



Sudan University of Science and Technology

College of Engineering Biomedical Engineering

Imported Medical Equipment Inspection and Coordination Program

A project Submitted In Partial Fulfilment for the Requirement of the Degree of B.Sc. (Honour) in Biomedical Engineering

Prepared By:

- 1) Balquees Kamal Eldeen Mohammed
- 2) Hnadi Musa Omer Musa
- 3) Obada Abbas Ibrahim Ahmed

Supervisor :

Dr. Elias Sidieg

October 2016

سورة البقرة الآبة ﴿ 32 ﴾

صدق الله العظيم

﴿ قَالُوا سُبْحَانَكَ لَا عِلْمَ لَنَا إِلَّا مَا عَلَّمْتَنَا إِنَّكَ أَنْتَ الْعَلِيمُ الْحَكِيمُ ﴾

بْشِمْ لِسَالَحْمَر الحَيْمِ أَنْ

قال تعالى:

200

Dedication

The prophet Mohammed "peace & blessing be upon him" said: "Who does not thank people does not thank Allah".

We dedicate this project to the people who kept lighting our way and without them we would never reached what we are today; our beloved parents, who kept encouraging us to make our dreams see the light one day, our family and friends who strengthen us with their worm wishes and prayers.

Our Special gratitude to Or.Elias Siddig who gave us this huge opportunity to work under his kind supervision and guidance.

We also don't forget to thank every engineer, doctor and employee that never refrained themselves giving us tons of valuable information.

Lastly, our gratitude and appreciation goes to whoever stood by us through the tough times and helped us to get here, thank you.

Acknowledgement

Sometimes words are not enough to tell how we appreciate having some people in our lives, people who support us, wish the best for us and walk with us through our life.

Our grateful thanks to Allah for guiding us and giving us the strength to complete this project, we would like to thank the generous heart and source of wisdom our supervisor Dr. Elias Siddig.

We must express our profound gratitude to E. Mutaz Hassan and E. Adil Abbas in Sudanese Standards and Metrology Organization (SSMO), also Dr. Khalil Mohammed, Dr. Hatem Omer, E. Mohammed Nasr Eldeen, E. Tasneem Sideeg and E. Azza Ahmed in Sudan National Medicines & Poisons Board (NMPB) and E. Osman Awad in National Medical supplies fund for their humble welcoming, caring and standing with us all the way from the start of this project till the end. Accept our thanks and appreciation.

Contents

Dedication	II
Acknowledgment	III
List of tables	VIII
List of figures	Х
Abbreviation	XIII XV
المستخلص	VXI
Chapter one: Introduction	1
1.1 General review	1
1.2 Problem statement	1
1.3 Solution	1
1.4 Objectives	1
1.4.1 General objectives	1
1.4.2 Specific objectives	2
1.5 Methodology	2
1.6 Project layout	2
Chapter two: theoretical fundamental	4
2.1 Terminology	4
2.2 Classification of medical device	5
2.2.1 Classification of general medical device	5
2.2.2 Classification for In-Vitro Diagnostic	7
2.3 Responsibility and regulation In Sudan	7
2.3.1 Sudan National Medicines and Poisons Board (NMPB)	7
2.3.2 Sudan Atomic Energy Commission (SAEC)	8
	TT 7

2.3.3 Sudanese Standards and Metrology Organization (SSMO)	8
Chapter three: Background studies	10
Chapter four: Methodology and data analysis	12
4.1 Methodology	12
4.2 data analysis	14
4.2.1 The agreement to the policy of import medical devices	14
4.2.2 The verification of the demand owner documents	15
4.2.3 The method of saving demand owner documents	16
4.2.4 The responsible bodies of inspection imported medical devices	17
4.2.5 The coordination between responsible bodies	19
4.2.6 The agreement to establish separate body to do all procedures	20
4.2.7 The validity of imported medical devices inspection method	21
4.2.8 The inspection done by specialist biomedical engineers	22
4.2.9 The need percentage of changing inspection method	23
4.2.10 The availability of laboratory tests for the imported medical devices	24
4.2.11 The percentage of the availability of inspection tools for the imported m	edical
devices	25
4.2.12 The responsibility of import medical devices damage due to late	26
4.2.13 The appropriate storage of imported medical devices	27
4.2.14 The atonement In case of device damage due to bad storage	28
4.2.15 The suggestion to improve the policies of import medical devices	29
4.2.16 Suggestion to improve the inspection procedures of import medical devices	31
4.2.17 The credibility in inspection or clearance of import medical devices	33
4.2.18 The linking method between responsible bodies and suggestions to improve i	t34

Chapter five: The Program	36
5.1 Opening the program	36
5.2 If the user is Company user	37
5.3 The SSMO new application order	38
5.4 The SAEC Import License order	39
5.5 The NMPB new application order	41
5.6 If the user is SSMO inspection engineer	42
4.7 If the user is SSMO inspection engineer	43
4.8 If the user is SSMO or NMPB administrator	44
Chapter six: Discussion	46
Chapter seven: conclusion and recommendation	47
7.1 Conclusion	47
7.2 Recommendation	48
References	49
Appendices	50

List of table

Table n	umber Title	Page number
4.1	The agreement to the policy of import medical devices	14
4.2	The verification of the demand owner documents	15
4.3	The method of saving the demand owner documents	16
4.4	The responsible bodies of inspection imported medical devices	17
4.5	The coordination between responsible bodies	19
4.6	The agreement to establish separate body to do all procedures	20
4.6	The validity of imported medical devices inspection method	21
4.7	The inspection done by specialist biomedical engineers	22
4.9	The need percentage of changing inspection method	23
4.10	The availability of laboratory tests for imported medical devices	25
4.11	The percentage of the availability of inspection tools for imported	
	medical devices	26
4.12	The responsibility of import medical devices damage due to late	28
4.13	The appropriate storage of imported medical devices	29
4.14	The atonement In case of device damage due to bad storage	30
4.15	Suggestions to improve the policies of import medical devices	31

Suggestions to improve the inspection procedures of import medical devices 33 4.16 The complete credibility in inspection or clearance 4.17 35 4.18 The communication link between responsible bodies and what are your

```
suggestions for improvement
```

36

List of figure

Figure num	iber Title	Page number	
4.1	schematic diagram of the methodology	13	
4.2	The agreement to the policy of import medical devices	14	
4.3	The verification of the demand owner documents	15	
4.4	The method of saving the demand owner documents	16	
4.5	The responsible bodies of inspection imported medical devices	17	
4.6	The coordination between responsible bodies	19	
4.7	The agreement to establish separate body to do all procedures	20	
4.8	The validity of imported medical devices inspection method	21	
4.9	The inspection done by specialist biomedical engineers	22	
4.10	The need percentage of changing inspection method	23	
4.11	The availability of laboratory tests for imported medical devices	24	
4.12	The percentage of the availability of inspection tools for imported		
	medical devices	25	
4.13	The responsibility of import medical devices damage due to late	26	
4.14	The appropriate storage of imported medical devices	27	
4.15	The atonement In case of device damage due to bad storage	28	
4.16	Suggestions to improve the policies of import medical devices	30	
4.17	Suggestions to improve the inspection procedures of import		
	medical devices	32	
4.18	The complete credibility in inspection or clearance	33	
4.19	The communication link between responsible bodies and what		
	your suggestions for improvement	35	

