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

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قال تعالى:

{قَالُوا سُبْحَانَكَ لَا عِلْمَ لَنَا إِلَّا مَا عَلَّمْتَنَا إِنَّكَ أَنْتَ الْعَلِيمُ الْحَكِيمُ}

صدق الله العظيم

سورة البقرة الآية (32)
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 warm wishes and prayers.

Our Special gratitude to Dr. 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.
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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
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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 لا يتجزأ من ممارسة مهنة الطب بل تعتبر الشرط المطلوب لجودة الخدمة الطبية وسلامتها. لذلك توجد بكل مستشفى صغيراً كان أم كبيراً عدد من الأجهزة الطبية والتي بدون إستثناء تصنع خارج السودان وهذا الوضع خلق كثيراً من الإشكاليات في كيفية الحصول على الجيد من هذه الأجهزة وطريقة الحفاظ عليها لعمل بسلامة وإستدامة وكفاءة.

هذا البحث يهدف إلى إعداد برنامج إلكتروني يقوم بالتنسيق بين الجهات المسؤولة من أجراءات استيراد الأجهزة الطبية وتفتيشها لضمان استيراد أجهزة طبية أمنة وأفضل جودة عالية، واستبدال المعاملات الورقية بالإلكترونية لتسهيل وتسريع الإجراءات.

ولتحقيق أهداف هذا البحث تم إجراء العديد من الزيارات والمقابلات لاستخلاص 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 الاستيراد والتخلص وضمان جودة وفعالية الأجهزة الطبية المستوردة.

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

XIII
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 stand-alone 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 I (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).
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 Branch. The SSMO also has an Information Centre.

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 Electro-technical Standardization Commission (AFSEC), International Organization for legal metrology (OIML), and 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, the Syrian Standards Organization (SASO), Emirates Authority for 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 work consisting of all regulatory authorities in the 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:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>43</td>
<td>71.7</td>
<td>71.7</td>
<td>71.7</td>
</tr>
<tr>
<td>No</td>
<td>17</td>
<td>28.3</td>
<td>28.3</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>56</td>
<td>93.3</td>
<td>93.3</td>
<td>93.3</td>
</tr>
<tr>
<td>No</td>
<td>4</td>
<td>6.7</td>
<td>6.7</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper</td>
<td>26</td>
<td>43.3</td>
<td>43.3</td>
<td>43.3</td>
</tr>
<tr>
<td>electronic</td>
<td>16</td>
<td>26.7</td>
<td>26.7</td>
<td>70.0</td>
</tr>
<tr>
<td>Both</td>
<td>18</td>
<td>30.0</td>
<td>30.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

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 finally 1.7% was not aware. As illustrated in figure (4.5) and table (4.4).

Table (4.4) : The responsible bodies of inspection imported medical devices:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>1</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
</tr>
<tr>
<td>NMPB</td>
<td>18</td>
<td>30.0</td>
<td>30.0</td>
<td>31.7</td>
</tr>
<tr>
<td>SSMO</td>
<td>10</td>
<td>16.7</td>
<td>16.7</td>
<td>48.3</td>
</tr>
<tr>
<td>NMPB&amp;SSMO&amp;SAEC</td>
<td>17</td>
<td>28.3</td>
<td>28.3</td>
<td>76.7</td>
</tr>
<tr>
<td>Others</td>
<td>1</td>
<td>1.7</td>
<td>1.7</td>
<td>78.3</td>
</tr>
<tr>
<td>NMPB&amp;SSMO</td>
<td>13</td>
<td>21.7</td>
<td>21.7</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
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).

