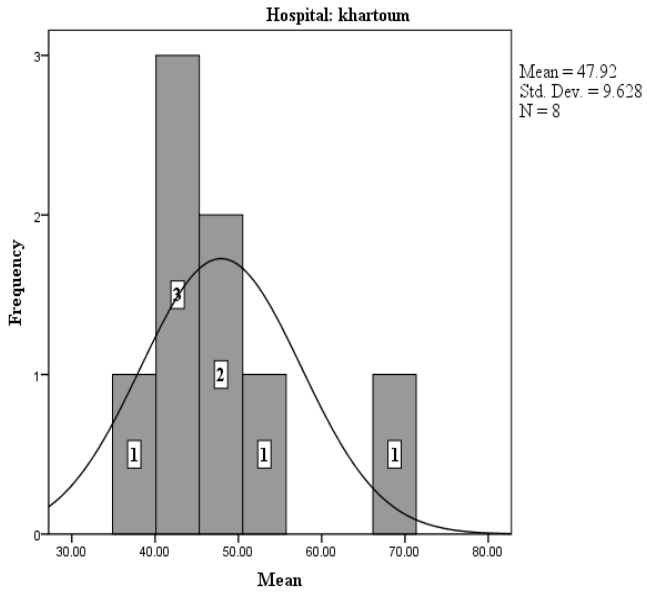

Figure 5.36: Histograms with Normal Distribution Curve for The Descriptive Statistics of Mean in Khartoum Hospital Each Histogram Displays The Frequency of Mean Occurs within The Sample.

5.11 Independent T – Test

The Table 5.19: 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

Table No 5.19 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) .

5.12 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.the following tables (5.20 –5.29) shown performance indicator results.

1. Sample No. 1

The Table 5.20: shows the result of sample No. 1.

Item	patient monitor	**Customers**	Military Hospital
Model	PM .7000	**Unit**	Critical Care Unit (CCU)
S.No.	CE - 01119760	**Date**	8 JUL 2012
Results			
No.	**Parameter**		**Status**
1	The arrhythmia		pass
2	The battery		pass
3	The Filter		pass
4	The Hart rate		pass

2. Sample No. 2

The Table 5.21: shows the result of sample No. 2.

Item	Electric shock	**Customers**	Military Hospital	
Model	DG 4000	**Unit**	Critical Care Unit (CCU)	
S.No.	108999100663	**Date**	8 JUL 2012	
Results				
No.	**Applied Energy(J)**	**Measurement Value (J)**	**Error**	**Status**
1	50 J	51.1 J	1.1 J	pass
2	200 J	205 J	5 J	pass
3	90 J	92.2 J	2.2 J	pass
4	120 J	122.2 J	2.2 J	pass

3. Sample No. 3

The Table 5.22: shows the result of sample No. 3.

Item	Electrocardiograph	**Customers**	Military Hospital
Model	A T 101	**Unit**	Critical Care Unit (CCU)
S.No.	080.13239	**Date**	8 JUL 2012
Results			
No.	**Parameter**		**Status**
1	The arrhythmia		pass
2	The battery		pass
3	The Filter		pass
4	The Hart rate		pass

4. Sample No. 4

The Table 5.23: shows the result of sample No. 4.

Item	General x - Ray	**Customers**	Military Hospital	
Model	R A D Series Et	**Unit**	Radiology	
S.No.	170/18079	**Date**	15 JUL 2012	
Results				
No.	**Applied Dose**	**Measurement Value**	**Error**	**Status**
1	80 KV	78 KV	2 KV	pass

5. Sample No. 5

The Table 5.24: shows the result of sample No. 5.

Item	General x - Ray	**Customers**	Military Hospital	
Model	Geni 500	**Unit**	Radiology	
S.No.	02058660	**Date**	15 JUL 2012	
Results				
No.	**Applied Dose**	**Measurement Value**	**Error**	**Status**
1	96 KV	70.9 KV	(-) 25.I KV	Fail
2	75 KV	53 KV	(-) 22 KV	Fail

6. Sample No. 6

The Table 5.25: shows the result of sample No. 6.