5.1	Login Window	36
5.2	Login Table	37
5.3	Company's Window	38
5.4	Company's SSMO new application form Window	38
5.5	Data Table of the medical devices	39
5.6	Order sent message	39
5.7	SAEC requirements window	39
5.8	SAEC Import License application window	40
5.9	SAEC Linear Data Table	40
5.10	SAEC Nuclear Data Table	41
5.11	SAEC Data sent message	41
5.12	NMPB New Application Window	42
5.13	SSMO Inspection form window	42
5.14	SSMO Inspection form Sent Message	43
5.15	NMPB Inspection form window	43
5.16	Administrator Licenses window	44
5.17	Administrator Users window	45

Abbreviations

SSMO	Sudanese Standards and Metrology Organization
NMPB	Sudan National Medicines & Poisons Board
SAEC	Sudan Atomic Energy Commission
SPSS	Statistical package for the Social Sciences
IAEA	International Atomic Energy Agency
GOS	Government of Sudan
ARSO	African Regional Organization for Standardization
ASMO	Arab Standards and Metrology Organization
AIDMO	Arab Industrial and Mining Organization
ICC	International Institute for Cereal Science and Technology
AFSEC	African Electro-technical Standardization Commission
OIML	International Organization for legal metrology
IEC	International Electrotechnical Commission
SPS	Sanitary and Phytosanitary
TBT	Technical Barrier to Trade
WTO	World Trade Organization
KEBS	Kenyan Bureau of Standards
KATS	Korean Agency for Standardization
JISM	Jordan Institution for Standards and Metrology
SASMO	Syrian Arab Organization for Standardization and Metrology
EOS	Egyptian Organization for Standardization and Quality
SASO	Saudi Arabia Standards Organization
ESMA	Emirates Authority for Standardization

TSE	Turkish National Center for Standardization
LNCSM	Libyan National Center for Standardization
SAC	Standardization Administration of China
UNBS	Uganda National Center for Standardization
INORPI	Tunis National Institute for Standardization
QSAE	Quality and Standards Authority of Ethiopia

Abstract

Healthcare especially diagnostic, therapeutic and rehabilitation developed due to the development of medical equipment technology. Medical devices become a part doesn't divide of medicine practice but consider the required condition for medical service quality, effectiveness and safety. Therefore every hospital whether it's large or small contains number of medical devices which without exception produced outside Sudan, this situation create a lot of problems in having the good of these devices and way of keeping it work safely, continuity and efficiency.

This project aim to design software program coordinates between regulation bodies that are responsible of importation and inspection of medical devices to ensure their safety and high quality, also replace paper system with electronic system to facilitate and accelerate the procedures.

To achieve the objectives of this research several visits and interviews were done to conclude the needed data through questionnaire analyzed by statistical program (SPSS).

Through the study, electronic link program between regulation bodies done (National Medicine and Poison Board, Sudanese Standards and Metrology Organization and Sudan Atomic Energy Commission) to facilitate and accelerate the procedures of importation and clearance, also to ensure the safety, quality and effectiveness of the imported medical devices.

Sudanese Standards and Metrology Organization and Sudan National Medicines & Poisons Board offered to experiment the program in their institutes so that if it achieve the hoped for goals they will implement it.

المستخلص

تطورت الخدمات الصحية خاصة العلاجية والتشخيصية والتأهيلية بتطور تكنولوجيا الأجهزة الطبية وأصبحت الأجهزة الطبية جزء لايتجزأ من ممارسة مهنة الطب بل تعتبر الشرط المطلوب لجودة الخدمة الطبية وكفاءتها وسلامتها. لذلك توجد بكل مستشفى صغيراً كان أم كبيراً عدد من الأجهزة الطبية والتى بدون إستثناء تصنع خارج السودان وهذا الوضع خلق كثيراً من الإشكاليات فى كيفية الحصول على الجيد من هذه الأجهزة وطريقة الحفاظ عليها لتعمل بسلامة وإستدامة وكفاءة .

هذا البحث يهدف الى اعداد برنامج إلكتروني يقوم بالتنسيق بين الجهات المسؤولة من اجراءات استيراد الأجهزة الطبية وتفتيشها لضمان إستيراد أجهزة طبية آمنة و ذات جودة عالية واستبدال المعاملات الورقية بالإلكترونية لتسهيل وتسريع الإجراءات.

ولتحقيق أهداف هذا البحث تم إجراء العديد من الزيارات والمقابلات لإستخلاص البيانات المطلوبة بواسطة إستبيان وتم تحليله بواسطة برنامج إحصائي(SPSS).

من خلال البحث تم عمل برنامج ربط إلكتروني بين الجهات المسؤولة من إستيراد الأجهزة الطبية (المجلس القومي للأدوية والسموم , الهيئة السودانية للمواصفات والمقاييس وهيئة الطاقة الذرية السودانية) لتسهيل وتسريع إجراءات الإستيراد والتخليص و ضمان جودة وفعالية الأجهزة الطبية المستوردة.

الهيئة السودانية للمواصفات والمقابيس والمجلس القومي للأدوية والسموم عرضوا تجربة البرنامج في مؤسساتهم , حيث أنه سيتم تنفيذه إذا حقق الأهداف المرجوة.

1.1 General Review:

Software program which coordinate the procedures of implementation and inspection imported medical equipment's and match it's specifications with the international standards and metrology of world health organization which followed in specific institutions in this scope with regard suitable usage in Sudan.

1.2 Problem Statement:

Lack of:

- Coordination, implementation of the operations for importing medical devices in Sudan which takes a lot of time and cost medical equipment company's fees which affects the consumer's economics or health.
- Appropriate inspection procedure of imported medical equipment's.

1.3 Solution:

Design a medical equipment inspection and coordination software program.

1.4 **Objectives:**

1.4.1 General objectives:

The General objective of this research is to:

Make communication link between regulation bodies that are responsible for importing medical equipment's (Sudanese Standards and Metrology Organization, National Medicines and Poisons Board, Sudan Atomic Energy Commission and Sudan customhouses).

1.4.2 Specific objectives:

The specific objectives of this research are to:

- 1. Create sequential software program to ensure product safety, quality and effectiveness.
- 2. Regulate inspection procedure.
- 3. Improve the awareness of the importance of matching imported medical equipment before enter the country and guide the personnel to do the ideal inspection.
- 4. Reduce time of importation and clearance.

1.5 Methodology:

The research used the questionnaire to survey all organizations and inspectors responsible of medical devices. The data was analyzed by using computer-based program statistical package for social science (SPSS) version 16.0. Software program for inspection and coordination was designed by using C# language.

1.6 Project layout:

This research includes seven chapters. Chapter one is an introduction that contains the general review, problem statement and the objectives of the research. Then the theoretical fundamental in chapter two and background studies in chapter three. Chapter four contains the data statistical analysis and methodology then the program in chapter five. The discussion was shown in chapter six. Chapter seven contains the conclusion and the recommendations.

2.1 Terminology

- **1. Health technology:** The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.[1] It is used interchangeably with health-care technology.
- **2. Medical device:** An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means. [2]
- **3. Medical equipment:** Medical devices requiring calibration, maintenance, repair, user training, and decommissioning activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices. [3]

4. Inspection: Refers to scheduled activities necessary to ensure a piece of medical equipment is functioning correctly. It includes both performance inspections and safety inspections. These occur in conjunction with preventive maintenance, corrective , or calibration but can also be completed as a standalone activity scheduled at specific intervals. [2]

5. Acceptance inspection: A detailed inspection performed before a device puts into use either after initial receipt (i.e. the incoming inspection of new

equipment) or following other service activities (e.g. a major Repair, Modification or Overhaul) as appropriate. [3]

- **6. Calibration:** A procedure used to determine a device's accuracy by using test equipment whose own accuracy is appropriate and has been verified and, as needed, adjusting that medical device to meet manufacturer's specifications. [3]
- **7. Benchmark:** A reference value for an indicator; it may be established by using internal or external benchmarking or regulation. [4]
- **8. CE mark:** CE markings indicate that a product meets European Union directive standards of performance and safety. [4]

2.2 Classifications of Medical Devices:

2.2.1 Classification of general Medical Devices:

The control of medical devices will be based on a risk assessment and risk management.