Table (4.5) : The coordination between responsible bodies:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>1</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
</tr>
<tr>
<td>Yes</td>
<td>42</td>
<td>70.0</td>
<td>70.0</td>
<td>71.7</td>
</tr>
<tr>
<td>No</td>
<td>17</td>
<td>28.3</td>
<td>28.3</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>17</td>
<td>28.3</td>
<td>28.3</td>
<td>28.3</td>
</tr>
<tr>
<td>No</td>
<td>43</td>
<td>71.7</td>
<td>71.7</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>1</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
</tr>
<tr>
<td>Yes</td>
<td>27</td>
<td>45.0</td>
<td>45.0</td>
<td>46.7</td>
</tr>
<tr>
<td>No</td>
<td>32</td>
<td>53.3</td>
<td>53.3</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>41</td>
<td>68.3</td>
<td>68.3</td>
<td>68.3</td>
</tr>
<tr>
<td>No</td>
<td>19</td>
<td>31.7</td>
<td>31.7</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>1</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
</tr>
<tr>
<td>0.0%</td>
<td>6</td>
<td>10.0</td>
<td>10.0</td>
<td>11.7</td>
</tr>
<tr>
<td>25%</td>
<td>8</td>
<td>13.3</td>
<td>13.3</td>
<td>25.0</td>
</tr>
<tr>
<td>50%</td>
<td>11</td>
<td>18.3</td>
<td>18.3</td>
<td>43.3</td>
</tr>
<tr>
<td>75%</td>
<td>21</td>
<td>35.0</td>
<td>35.0</td>
<td>78.3</td>
</tr>
<tr>
<td>100%</td>
<td>13</td>
<td>21.7</td>
<td>21.7</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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 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:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>1</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
</tr>
<tr>
<td>Yes</td>
<td>17</td>
<td>28.3</td>
<td>28.3</td>
<td>30.0</td>
</tr>
<tr>
<td>No</td>
<td>42</td>
<td>70.0</td>
<td>70.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>4</td>
<td>6.7</td>
<td>6.7</td>
<td>6.7</td>
</tr>
<tr>
<td>0,0%</td>
<td>25</td>
<td>41.7</td>
<td>41.7</td>
<td>48.3</td>
</tr>
<tr>
<td>25%</td>
<td>17</td>
<td>28.3</td>
<td>28.3</td>
<td>76.7</td>
</tr>
<tr>
<td>50%</td>
<td>6</td>
<td>10.0</td>
<td>10.0</td>
<td>86.7</td>
</tr>
<tr>
<td>75%</td>
<td>5</td>
<td>8.3</td>
<td>8.3</td>
<td>95.0</td>
</tr>
<tr>
<td>100%</td>
<td>3</td>
<td>5.0</td>
<td>5.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>12</td>
<td>20.0</td>
<td>20.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Owner</td>
<td>36</td>
<td>60.0</td>
<td>60.0</td>
<td>80.0</td>
</tr>
<tr>
<td>inspection institute</td>
<td>12</td>
<td>20.0</td>
<td>20.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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).

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

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
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<td>2</td>
<td>3.3</td>
<td>3.3</td>
<td>3.3</td>
</tr>
<tr>
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<td>23</td>
<td>38.3</td>
<td>38.3</td>
<td>41.7</td>
</tr>
<tr>
<td>No</td>
<td>35</td>
<td>58.3</td>
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</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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 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:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>12</td>
<td>20.0</td>
<td>20.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Yes</td>
<td>19</td>
<td>31.7</td>
<td>31.7</td>
<td>51.7</td>
</tr>
<tr>
<td>No</td>
<td>29</td>
<td>48.3</td>
<td>48.3</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
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<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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).

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

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>27</td>
<td>45.0</td>
<td>45.0</td>
<td>45.0</td>
</tr>
<tr>
<td>NMPB agreement before import</td>
<td>9</td>
<td>15.0</td>
<td>15.0</td>
<td>60.0</td>
</tr>
<tr>
<td>import medical devices with high quality and good specifications</td>
<td>12</td>
<td>20.0</td>
<td>20.0</td>
<td>80.0</td>
</tr>
<tr>
<td>one administration to accelerate procedures</td>
<td>12</td>
<td>20.0</td>
<td>20.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
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.

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).

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

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>22</td>
<td>36.7</td>
<td>36.7</td>
<td>36.7</td>
</tr>
<tr>
<td>inspection done by committee of professional engineers</td>
<td>15</td>
<td>25.0</td>
<td>25.0</td>
<td>61.7</td>
</tr>
<tr>
<td>provide inspection tools and equipment's</td>
<td>14</td>
<td>23.3</td>
<td>23.3</td>
<td>85.0</td>
</tr>
<tr>
<td>provide laboratories</td>
<td>4</td>
<td>6.7</td>
<td>6.7</td>
<td>91.7</td>
</tr>
<tr>
<td>professional engineers and inspection tools</td>
<td>5</td>
<td>8.3</td>
<td>8.3</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
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.