Item	Dental x -Ray	**Customers**	Military Hospital	
Model	YITENG	**Unit**	Radiology	
S.No.	GB4505-84	**Date**	8 AUG 2012	
Results				
No.	**Applied Dose**	**Measurement Value**	**Error**	**Status**
1	65 KV	60.2 KV	(-) 4.8 KV	Pass

7. Sample No. 7

The Table 5.26: shows the result of sample No. 7.

Item	Dental x -Ray	**Customers**	Military Hospital	
Model	Kodak 2100	**Unit**	Radiology	
S.No.	UIYA539	**Date**	16 JUL 2012	
Results				
No.	**Applied Dose**	**Measurement Value**	**Error**	**Status**
1	60 KV	61.9 KV	1.9 KV	Pass

8. Sample No. 8

The Table 5.27: shows the result of sample No. 8.

Item	Incubator	**Customers**	Military Hospital		
Model	30 – 200C˚	**Unit**	Operation theaters		
S.No.	4880 - KJ	**Date**	25 JUL 2012		
Results					
No.	**Applied Temp**	**Measurement Value**	**UUT Reading**	**Error**	**Status**
1	200 C˚	198.913 C˚	240 C˚	41.084 C˚	Fail

9. Sample No. 9

The Table 5.28: shows the result of sample No. 9.

Item	Dialysis machine	**Customers**	Military Hospital	
Model	Fresenius media	**Unit**	Operation theaters	
S.No.	0VCAUS 39	**Date**	25 JUL 2012	
Results				
No.	**Parameter**	**Measurement Value**	**Error**	**Status**
1	Temp 36.95 C˚	37.3 C˚	0.4 C˚	Pass
2	Conductivity 14.1 S/m	14.18 S/m	0.08 S/m	Pass

10.Sample No 10

The Table 5.29: shows the result of sample No. 10.

Item	NIBP - patient monitor	**Customers**	Khartoum Hospital	
Model	ARGUS LCM plus	**Unit**	Operation theaters	
S.No.	780.01922	**Date**	19 May 2014	
Results				
No.	**Applied Pressure**	**Measurement Value**	**Error**	**Status**
1	120 mmHg	113 mmHg	7 mmHg	Fail

5.13 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 [5]. 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 [6]. 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 [7].

CHAPTER SIX

DISCUSSION

Chapter Six

Discussion

The research was discussed the hypothesis of impact of model variables to develop healthcare facilities, In conformity with the life cycle phases of medical equipment. The results contributed to answer its questions and hypotheses of the research and the most prominent of these discussions. 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 case of documents, the research found the trend shows not exiting the following; The documentation of calibration in military hospital (88.2%) and the Khartoum hospital (100%) , reporting incidents in military hospital (94.1%) and Khartoum hospital (87.5%) , certificate of conformity in military hospital (94.1%) and Khartoum hospital (87.5%) , list of spare parts and disposables in military hospital (88.2%)and Khartoum hospital (62.5%), record of Equipment out of service in military hospital (82.4%) and Khartoum hospital (50.0%) , list of devices that need to be repaired in military hospital (64.7%) and Khartoum hospital (75.0%) , list of inventory storage devices in military hospital (94.1%) and Khartoum hospital (62.5%) , Record of risk management in military hospital (100%) and Khartoum hospital (100%), documentation for training and documentation of inspections and testing in military hospital (94.1 %) and Khartoum hospital (87.5%).

The research found that there are no policies and procedures accredited to monitor the activities and management of medical devices as the following:The equipment management manual in military hospital (100%) and Khartoum hospital (100%), policy to create a file for devices

in Khartoum hospital (50%), policies for preventive maintenance in military hospital (88.2%) and Khartoum hospital (100%), policy to develop and improve the work of devices in military hospital (100%) and Khartoum hospital (100%) , monitoring of performance indicators in military hospital (100%) and Khartoum hospital(87.5%), reporting system in Khartoum hospital (37.5%), policies for corrective maintenance in military hospital (100%) and Khartoum hospital(100%) and Khartoum hospital(100%), Policies for the Structure and staff in Khartoum hospital(100%), Policies to train operators in military hospital (94.1%) and Khartoum hospital(100%) and Policies to train engineers in Khartoum hospital(100%).However, because medical devices are complex to select, manage and use, it is important to ensure that policies are developed appropriately and modified as necessary to make them as effective as possible.