The level of regulatory control applied to the medical device is proportional to the degree of perceived risk associated with the device. The requirements of the review process differ for each class, type and technology of medical device.

Medical devices may be classified into 4 classes: Class 1 (low risk). Class II and III (medium risk) or IV (high risk). Refer to annex 1 for classification rules of general medical devices.

Class I Devices – those needing the lowest level of regulation because of low risk to the patient except sterile products. They are subject to the General

Controls requirements. Declaration of conformity is accepted from the legal manufacturer.

Class II Devices are of a medium risk. These devices are invasive in their interaction with the human body, but the methods of invasion are limited to natural body orifices. The category may also include therapeutic devices used in diagnosis or in wound management.

Class III Devices are of a medium risk. They are either partially or totally implantable within the human body, and may modify the biological or chemical composition of body fluids.

Class IV devices are of high risk and require design/clinical trial reviews, product certification and an assessed quality system involving clinical trials. These devices affect the functioning of vital organs and/or life-support systems. Devices are usually invasive,

Life-sustaining, life-supporting, or is used "in preventing impairment of human health or if the device presents a potential unreasonable risk of illness or injury".

2.2.2 Classification for In-Vitro Diagnostic:

In-Vitro Diagnostic medical devices are based on the potential risk involved in their use and interpretation clinically, refer to Annex 2 for their classification rules.

In-Vitro Diagnostic medical devices may be classified into 4 classes:

Class A (Low Individual Risk and Low Public Health Risk).

Class B (Moderate Individual Risk and/or Low Public Health Risk).

Class C (High Individual Risk and/or Moderate Public Health Risk).

Class D (High Individual Risk and High Public Health Risk). [5]

2.3 Responsibility and regulation In Sudan:

2.3.1 Sudan National Medicines And Poisons Board (NMPB)

In accordance with the Medicines and Poisons Act 2009 which gave National Medicines and Poisons Board (NMPB) the responsibility to regulate medical devices in Sudan. NMPB issued the regulation of medical device in 2010 which came to stress the importance of regulating medical devices that connect intimately with human health. The Sudan medical devices market is growing rapidly in consequence of a tremendous advance in technology, thus, the presence of a registration system is important to ensure safety, quality and effectiveness of medical devices. The main objectives of the Medical Devices Registration Directorate are to protect and maintain public health within the Sudan by implementation of provisions assuring a high level of safety and health protection of patients and users with regard to the use of medical devices.[6]

2.3.2 Sudan Atomic Energy Commission (SAEC)

The International Atomic Energy Agency (IAEA) was established in 1957. Sudan became a member of the International Atomic energy Agency in 1958. In 1962 the Minister of Foreign Affairs established The Sudanese National Committee for Atomic Energy and the Director of Geology Department Ministry of Energy and National Resources was appointed as Chairman, with membership drawn from bodies associated with international relations or use of techniques (foreign affairs, irrigation, health, agriculture, geology and University of Khartoum).Sudan Atomic Energy Committee was constituted to act as a focal point responsible for co-coordination between Government of Sudan (GOS) and the Agency in matters relating to nuclear energy.

The Objective of SAEC is to Care for the national interests, at both the international and national levels, with respect to the atomic energy affairs, and follow-up the developments thereof, - Enable the State to utilize atomic energy, in the peaceful purposes, in service of the plans and programs of economic development, - Ensure the safety of human beings, animals and the environment, in general. SAEC Units and Departments are Isotopes, Chemistry, Radiation Protection, Physics and Instrumentation. [8]

2.3.3 Sudanese Standards and Metrology Organization (SSMO)

The Sudanese Standards and Metrology Organization (SSMO) is a Governmental organization set up under the private law of SSMO, issued in 1993.

SSMO has its headquarters in Khartoum and state offices located in Khartoum airport, Port Sudan Harbour, Alobied, Kassala, Karima, Wad Madani, Wadi Halfa, Eldamazine, Dungula, Neyalla, Juba, Waw, Malakal and Algadarif; the structure includes 15 laboratories in addition to those established at the SSMO Branches, most important and well equipped ones are those in Port Sudan **SSMO** Branch. The also Information Centre. has an SSMO is a member of ISO, the African Regional Organization for Standardization (ARSO), the Arab Standards and Metrology Organization (ASMO), and Codex Alimentarius Commission, the Arab Industrial and Mining Organization (AIDMO), the Islamic Institute for Standardization, the International Institute for Cereal Science and Technology (ICC), African Standardization Commission Electro-technical (AFSEC). International Organization for legal metrology (OIML), an affiliate member of IEC. Besides being the focal point for SPS and TBT WTO Agreements. SSMO also signed several; bilateral agreements with the following: the Kenyan Bureau of Standards (KEBS), the Korean Agency for Standardization (KATS), the Jordan Institution for Standards and Metrology (JISM), the Syrian Arab Organization for Standardization and Metrology (SASMO), the Egyptian Organization for Standardization and Quality (EOS), the Saudi Arabia Standards Organization, Standards Organization (SASO), Emirates Authority for the Syrian Standardization (ESMA), Turkish National Center for Standardization (TSE), Libyan National Center for Standardization (LNCSM), General Administration for Chinese Standards (SAC), Uganda National Center for Standardization (UNBS), Tunis National Institute for Standardization (INORPI) and the in the process of signing with the Ethiopian Standards Authority (QSAE) The Standards Act (2008), Metrology Act (2008) and Precious Stones Act (2008), which allocates more power to SSMO. [9]

Dr. Ehab Youssef-et al., (2011) United Arab Emirates say : All devices should carry a clear label indicates the name of the company which is responsible for placement of the product in UAE market, manufacturer in country of origin , local distributor's address or website shows local distributor's name, and contact numbers and address. The local distributors can stick stickers on the outer pack of their products in a way that doesn't conceal any basic or essential information. Any medical device carries no distributor contact information will be liable for confiscation. The sticker should be approved by specific standard.

Used medical devices are not permitted for importation and marketing into UAE. For medical devices need to be exported from and then re-imported into UAE for refurbishment, upgrading and maintenance purposes. The importer should ensure the submission of documents which proof that medical devices were imported into UAE through legal channels, and then exported under approval. Such consignments will be cleared only upon pre import permit signed based on proper documentation.

Judith A. Johnson (June 25, 2012) FDA United State of American says: (Medical device regulation is complex, in part because of the wide variety of items that are categorized as medical devices. They may be simple tools used during medical examinations, such as tongue depressors and thermometers, or high-tech life-saving implants like heart valves and coronary stents. The medical device market has been characterized by including eight industry sectors: surgical and medical instrument manufacturing, surgical appliance and supplies, in-vitro diagnostic products (IVDs, or laboratory tests), electro medical and electrotherapeutic apparatus, irradiation apparatus, dental equipment and supplies, ophthalmic goods, and dental laboratories.

The federal agency is primarily responsible for regulating medical devices is the Food and Drug Administration (FDA)—an agency within the Department of Health and Human Services (HHS).