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

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>15</td>
<td>25.0</td>
<td>25.0</td>
<td>25.0</td>
</tr>
<tr>
<td>Yes</td>
<td>29</td>
<td>48.3</td>
<td>48.3</td>
<td>73.3</td>
</tr>
<tr>
<td>No</td>
<td>16</td>
<td>26.7</td>
<td>26.7</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Answer</th>
<th>Frequency</th>
<th>Percent</th>
<th>Valid Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not aware</td>
<td>19</td>
<td>31.7</td>
<td>31.7</td>
<td>31.7</td>
</tr>
<tr>
<td>paper, electronic link</td>
<td>33</td>
<td>55.0</td>
<td>55.0</td>
<td>86.7</td>
</tr>
<tr>
<td>paper, one office</td>
<td>7</td>
<td>11.7</td>
<td>11.7</td>
<td>98.3</td>
</tr>
<tr>
<td>Both</td>
<td>1</td>
<td>1.7</td>
<td>1.7</td>
<td>100.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>
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)

![Login Window](image)

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

<table>
<thead>
<tr>
<th>رابع</th>
<th>نوع</th>
<th>الجزء</th>
<th>المنشأ</th>
<th>الأيزويدين</th>
<th>العدد</th>
<th>النوع</th>
<th>الوالد</th>
<th>السرعة</th>
<th>الكشف</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/15/2016</td>
<td>MD</td>
<td>GER</td>
<td>TOSHIBA</td>
<td>3</td>
<td>500</td>
<td>GER</td>
<td>KHI</td>
<td>fast</td>
<td></td>
</tr>
<tr>
<td>1/15/2016</td>
<td>MD</td>
<td>UK</td>
<td>flexcare medical</td>
<td>16</td>
<td>20</td>
<td>UK</td>
<td>KHI</td>
<td>asza</td>
<td></td>
</tr>
<tr>
<td>1/20/2016</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>NULL</td>
<td>NULL</td>
<td>NULL</td>
<td>NULL</td>
<td>NULL</td>
<td>NULL</td>
<td>NULL</td>
<td>NULL</td>
<td>NULL</td>
<td></td>
</tr>
</tbody>
</table>

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.

![SAEC Import License application window](image)

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:

![SAEC Linear Data Table](image)

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:

![SAEC Nuclear Data Table](image)

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:

![SAEC Data sent message](image)

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:
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:

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:

![SSMO Inspection form Sent Message](image)

### 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 form window](image)

### 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:

![SSMO_Admin window](image)

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:

![SSMO_Admin Users window](image)

**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


Appendix (A)

جامعة السودان للعلوم والتكنولوجيا
كلية الهندسة
قسم الهندسة الطبية الحيوية

الاستبيان

يرسنا أن نضع بين أيديكم هذه الإستبانة التي صممت لجمع المعلومات اللازمة للبحث الذي يقوم بإعداده لخريجي درجة البكالوريوس بعنوان: برنامج فحص الأجهزة الطبية المستوردة، نرجو منكم التكرم بالإجابة على جميع فقرات الإستبانة لاغناء مادة البحث العلمي علمًا بأنه سيتم استخدامه لأغراض البحث العلمي فقط وستكون في غاية السرية.

المهنة: ........................................... التخصص: .......................................

المؤهل التعليمي:

- دبلوم
- بكالوريوس
- دراسات عليا

/ هل أنت مع السياسات المتبعة عند استيراد الأجهزة الطبية؟
  - نعم
  - لا

/ هل يتم التحقق من المستندات المقدمة من صاحب طلب الاستيراد؟
  - نعم
  - لا

/ كيف يتم توثيق وحفظ المستندات المقدمة من صاحب طلب استيراد الجهاز؟
  - نعم
  - لا

/ فحص الأجهزة الطبية المستوردة يتبع لإدارة:
  - المجلس القومي للابدية والسموم
  - الهيئة السودانية للمواصفات والمقاييس
لجنة مكونة من الأدوية والسموم والمواصفات والمقاييس وهيئة الطاقة الذرية السودانية