Figure 6.1: Status of Ambulance

Equipment inventory is an essential part of an effective health-care technology management (HTM) system. The inventory may be used to develop budgets for capital purchases, maintenance and running costs; to build and support an effective clinical engineering department, by allowing for workshop planning, hiring and training of technical support staff, and establishing and maintaining service contracts; to support an

effective medical equipment management programme, such as planning preventive maintenance activities and tracking work orders; and to plan the stock of spare parts and consumables. The inventory may also be used to facility risk analysis and mitigation, and emergency and disaster planning, are also supported by an inventory and the research found the trend shows not exiting the following: The conducting clinical trials in military hospital (5.9%) and Khartoum hospital (62.5%), checking risks in Khartoum hospital (50%), entering information into the database in Khartoum hospital (75%) ,storage of devices by classification in military hospital(5.9%) and Khartoum hospital (75%), intervals PM for the stored equipment classification in military hospital (5.9%) and Khartoum hospital (75%) , plan of distributing devices and spare parts in Khartoum hospital (50%), labeling safety signs in Khartoum hospital (75%) **,** checking temperature in storage in Khartoum hospital (62.5%)**,** checking humidity in storage in military hospital (5.9%) and Khartoum hospital (75%) **,** appropriate distance between the device and the surfaces in military hospital (11.8%) and Khartoum hospital (62.5%) **,** checking store inventory devices by scheduling in Khartoum hospital (75%).

Figure 6.2: Waterproofing From Surface of The Store

There is a risk to the patient in the event of current leaking from the device. Current can also be transmitted through a caregiver such as a nurse in contact with an electronic device near the patient. Electrical shock can cause disruptions during health care procedures and result in injury or death. This makes electrical safety a topic of very high importance in medical device quality assurance and the research found the trend indicators not exiting the following: The electrical earthing systems in Khartoum hospital (75%), electrical safety testing in military hospital (100%) and Khartoum hospital (100%), environmental safety testing in military hospital (100%) and Khartoum hospital (100%) and the warning signs in military hospital (88.2%) and Khartoum hospital (62.5%).

Figure 6.3: Mobile X-Ray Found in The Yard of The Hospital

In general, developing the human resources necessary to operate an effective maintenance programme is a slow and steady process for the safety of the patient and the user. This program defines procedures and policies to manage activities related to medical equipment, from their selection and acquisition to Replacement or disposal. In the realm of medical devices there is little standardization of how key specifications

are set and measured. In fact, few manufacturers provide sufficient detail as to how they test their devices. However, the research found Performance Vocational trend shows not exiting the following: The development and implementation of Medical equipment management plan in military hospital (100%) and Khartoum hospital (100%), knowledge of international standards and recent recommendations in military hospital (70.6%) and Khartoum hospital (62.5%) and the continuous training in Khartoum hospital (75%). The case of Visual inspection, the research found the trend shows not exiting the following: The standard operating procedure (SOP) in Khartoum hospital (62.5%), equipment cards in Khartoum hospital (87.5%), connecting the device to the grounding system in Khartoum hospital (75%) and calibration stickers in military hospital (100%) and Khartoum hospital (87.5%). Preventive maintenance (PM) aims to extend the life of the equipment and reduce failure rates. Additionally, some hidden problems may be discovered during a scheduled Preventive maintenance, so that functioning status of the equipment could be known and equipment is readily available whenever its use is needed. Proper maintenance of medical equipment is essential to obtain sustained benefits and to preserve capital investment. Medical equipment must be maintained in working order and periodically calibrated for effectiveness and accuracy of the results. The research found no preventive maintenance activities doing as the following: The schedule illustrating dates of periodic maintenance in military hospital (94.1%) and Khartoum hospital (87.5%), providing the necessary consumables for periodic preventive maintenance in military hospital (82.4%) and Khartoum hospital (62.5%) , making the card or file for follow-up in military hospital (82.4%), preventive maintenance procedures in military hospital (100%) and Khartoum hospital (100%), inspections and testing of medical equipment

maintenance in military hospital (94.1%) and Khartoum hospital (87.5%) and calibration of equipment in military hospital (100%) and Khartoum hospital (100%) .