A manufacturer must receive FDA permission before its device can be legally marketed in the United States. FDA's Center for Devices and Radiological Health (CDRH) is primarily responsible for medical device review. Another center, the Center for Biologics Evaluation and Research (CBER), regulates devices associated with blood collection and processing procedures, cellular products and tissues.

Sahar Khiri, in M.Sc... SUST (2014) say: Medical devices play an important role in human being health. Consequently, it is important that there should be unified inspection method for imported medical devices and unify a team of consisting of all regulatory authorities in the work country. A protocol for inspection of imported medical devices was prepared and explained in figure (flow chart) which was conducted by a questionnaire directed for interested people in charge of regulating and inspecting of imported medical devices. Data was analyzed by using SPSS; in addition to a comparison and by reference to experiences of other countries. Throughout the study, it was turned up that it is important to work as a team for inspection and maintenance of quality of imported medical devices by using laboratories to check through the quality of imported medical devices.

4.1 Methodology

This chapter explains the steps that followed on this research. This research is qualitative and quantitative which describes specific current situation by using questionnaire.

To determine the significant problems that causes lack of coordination, implementation of the operations and appropriate inspection procedures for imported medical devices questionnaire and interviews from several places were carried out starting with National Medicines and Poisons Board, Sudanese Standards and Metrology Organization, Sudan Atomic Energy Commission, Medical companies and finally ending up with Sudan customhouses where we entered a course for 10 days. Then data was been collected and analyzed by using (SPSS) version 16.0.



Figure(4.1): Schematic diagram of the methodology

4.2 Data analysis

The statistical study was carried out from 60 samples and showed that:

4.2.1 The agreement to the policy of import medical devices:

- The question was: Do you agree with the conventional policy of importing medical devices?
- Through the analysis it turned up that 71.7% of respondents were agree and 28.3% were not. As illustrated in figure (4.2) and table (4.1).

Table (4.1) : The agreement to the policy of import medical devices:

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	43	71.7	71.7	71.7
No	17	28.3	28.3	100.0
Total	60	100.0	100.0	



Figure (4.2) : The agreement to the policy of import medical devices

• The majority of respondents indicate that the policy of import medical devices have the agreed by 71.7%.

4.2.2 The verification of the demand owner documents:

- The question was: Does the documents of demand owner been verified?
- Through the analysis it turned up that 93.3% of respondents indicate that the documents get verified and 6.7% says it does not. As illustrated in figure (4.3) and table (4.2).

Table (4.2) : The verification of the demand owner documents:

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	56	93.3	93.3	93.3
No	4	6.7	6.7	100.0
Total	60	100.0	100.0	



Figure (4.3): The verification of the demand owner documents

• The majority of respondents indicate that the owner documents get verified by 93.3%.

4.2.3 The method of saving demand owner documents:

- The question was: How the documents of demand owner been saved?
- Through the analysis it turned up that 43.3% of respondents indicate that the documents get saved on paper, on the other hand 26.7% says it get saved electronically and 30% say both ways have been done. As illustrated in figure (4.4) and table (4.3).

Table (4.3): The method of saving the demand owner documents

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Paper	26	43.3	43.3	43.3
electronic	16	26.7	26.7	70.0
Both	18	30.0	30.0	100.0
Total	60	100.0	100.0	



Figure (4.4) : The method of saving the demand owner documents

• The majority of respondents indicate that the owner documents get saved on paper by 43.3%.

4.2.4 The responsible bodies of inspection imported medical devices:

The question was: The inspection of imported medical devices followed to which body?

Through the analysis it turned up that 30% of respondents said it followed to National Medicine and poison board (NMPB), 16.7% of respondents said Sudanese Standards and Metrology Organization (SSMO), 28.3% of respondents answered (NMPB), (SSMO) and Sudan Atomic Energy Commission (SAEC). 21.7% of respondents said (NMPB) and (SSMO). And finally1.7% was not aware. As illustrated in figure (4.5) and table (4.4). Table (4.4) : The responsible bodies of inspection imported medical devices:

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	1	1.7	1.7	1.7
NMPB	18	30.0	30.0	31.7
SSMO	10	16.7	16.7	48.3
NMPB&SSMO&SAEC	17	28.3	28.3	76.7
Others	1	1.7	1.7	78.3
NMPB&SSMO	13	21.7	21.7	100.0
Total	60	100.0	100.0	



Figure (4.5) : The responsible bodies of inspection imported medical devices

 The majorities of respondents indicate that the responsibility of import medical devices followed to National Medicine and poison board (NMPB) by 30%.

4.2.5 The coordination between responsible bodies:

- The question was: Is there is any coordination between responsible bodies of importing medical devices?
- Through the analysis it turned up that 70% of respondents said that there is coordination, 28.3% said not and 1.7% was not aware. As illustrated in figure (4.6) and table (4.5).

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	1	1.7	1.7	1.7
Yes	42	70.0	70.0	71.7
No	17	28.3	28.3	100.0
Total	60	100.0	100.0	

Table (4.5) : The coordination between responsible bodies:



Figure (4.6) : The coordination between responsible bodies:

• The majority of respondents indicate that the coordination between responsible bodies of import medical devices is exist by 70%.

4.2.6 The agreement to establish separate body to do all procedures:

- The question was: Is it necessary to establish separate body to do all procedures?
- Through the analysis it turned up that 28.3% of respondents were agree 71.7% were not. As illustrated in figure (4.7) and table (4.6).

Table (4.6) : The agreement to establish separate body to do all procedures:

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	17	28.3	28.3	28.3
No	43	71.7	71.7	100.0
Total	60	100.0	100.0	



Figure (4.7) : The agreement to establish separate body to do all procedures

• The majority of respondents indicate that it is not necessary establish separate body responsible of all procedures of import medical devices by 71.7%.

4.2.7 The validity of imported medical devices inspection method:

- The question was: Is the inspection of imported medical devices done correctly?
- Through the analysis it turned up that 45% of respondents were agreed, 53.3% were not and 1.7% was not aware. As illustrated in figure (4.8) and table (4.7).

Table (4.7) : The validity of imported medical devices inspection method

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	1	1.7	1.7	1.7
Yes	27	45.0	45.0	46.7
No	32	53.3	53.3	100.0
Total	60	100.0	100.0	



Figure (4.8) : The validity of imported medical devices inspection method

• The majority of respondents indicate that the method of inspecting imported medical devices is not done correctly by 53.3%.

4.2.8 The inspection done by specialist biomedical engineers:

- The question was: Is the inspection done by specialist biomedical engineers?
- Through the analysis it turned up that 68.3% of respondents said that the inspection done by specialist biomedical engineers and 31.7% deny it. As illustrated in figure (4.9) and table (4.8).

Table (4.8) : The inspection done by specialist biomedical engineers:

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Yes	41	68.3	68.3	68.3
No	19	31.7	31.7	100.0
Total	60	100.0	100.0	



Figure (4.9) : The inspection done by specialist biomedical engineers

• The majority of respondents indicate that the inspection of imported medical devices is done by specialist biomedical engineers by 68.3%.