Figure 6.4: Water Falling on A CT Scan Device

The corrective maintenance (CM) of medical equipment restores the function of a failed device and allows it to be put back into service. Ensures that maximum availability and reliability of equipment, minimum downtime and maximum uptime, maximum return on investment end extended useful life of equipment. However, the research found corrective maintenance trend shows not exiting the following: The availability of spare parts in Khartoum hospital (75%), corrective maintenance procedures in military hospital (100%) and Khartoum hospital (100%) and calibration after maintenance in military hospital (100%) and Khartoum hospital (100%).

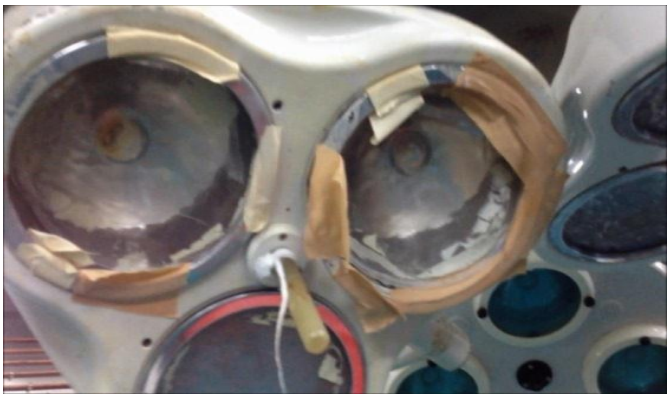

Figure 6.5: Status of Operating Room Lamp

CHAPTER SEVEN

CONCLUSION AND RECOMMENDATIONS

Chapter Seven

Conclusion And Recommendations

7.1 Conclusion

This research aims at identify the models to improve current inspection and evaluation strategies for medical devices in healthcare facilities. The foremost important aspect of this research is to figure out the ability of the proposed model variables techniques to assessing a case of medical devices throughout the device's lifecycle. 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. Results were obtained from applying the model to 25 departments and sections that working with different medical devices in the military hospital and Khartoum hospital reflected 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. This result showed the potential to cause medical devices Risks to patients and users. As evidenced that 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 of (30%) of the sample .The Survey results indicated 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 =.744 and it was greater than (0.05). The results indicated evidence to support the hypothesis that current inspection and evaluation activities for medical devices have no effect in the development of health care at the state of Khartoum, because The absence of medical metrology system on the performance indicators and risk management of medical equipment and also absence of external inspections and leniency in internal resulting in the effectiveness and reliability of devices.. The degree of change and effectiveness causes risk to the patient, users and the economy.

7.2 Recommendations

1. Medical devices Performance Tests must be performed at stage of registration procedures before being allowed to enter the country.
2. Must circulate inspection and evaluation for licensure often only before new health facilities, particularly in the private sector; with take legal action.
3. Using the model in the evaluation and inspection of health facilities for its ability to reverse the true picture.
4. Building of medical equipment management plan.
5. Legislation and law obliged to calibrate medical devices.
6. Continuous training of biomedical engineers.
7. Applied this study on health care facilities at Sudan.

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Appendices

Appendix A

JCAHO
Environment of Care Pre-Assessment Questionnaire

Medical Equipment

B.1 Management Plan

(1) Is there a written management plan that outlines the requirements of the medical equipment program at the installation?

(2) Does the plan contain a table of contents, is dated and the pages are numbered?

(3) Was the plan reviewed by the safety committee and approved by the installation top management official?