4.2.9 The need percentage of changing inspection method:

- The question was: What is the need percentage of changing inspection method?
- Through the analysis it turned up that 35% of respondents said that the need percentage of changing inspection method is 75%, 21.7% of respondents said 100%, 18.3% of respondents said 50%, 13.3% of respondents said 25%, 10% of respondents said 0% and 1.7% were not aware. As illustrated in figure (4.10) and table (4.9). Table (4.9) : The need percentage of changing inspection method:

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	1	1.7	1.7	1.7
0.0%	6	10.0	10.0	11.7
25%	8	13.3	13.3	25.0
50%	11	18.3	18.3	43.3
75%	21	35.0	35.0	78.3
100%	13	21.7	21.7	100.0
Total	60	100.0	100.0	



Figure (4.10) : The need percentage of changing inspection method

• The majority of respondents indicate that the inspection method of imported medical devices must be changed.
4.2.10 The availability of laboratory tests for the imported medical devices:

- The question was: Is there is an availability of laboratory tests for the imported medical devices?
- Through the analysis it turned up that 28.3% of respondents said yes, 70% deny and 1.7% was not aware. As illustrated in figure (4.11) and table (4.10).

Table (4.10) : The availability of laboratory tests for imported medical devices:

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	1	1.7	1.7	1.7
Yes	17	28.3	28.3	30.0
No	42	70.0	70.0	100.0
Total	60	100.0	100.0	



Figure (4.11) : The availability of laboratory tests for imported medical devices

• The majority of respondents indicate that the laboratory tests for imported medical devices are available by 28.3%.

4.2.11 The percentage of the availability of inspection tools for the imported medical devices:

- The question was: What is the percentage of the availability of inspection tools for the imported medical devices?
- Through the analysis it turned up that 41.7% of respondents said that the availability percentage of inspection tools is 0%, 28.3% of respondents said 25%, 10% of respondents said 50%, 8.3% of respondents said 75%, 5% of respondents said 100% and 6.7% were not aware. As illustrated in figure (4.12) and table (4.11).

Table (4.11) : The percentage of the availability of inspection tools for imported medical devices:

Answer	Frequency	Percent Valid Percent		Cumulative Percent
Not aware	4	6.7	6.7	6.7
0,0%	25	41.7	41.7	48.3
25%	17	28.3	28.3	76.7
50%	6	10.0	10.0	86.7
75%	5	8.3	8.3	95.0
100%	3	5.0	5.0	100.0
Total	60	100.0	100.0	



Figure (4.12) : The percentage of the availability of inspection tools for imported medical devices

• The majority of respondents indicate that the inspection tools of imported medical devices are not available at all by 41.7%.

4.2.12 The responsibility of import medical devices damage due to late:

- The question was: Who affords the responsibility when imported medical devices get damaged due to procedures late?
- Through the analysis it turned up that 60% of respondents said the owner, 20% said that the inspection body which causes the late afforded and 1.7% was not aware. As illustrated in figure (4.13) and table (4.12).

Table (4.12) : The responsibility of import medical devices damage due to late:

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	12	20.0	20.0	20.0
Owner	36	60.0	60.0	80.0
inspection institute	12	20.0	20.0	100.0
Total	60	100.0	100.0	



Figure (4.13) : The responsibility of import medical devices damage due to late

• The majority of respondents indicate that the damage which occurs in imported medical devices due to late fall on the owner shoulder by 60%.

4.2.13 The appropriate storage of imported medical devices:

- The question was: Does imported medical devices get appropriate storage?
- Through the analysis it turned up that 38.3% of respondents said the storage is good, 58.3% deny that and 3.3% was not aware. As illustrated in figure (4.14) and table (4.13).

Answer				
	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	2	3.3	3.3	3.3
Yes	23	38.3	38.3	41.7
No	35	58.3	58.3	100.0
Total	60	100.0	100.0	

Table (4.13) : The appropriate storage of imported medical devices:



Figure (4.14) : The appropriate storage of imported medical devices

• The majority of respondents indicate that the damage which occurs in imported medical devices due to late fall on the owner shoulder by 60%.

4.2.14 The atonement In case of device damage due to bad storage:

- The question was: In case of device damage due to bad storage is there is any atonement given?
- -Through the analysis it turned up that 31.7% of respondents said that there is atonement, 48.3% deny that and 20% was not aware. As illustrated in figure (4.15) and table (4.14).

Table (4.14) : The atonement In case of device damage due to bad storage:

Answer	Frequency Percent		Valid Percent	Cumulative Percent
Not aware	12	20.0	20.0	20.0
Yes	19	31.7	31.7	51.7
No	29	48.3	48.3	100.0
Total	60	100.0	100.0	



Figure (4.15) : The atonement In case of device damage due to bad storage

• The majority of respondents indicate that there is no atonement given in case of damage due to bad storage by 48.3%.

4.2.15 The suggestion to improve the policies of import medical devices:

- The question was: What are your suggestions to improve the policies of import medical devices?
- Through the analysis it turned up that 20% of respondents indicate that establishing one administration for all procedures to accelerate it is necessary, on the other hand 20% suggest importing medical devices with high quality and good specifications, 15% suggest having NMPB agreement before import and 45% of respondents were not aware. As illustrated in figure (4.16) and table (4.15).

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	27	45.0	45.0	45.0
NMPB agreement before import	9	15.0	15.0	60.0
import medical devices with high quality and good specifications	12	20.0	20.0	80.0
one administration to accelerate procedures	12	20.0	20.0	100.0
Total	60	100.0	100.0	

Table (4.15) : Suggestions to improve the policies of import medical devices:



Figure (4.16) : Suggestions to improve the policies of import medical devices

• The respondents indicate that the policies of import medical devices could be improved by import high quality medical devices, take the NMBP agreement before import and establish one administration to accelerate the procedures.

4.2.16 Suggestion to improve the inspection procedures of import medical devices:

- The question was: What are your suggestions to improve the inspection procedures of import medical devices?
- Through the analysis it turned up that 25% of respondents suggest that the inspection should be done by committee of professional engineers, on the other hand 23% suggest providing inspection tools and equipment's, 6.7% of respondents suggest providing laboratories with both professional engineers and inspection tools. 22% of respondents were not aware. As illustrated in figure (4.17) and table (4.16).

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	22	36.7	36.7	36.7
inspection done by committee of professional engineers	15	25.0	25.0	61.7
provide inspection tools and equipment's	14	23.3	23.3	85.0
provide laboratories	4	6.7	6.7	91.7
professional engineers and inspection tools	5	8.3	8.3	100.0
Total	60	100.0	100.0	

Table (4.16)	: Suggestions to	improve the	inspection	procedures of	of import	medical device	es



Figure (4.17) : Suggestions to improve the inspection procedures of import medical devices

• The respondents indicate that the inspection procedures of imported medical devices could be improved by providing inspection tools and laboratories. Also by making the inspection of imported medical devices done by committee of professional engineers.

4.2.17 The credibility in inspection or clearance of import medical devices:

- The question was: Is there is complete credibility in inspection or clearance of imported medical devices?
- Through the analysis it turned up that 48.3% of respondents said that there is complete credibility, 26.7% deny that and 25% was not aware. As illustrated in figure (4.18) and table (4.17).

Table (4.17) : The complete credibility in inspection or clearance:

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	15	25.0	25.0	25.0
Yes	29	48.3	48.3	73.3
No	16	26.7	26.7	100.0
Total	60	100.0	100.0	



Figure (4.18) : The complete credibility in inspection or clearance

• The majority of respondents indicate that the credibility in inspection and clearance procedures by 48.3%.

4.2.18 The linking method between responsible bodies and suggestions to improve it:

- The question was: What is the communication link between responsible bodies? And what are your suggestions for improvement?
- Through the analysis it turned up that 55% of respondents indicate that the communication link is paper and suggest to convert it into electronic, on the other hand 11.7% of respondents indicate that the communication link is paper and suggest to establish one office. 1.7% of respondents indicate that the communication link is paper and suggest to convert it into electronic and establish one office. 31.7% of respondents were not aware. As illustrated in figure (4.19) and table (4.18).

Table (4.18) : The communication link between responsible bodies and what your suggestions for improvement:

Answer	Frequency	Percent	Valid Percent	Cumulative Percent
Not aware	19	31.7	31.7	31.7
paper, electronic link	33	55.0	55.0	86.7
paper, one office	7	11.7	11.7	98.3
Both	1	1.7	1.7	100.0
Total	60	100.0	100.0	



Figure (4.19) : The communication link between responsible bodies and what your suggestions for improvement

• The majority of respondents indicate that papers are the communication link between responsible bodies and suggest establishing an electronic link for improvement by 55%.

Description of the computerized Medical Equipment inspection and coordination program:

The steps of designing the parts of the Medical Equipment inspection control program using the C Sharp language have been described below in addition to explaining the program contents and how to use it to have the desired results.

5.1 Opening the program:

When clicking the program icon to open it, the program is opened and this window appears in Figure (5.1)

Figure (5.1) : Login Window

The login window allows any user that is registered on the program by the administrators to access a specific form (window) of the program according to his role on the database table.

	username	password	role	name	gender	berth	address	education
\rangle	company	1292	company	NULL	NULL	NULL	NULL	NULL
	NMPB	1234	NMPB	NULL	NULL	NULL	NULL	NULL
	NMPB admin	2222	nadmin	NULL	NULL	NULL	NULL	NULL
	SSMO	123	SSMO	NULL	NULL	NULL	NULL	NULL
	SSMO admin	1111	sadmin	NULL	NULL	NULL	NULL	NULL
0	NULL	NULL	NULL	NULL	NULL	NULL	NULL	NULL

Figure (5.2) : Login Table

5.2 If the user is Company user:

The security part had been designed and it appears when the program is opened, and it work on protecting the program generally and the data base and the information about the medical devices in it specially by preventing to change or delete or modify this information by non-authorized users. And to do that the validity of accessing the data in the data base and the ability to modify it or delete it or to add new devices had been made available for the administrator only who manage other users and that by giving every user a special password so those user are able to use the program only in applying a new applications by company's or inspecting this orders by biomedical engineers; the devices in the database and do some available process in the program such as:

Send application for a new medical devices order to the (SSMO), Send application for a new medical devices order to the (NMPB), Send application for a new medical devices that's use radiation order to the (SAEC) if the user is a company that is registered on the (NMPB).



Figure (5.3) : Company's Window

5.3 The SSMO new application order:

After the authorized company user login into his account he can apply for a new device application and fill the form after clicking the new application on the menu.



Figure (5.4) : Company's SSMO new application form Window

	التاريخ	المرجع	المنتج	المنشأ	الماركة	العدد	الوزن	الشحن	الوصول	الكشف
\rangle	8/15/2016	1	MD	GER	TOSHIBA	3	500	GER	KHR	fast
	8/15/2016	1	MD	UK	flexicare medic	16	20	UK	KHR	azza
	8/20/2016	1	2	3	4	5	6	7	8	9
0	NULL	NULL	NULL	NULL	NULL	NULL	NULL	NULL	NULL	NULL

After filling the SSMO form the program save the data on the database:

Figure (5.5): Data Table of the medical devices

And show this message:



Figure (5.6) : order sent message

5.4 The SAEC Import License order:

The user can see the requirements and the procedures of the SAEC by choosing them from the menu string and it shows on the window:



Figure (5.7) : SAEC requirements window

If the medical device is a radioactive the program sends the user to fill the SAEC Import License so it gets to be approved by the SAEC.

•	Import license	- 🗆 🗙
licence No :		رقم رخصة الترخيص :
applicant name :		اسم المرخص له :
physical address :		العنوان :
Tel :		الها تف :
E-mail :		بريد الكتروني :
Nucluer		Linear
Send Update		

Figure (5.8) : SAEC Import License application window

If the device is linear when the user click on the linear button it shows the linear data table to the user:

		Ir	nport license		- 🗆 ×
licence	No :				رقم رخصة الترخيص :
applica	nt name :				اسم المرخص له :
physica	al address :				العنوان :
Tel :					الهاتف :
E-mail :					بريد الكتروني :
Nuc	luer				Linear
	manufacture	device	sn	model	Mev
<					>
Se	end Update	:			

Figure (5.9) : SAEC Linear Data Table

If the devise is nuclear when the user click on the nuclear button it shows the nuclear data table to the user:

Nuc	Nucluer								
	source	activity	manufacture						
*									
<					>				
Cand Hodata									
2	opual								

Figure (5.10) : SAEC Nuclear Data Table

After the user fill the data that required, by clicking the send button he send the data to the SAEC to be approved and the program shows this message:



Figure (5.11) : SAEC Data sent message

5.5 The NMPB new application order:

After the imported medical device is approved by the SSMO – and the SAEC if needed - it need to be approved by the NMPB ; by clicking the NMPB new application it shows the NMPB new order form:

 NMPB licence	- 🗆 🗙
العرجة : العرجة : العرجة : 20/201	مطابقة صادر التاريخ : ▼ 10 6 رقم البوليصة : رقم الفاتورة : عدد الوحدات : المنشأ :
بية 📄 اجهزة طبية معملية 📄 مستهلكات طبية 🦳 محاليل - كواشف Next Cancel	نوع الاصناف : اجهزة ط

Figure (5.12): NMPB New Application Window

After the user finish filling the application the program show the same message on (Figure 5.6).

5.6 If the user is SSMO inspection engineer:

If the user is authorized biomedical engineer that is registered on the database as inspection engineer the program shows the SSMO inspection form:

SSMO	- 🗆 🗙
بولیصة الشحن شهادة المنشأ شهادة تحلیل	مطابقة المستندات : الفاتورة قائمة المحتويات الشهادات الفنية تصديق الجهة ذات الصلة
 غیر مطابق صندوق طبلیة اخری: غیر تالف تلف جزئی 	الكشف الظاهري. درجة الحرارة : مطابق طريقة الشحن : حاوية الحالة العامة : تالف
 غیر موضح غیر مطابق غیر موضح غیر موضح غیر مطابق 	بطاقة البيان : اسم المنتج : موضح فترة الصلاحية : مطابق المنشأ : موضح اللغة : مطابق
_ غير موضح	وزن العبوة : موضح التغنيش الميدانى :
1	Exit Send

Figure (5.13) : SSMO Inspection form window

After the inspection engineer fills the form he writes his opinion if the order is passes the inspection or not and send it to the SSMO admin; the program show this message:



Figure (5.14): SSMO Inspection form Sent Message

5.7 If the user is SSMO inspection engineer:

If the user is authorized biomedical engineer that is registered on the database as inspection engineer on NMPB the program shows the NMPB inspection form:

	NMPB inspection	- 🗆 ×
الورجع : 1 🚽	8/20/2016	التاريخ : 🔻
	ف 🗆 غير جيدة	حالة التخزين 🔲 حيدة
	ةمجددة مستعملة	حالة الاجهزة: 🔄 جديد
	دليل المستخدم 📃 دليل الصيانة	وجود الكتلوجات : 🔄 د
	نة 📃 غير مطابقة	لغة الديباجة : 📃 مطابة
		محتويات الديباجات :
	الموديل المنشا	
	المصنع الريخ التصنيع	
		توجيهات المصنع : محتويات الفاتورة :
		التوصية : التوصية :
		ملاحظات :
1		التوصية :
	Exit	Send

Figure (5.15) : NMPB Inspection form window

After the inspection engineer fill the form he write his opinion if the order is pass the inspection or not and send it to the NMPB admin; the program show the message on (Figure 5.14).