(4) Does the management plan establish a medical equipment program based on monitoring and evaluation of failure incidents, equipment disruptions, and maintenance history?

(5) Does the plan establish a requirement for a medical equipment maintenance for inspection, testing, and maintenance of equipment through;

a. PM program written procedures;

b. Equipment cards;

c. Documentation of PM (books/logs/forms);

d. Testing and inspection guidelines?

(6) Does the plan establish a requirement to maintain a current (within six months), accurate, unique inventory of all medical equipment in the program, regardless of ownership or purpose?

(7) Does the plan require equipment assessments to minimize the clinical and physical risks associated with portable and fixed medical equipment?

(8) Does the plan require each piece of equipment be tested prior to use and at least annually thereafter, and that such testing is documented?

(9) Does the plan require monitoring and appropriate action on medical equipment hazard notices and recalls?

(10) Does the plan establish a training program for medical equipment users and maintainers?

(11) Does the plan require reporting incidents in accordance with the Safe Medical Devices Act?

(12) Does the plan establish the requirements of an annual evaluation of the effectiveness of the program?

B.2 PROCEDURES

(1) Are there procedures that outline actions to be taken by the clinical engineering staff to restore medical equipment when it fails?

(2) Are there procedures for clinical interventions to be taken by clinical staff, in each department, (if applicable) when medical equipment fails?

(3) Are there procedures that outline the availability of and access to spare equipment when equipment fails?

(4) Are there procedures for actions to obtain repair services when equipment fails?

(5) Are there procedures that establish criteria for selection and acquisition of medical equipment?

(6) Are there procedures that establish criteria to identify, evaluate, and inventory new and existing medical equipment to be included in the equipment management program? (Ownership, purchase, rental or lease options are not a consideration) The criteria (if utilized) must address;

a. Clinical application (diagnosis, treatment, and monitoring);
b. Physical risks associated with the equipment during usage;
c. Equipment maintenance requirements;
d. Equipment incident history.

(7) Are there procedures for reporting of required equipment incidents to the Food and Drug Administration (FDA) in accordance with the Safe Medical Devices Act? (A report is only generated when information is received that reasonably suggest that a medical devise may have caused or contributed to the death, serious injury, or illness of a patient)

(8) Are there procedures for identification, reporting, investigation, and documentation of equipment problems, failures and user errors that have an adverse effect on patient safety and/or quality of care?

(9) Are relevant summaries of equipment failures and user errors reported to the safety officer, quality assurance or risk management function?

(10) Are there procedures for reporting identified problems and the actions taken to resolve them?

(11) Are there procedures for the Radiology Department that addresses quality control issues for the following:

a. Collimation
b. Beam alignment 24
c. Timers
d. Film processing
e. Image intensifiers and display monitors?

(12) Are departmental procedures reviewed as frequently as necessary, but no less frequently than every three years?

(13) Are there written procedures that address?

a. Review of New Equipment Purchase Requisitions
b. Acceptance Testing of New Equipment
c. Equipment Inventory and Repair History
d. Inventory Entry and Deletion
e. Management of Equipment Maintenance Service Contracts
f. Management of Loaned or Leased Equipment
g. Biomedical PM Program
h. Electrical Safety
i. Equipment Hazard Surveillance Program
j. Equipment User Training
k. Biomedical Personnel Equipment Training
l. Removal of Unsafe Equipment from Service

(14) Are departmental procedures dated, signed by the department head and approved by the safety committee?

(15) Are procedures distributed, practiced, and enforced?

B.3 Training

(1) Is there a training program that address orientation of all new users and maintainers?

(2) Is there refresher training for all users and maintainers?

(3) Does the training include medical equipment capabilities, limitations, and special applications for its users?

(4) Does the training include basic operating and safety procedures that medical equipment users should follow when using the equipment?

(5) Does the training include proper emergency procedures users should follow when equipment fails?

(6) Does the training include information and skills medical equipment maintainers need to perform the assigned maintenance duties?

(7) Does the training include reporting of equipment problems, failures, and user errors?

(8) Is there documentation for all training?