5.8 If the user is SSMO or NMPB administrator:

After the company user send the data and the medical device been inspected by the inspection engineer they will be shown into the administrator window:

G				SSM	O_Admin			×
li	cences	Users						
	Se	arch						
		التاريخ	المرجع	المنتج	المنشأ	الماركة	العدد	
	•	8/15/2016	1	MD	GER	TOSHIBA	3	
		8/15/2016	2	MD	UK	flexicare medical	16	
		8/20/2016	1	2	3	4	5	
	*							
					· · ·	· ·		
	<							>

Figure (5.16) : Administrator Licenses window

When the administrator receives the report at the end of the inspections interval for every device he makes the right decision according to the information in the report which is:

- 1. Modify the forms if the entered data was not correct.
- 2. If the forms were correct the fault may be made by the users therefore they need training to have proper use for the program.
- 3. The device inspection report may not be conformity so the administrator can fix it.

Also the administrator can add a new user to the program login table using this tab window:

9	SSMO_Admin – 🗆 🗙
licences Users	
Name	
Gender	O Male O Female
D.O.B	Saturday , August 20,2016
Address	
Education	✓
Usemame	
password	
confirm password	
	Register

Figure (5.17) : Administrator Users window

The program is ended when the administrator approves the application that sends by the user and sends that this medical device is approved by both SSMO and NMPB and it allowed entering the Sudan market to the Sudanese customhouses. From the knowledge that was concluded from the data analysis of questionnaire and interviews, the responsible bodies of import medical devices were NMPB, SSMO and SAEC.

The coordination between these regulation bodies was not as required; most of the procedures were by paper, the inspection made by NMPB and SSMO which they do approximately same inspection which cause duplication of fees and waste time.

After data analysis and observations software program was implemented by using C# language to connect the three regulation bodies together.

The program is available for authorized users (companies) and each one of regulation bodies. When the program confirms that the user is registered in the system, then the user will be allowed to send an application to SSMO as the first step of confirmation, if the device is radioactive SAEC confirmation should be provided, after that NMPB application should be provided and after this step the approval of medical device sent to Sudan customhouses to allow the medical device to enter Sudan markets.

Sudanese standard and metrology organization, National medicine and poison board and redeemers of customs were much supported to the program and agreed that it will facilitate and accelerate the procedures of importation and clearance. Also NMPB offered to experiment the program in their institute so that if it achieve the goals they will implement it.

7.1 Conclusion

The project was completed according to the suggested plan; the connection link between regulation bodies become electronically which is faster and secure.

Paper system had no security and password required, could be lost and documents storage were a big issue which is not easily manageable.

Electronic system on the other hand is light weight, doesn't occupies wide areas, small, portable and fast. Also hold thousands of documents and information.

7.2 Recommendations

- Connect the program with: SSMO, NMPB, SAEC and Sudan ASYCUDA World customs.
- Connect the program with banks for fees acquisitioning.
- Verify the international certificates of the medical device.
- Insert the specifications of medical devices inside the program.
- Periodic inspection for medical devices after entering the country (during purchase and after sale).

References

[1] Recommended practice for a medical equipment management program," Retrieved February, vol. 19, 1999.

[2] L. Fennigkoh and B. Smith, "Clinical equipment management," JCAHO PTSM Series, vol. 2, pp. 5-14, 1989.

[3] "guiding principles of ministry of health in sudan," 2010.

[4] P. N. Y. M. A. Dr. Ehab Youssef Abu Eida. (2015). Guidance on Medical Device Compliance and Enforcement (GUI-0073). Available: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/gui-0073eng.php

[5] "Medical Device Registration Guideline," Registration and Drug Control Department Ministry of Health - UAE 2011.

[6] S. M. M. Khiri, "Development of protocol for Inspecting Imported Medical device," Sudan University of science and technology, 2015.

[7] J. A. Johnson, "FDA regulation of medical devices," Congr. Res. Serv, 2012.

[8] http://www.icpsr.org.ma/?Page=showInstitute&InstituteID=SAEC24&CountryID=Sudan Date access 24/10/2016.

[9] http://www.iso.org/iso/about/iso_members/iso_member_body.htm?member_id=2078Date access 24/10/2016.

السودان للعلوم والتكنولو	جامعة	
كلية الهندسة		
، الهندسة الطبية الحيوية	فسح	* 2
الإستبيــــــــــــــــــــــــــــــــــــ		Crystan (1997) Patricka
ستبانة التي صممت لجم	لمع بين أيديكم هذه الإ	يسرنا أن نط
برنامج فحص الأجهزة	البكلاريوس بعنوان: ب	بإعداده لنيل درجة
، مادة البحث العلمي علم	فقرات الإستبانة لإغناء	بالإجابة على جميع
	في غاية السرية.	العلمي فقط وسنكون
التخصص:		المهنة:
		المؤهل التعليمي:
در اسات	بكلاريوس	دبلوم
اد الأجهزة الطبية؟	سات المتبعة عند إستير	1/ هل أنت مع السيا
	لا	نعم
ن صاحب طلب الإستير ا	ل المستندات المقدمة مر	2/ هل يتم التحقق مر
	لا	نعم
ة من صاحب طلب إستير	حفظ المستندات المقدم	3/ كيف يتم توثيق و
	لا	نعم
إدارة:	طبية المستوردة يتبع ا	4/ فحص الأجهزة ال
	رية والسموم	المجلس القومي للأدو
	اصفات والمقاييس	الهيئة السودانية للمو
	السودان للعلوم والتكنولو كلية الهندسة م الهندسة الطبية الحيوية <u>الإستيان</u> م مادة التي صممت لجم برنامج فحص الأجهزة م مادة البحث العلمي علم مادة البحث العلمي علم راد الأجهزة الطبية؟ ن صاحب طلب الإستيرا من صاحب طلب الإستير بردارة:	جامعة السودان للعلوم والتكنولو جامعة السودان للعلوم والتكنولو تقسم الهندسة الطبية الحيوية تسع بين أيديكم هذه الإستبانة التي صممت لجم البكلاريوس بعنوان: برنامج فحص الأجهزة فقرات الإستبانة لإغناء مادة البحث العلمي علم في غاية السرية. بكلاريوس دراسات سات المتبعة عند إستيراد الأجهزة الطبية؟ لا المستندات المقدمة من صاحب طلب الإستيرا لا المنيور حفظ المستندات المقدمة من صاحب طلب إستيرا لا المنيور بية والسموم

Appendix (A)





15/ ما هي إقتراحاتك لتطوير السياسات المتبعة لإستيراد الأجهزة الطبية؟

16/ ما إقتر احاتك لتطوير عملية فحص الأجهزة الطبية المستوردة؟

.....

17/ هل يوجد مصداقية تامة في عملية فحص أو تخليص الأجهزة الطبية المستوردة؟

.....

18/ ماهي الطريقة المتبعة للربط بين الإدارات المختلفة (المجلس القومي للأدوية والسموم، الهيئة السودانية للمواصفات والمقاييس، هيئة الطاقة الذرية السودانية)؟ وهل بها عيوب؟ وما مقترحاتك لتحسينها؟

	ž	13月1日 13月1日			
~	وم والتكنولوجيا	جامعة السودان للعا			
	ندسة	كلية اله			À
	طبية الحيوية	قسم الهندسة ال			
united to a charter	<u>ä_1</u>	مقـــــاب		united the state of the	51
				: ā	الهيئ
				ة:	المهذ
			,	سص :	التخد
				هل التعليمي:	المؤه
أخرى	در اسات عليا	يو س	البكالور		دبلوم
	 هزه الطبية ؟	بئه عند استيراد الاج	ذي تقوم به الهي	ا هو الدور الذ	1/ مـ
		جهزه الطبية ؟	ت استيراد الا	ا هي اجراءا	2/ ما

3/ ما هي المستندات المطلوبة وماهي الطريقة المتبعة للتحقق منها ؟

	•••••												•••••		
	•••••												•••••	•••••	
ç	لها	المطلوبة	المواصفات	؟ و	أقسامها	و	الطبية	هزة	الأج	صنيف	يقة ت	طر	هي	ما	/4
	•••••														
••						?	ة الطبية	الاجهز	ىتىراد	تواجه الا	، التي ن	ئىاكل	ي المن	ما ھے	
					1	·····						•••••			
					و اصفائها	<u>ف</u> ه م	ة و مطاب	الاجهرة	، من ا	له للتحقق	، المنبع	ريفه 	ي الط 	ما ھ _و	
	•••••														
					ę	ער .) الی الب	الدخول	ية بعد	بزة الطب	ة للاجه	رقابة	وجد (هل يو	17
••															
••	• • • • • • •			• • • • • • • •	• • • • • • • • • • • •	• • • • •	• • • • • • • • • •	• • • • • • • • •	• • • • • • • •	• • • • • • • • • •		•••••	• • • • • •	• • • • • •	• • • •

Appendi	x (B)
. .	· · ·



وزارة مجلس الوزراء الهينة السودانية للمواصفات والمقاييس



استمارة طلب شهادة تقييم مطابقة صادر وارد

التاريخ ١ / ٢

لرجع:
وع المنتج:
لتشا:
لاركة:
ىدد الوحدات:
وزن الإجمالي:

-	ميناء الشحن:
	ميناء الوصول:
	موقع الكشف:
	موقع التخزين:
رقم البوليصة	الشهادة الجمركية:
	رقم الإيداع:

إسم المورد/المصدر:
عنوان المورد/المصدر ورقم الهاتف:
إسم المخلص ورقم الهائف:
رقم رخصة التخليص:
التوقيع:

للإستعمال الرسمى:

الإسم:		
التوقيع:		
رقم الإيصال المالي:	التاريخ	
رقم الشهادة:	التاريخ:	
رقم الإصدار: 01	قاريخ الإصدار :2014/2/25م	الرمز: WI-32-01-F1

	استمارة التقنيس	C. B.
	e	الرقم المسلسل :
Г		
		مطابقه المستندات: ملاحظات:
		الفاتوره أو الفورم (48):
		بوليصة الشحن:
2		قائمة المحتوياتار الفورم (48):
		شهادة المنشأ أو المنشأ الموضح بديباجة المنتج:
. 1	3	الشهادات القنيه:
		شهادة تحليل (شهادة فلية):
		تصديق الجهه ذات الصله
		الكشف الظاهرى:
	غیر مطابق 🗌 اخراب 🗌	درجة الحرارة : مطابق ل
		طريقة الشحن: حاويه
-	عرز دافت 📋 🚥 جرمي 📋	الحاله العامه: تالف ل
	1	
		بطاقه البيان:
	مير مركس في	إسم الملائج مرضيح
		فترة الصلاحية: معادى
	غير موالة.	المنشا: موضيح
		ورن اعبود مرسى

SSA المرتبة السردانية للتر اعدلات والتقصي التقلقي المبدائين ****** ملاحظات الفني المختصى: التاريخ:..... الترقيع :..... توصية رئيس الوحدة : ر نيمن الوحدة الأسم : التوقيع : التاريخ: القرار النهائمي: ***************** إعتماد: الاسم: التاريخ: الترايع: الرمز:WI-32-02-F1 تاريخ الإصدار 2015/3/18م رقم الإصدار : 01 Page 2 of 2

Republic of Sudan Federal Ministry of Health National Medicines & Poisons Board Secretariat General



شهادة تسجيل مستلزم طبي Registration Certificate for Medical Device

هذا المستئد هو ملك للمجلس القومي للأدوية والسّموم وتجب This document is the property of the NMPB and must إعادته عند الطلب.

تلفون: ١٩٠ ٨٨٠ - ٢٧١ ٨٨٠ (٢٤٩) - فاكس: ٢٢٢٦٢ ٥ ١٨٢ (٢٤٩) - ص.ب: ٢١٨ الخرطوم - السودان



يسم الله الرحمن الرحيم وزارة الحاجلية/رياسة قوارص الشرطة عيدة الجمارات الاحارة العامة للعمليات الممرغية حاذرة جمارات الخرطوم إحارة جمارات مطار الخرطوم



النمرة : ود/ ه ج/ دج خ/ ج م خ/٩ : // / ١

التاريخ ٢٠١٦/٢/١٥

شهادة لمن يهمهم الأمر

- - للتكوم بالعلم •
 - ۳. جزأكم الله خيرا •

ملازم شرط أسامه الفكي يوسف

٤/ عميد شرطة /

مدير إدارة جمسارك مطار الخرطوم



يسم الله الرحمن الرحيم وزارة الحاجلية/رناسة قوابم الشرطة ميزة الجمارات الاحارم العامة للعمليام البمركية حافرة جمارات العرطوم إحارة جمارات مطار الغرطوم



النمرة : ود/ ه ج/ د ج خ/ ج م خ/ ٤ ۱ / ۱ / ۱

شهادة لمن يهمهم الأمر

- تشهد إدارة جمارك مطار الخرطوم بان الطالب / عباده عباس إبراهيم احمد تلقه دورة تدريبيه في الفترة من ١/٢٥ حتي ١٥ /٢٠١٦٦ م وتنقلت خلالها علي أقســــام (الإدارة -العمومي - الاسكودا -القرية الجديدة(تعريفة)-مخزن السودانية-شهادة الوارلا) وكان أداؤه ممتاز٠ ٢. للتكرم بالعلم ٠
 - ٣. جزأكم الله خيرا •

التاريخ ٢٠١٦/٢/١٥

ملازم شرطة أسامه الفكي يو ع/ عميد شرطة /

مدير إدارة جمسارك مطار الخرطوم


يسم الله الرحمن الرحيم وزارة الحاجلية/رياسة قوابت الشرطة مينة الجمارك الأحارة العامة للعمليات الجمركية حابرة جمارك الخرطوم إحارة جمارك مطار الخرطوم



التمرة : ود/ هـ ج/ د ج خ/ ج م خ/١٤٩ / ١

شهادة لمن يهمهم الأمر

- تشهد إدارة جمارك مطار الخرطوم بان الطالبة / هنادي موسي عمرموسي تلقت دورة تدريبيه في الفترة من ١/٢٥ حتي ١٥ /٢٠١٦/٢ م وتنقلت خلالها علي أقــــــام (الإدارة –العمومي – الاسكودا –القرية الجديدة(تعريفة)–مخزن السودانية–شهادة الوارد) وكان أداؤها ممتاز.
 - ٢. للتكوم بالعلم •
 - ۳. جزأكم الله خيرا •

التاريخ ١٥/٢/١٥ ،

ملازم شيرطية أسامه الفكي يوسف ع/ عميد شرطة /

مدير إدارة جمارك مطار الخرطوم