(9) Does the documentation include?

a. Names of Attendees

b. Topic

c. Brief outline of the training topic

d. Instructor's name

e. Duration of course

B.4 Performance Standards

(1) Are there performance standards that measure user and maintainer knowledge and skill requirements regarding their role in the medical equipment program?

(2) Are there performance standards that measure routine emergency and incident reporting procedures, including when and to whom such reports are to be communicated?

(3) Are there performance standards that measure inspections, PM, and testing of medical equipment?

B.5 Effectiveness Review

(1) Is an annual program evaluation conducted in writing?

(2) Was the evaluation reviewed by the installation safety committee?

(3) Was the evaluation submitted to the Governing Body for approval?

B.6 Documents A Surveyor May Ask To See To Verify Compliance

a. Departmental medical equipment management plans

b. Departmental training plans and training record

c. Failure/user error summary reports

d. Departmental procedures that address the operation of equipment

e. Documentation of inspections, PM, and testing of medical equipment

f. Annual effectiveness report

g. Random staff interviews to determine employee knowledge

Appendix B

The Accuracy Of Temperature Monitoring Of The Incubator For Newborns

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ABSTRACT - The objective of this paper is to investigate the performance of the Incubator for Newborns at the departments of intensive care in Jafer Ibn Aouf Reference Children Hospital, is governmental Children specialized hospital. Using INCUTM Incubator Analyzer to analyzing the various aspects of performance of neonatal incubator and its compliance with the set requirements and regulations according to the technical standard IEC (International Electro technical Commission) 60601-2-19. The data used in this study were obtained by interpreting of the performance test results of neonatal incubator.

Keyword: Neonatal Incubator; Temperature; Performance Test.

المستخلص - الهدف من هذه الورقة هو تحقق من كفاءة أداء أجهزة حضانات الأطفال بمستشفى الأطفال المرجعى جعفر بن عوف . تم استخدام جهاز (Fluke INCU Incubator Analyzer) لتحليل درجات الحرارة داخل الحضانة وفقاً لمتطلبات ولوائح المواصفة الفنية الخاصة بها (IEC 60601-2-19). تم الحصول على البيانات المستخدمة في هذه الدراسة من خلال تفسير نتائج اختبار كفاءة أداء حاضنة الأطفال حديثي الولادة.

INTRODUCTION

A neonatal incubator, which is represented in Figure No (1) considered as an air conditioned room with special specification which we can control it with respect to the condition of baby in incubator. Incubators are designed to provide an optimal environment for newborn babies with growth problems (premature baby) or with illness problems. The incubator is an isolated area environment with no dust, bacteria, and has the ability to control temperature, humidity, and oxygen to remain them in acceptable .Newborn babies with growth problems usually have a net body area greater than normal babies from the same age[1]. Hospitals must create a safe environment for patients, relatives and employees. To achieve this goal, like the management of the physical environment and human resources, management of the medical devices is very important. Here, the main target is the patient safety because of the potential hazards that may be caused by the bad performance of the medical devices. The management of the performance control of medical devices is becoming more prominent as the number of medical devices increases [2].

Figure B1: A Commercial Incubator.

Temperature measurement is a vital part of daily neonatal care. Accurate measurements are important for detecting deviations from normal values for both optimal incubator and radiant warmer functioning. The purpose of monitoring the temperature is to maintain the infant in a thermo neutral environmental zone. This physiological zone is defined as the narrow range of environmental temperatures in which the infant maintains a normal body temperature without increasing his or her metabolic

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Date: 1/12/2014

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Title of the paper:

The Accuracy of Temperature Monitoring of the Incubator for Newborns

Dear Sir,

It gives me pleasure to inform you that the above mentioned paper has been accepted for publication in the *Journal of Science and Technology* (*Journal of Engineering & Computer Sciences*). The paper will be published according to priority of flow.

We appreciate your contribution to the Journal.

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Figure B2: Approval for Publication

Appendix C

Metrological Model For Inspection and Evaluation Of Medical Devices

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

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Figure C1: Approval for Publication