إدارة أخرى

5/ هل هناك تسويق بين الإدارات المنفولة عن إكمال إجراءات الاستيراد بوجود رابط بينها؟
- نعم
- لا

6/ هل هناك ضرورة لعمل إدارة أخرى منفصلة لتقوم بجميع الإجراءات؟
- نعم
- لا

7/ هل فحص الأجهزة المستوردة يتم بصورة صحيحة؟
- نعم
- لا

8/ هل يقوم بهذا الفحص مهندس مختص؟
- نعم
- لا

9/ نسبة الحوصلة لتغير الطريقة المتبعة لفحص الأجهزة الطبية:
- 100%
- 75%
- 50%
- 25%
- 0%

10/ هل هناك اختبارات معملية يتم إجراءها للأجهزة؟
- نعم
- لا

11/ ما مدى توفر أجهزة فحص الأجهزة الطبية؟
- 100%
- 75%
- 50%
- 25%
- 0%

12/ من يتحمل الضرر في حالة تأخر الإجراءات؟
- المقدم الطلب
- الإدارات المنفولة عن الفحص

13/ هل يتم تخزين الأجهزة بصورة لائقة؟
- نعم
- لا

14/ عند تلف الجهاز بسبب التخزين السيء هل يتم تقديم تعويض؟
- نعم
- لا
15/ ما هي إقتراحاتك لتطوير السياسات المتبعة لإستيراد الأجهزة الطبية؟

.............................................................................................................................................
.............................................................................................................................................
.............................................................................................................................................
.............................................................................................................................................

16/ ما إقتراحاتك لتطوير عملية فحص الأجهزة الطبية المستوردة؟

.............................................................................................................................................
.............................................................................................................................................
.............................................................................................................................................
.............................................................................................................................................

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

.............................................................................................................................................
.............................................................................................................................................
.............................................................................................................................................
.............................................................................................................................................

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

.............................................................................................................................................
.............................................................................................................................................
.............................................................................................................................................
.............................................................................................................................................
المهنة: ..........................................
التخصص: ......................................
المؤهل التعليمي:
البكالوريوس □
دبلوم □
دراسات عليا □
أخرى □

1/ ما هو الدور الذي تقوم به الهيئة عند استيراد الأجهزة الطبية؟
....................................................................................................................
.........................................................................................
........................................................................................................
..................................................
....................................................................................................................
.....................................................................................................
.............

2/ ما هي إجراءات استيراد الأجهزة الطبية؟
....................................................................................................................
.........................................................................................
........................................................................................................
..................................................
....................................................................................................................
.....................................................................................................
.............
3/ ما هي المستندات المطلوبة وماهي الطريقة المتبعة للتحقق منها؟

4/ ما هي طريقة تصنيف الأجهزة الطبية و أقسامها؟ والمواصفات المطلوبة لها؟

5/ ما هي المشاكل التي تواجه استيراد الأجهزة الطبية؟

6/ ما هي الطريقة المتبعة للتحقق من الأجهزة و مطابقة مواصفاتها؟

7/ هل يوجد رقابة للاجهزة الطبية بعد الدخول الى البلاد؟
Appendix (B)
وزارة مجلس الوزراء
الهيئة السودانية للمراعات والتفتيش
استمارة التفتيش

الملاحظات:
- الدافع أو الفorum (48):
- بوليصة الشحن:
- قائمة المحروقات أو القوام (48):
- شهادة البناء أو النشأة والموضوع بديلة النتائج:
- الشهادات القانونية:
- شهادة تحاليل (شهادة فنية):
- تصريح الجهات ذات الصلة

الكشف الظاهري:
- درجة الحرارة:
- طريقة الشحن:
- الحلول العامة:

بيانات البضائع:
- اسم المنتج:
- طبقات السلامة:
- النشأة:
- الجسم:
- الوزن الحاوي:

رقم الإصدار: 01
تاريخ الإصدار: 18/3/2015
الرقم: F1-32-02
يسمى الله الرحمن الرحيم
وزارة الداخلية/熔司 contradictory
 الهيئة العامة
الإدارة العامة للتعليم الإبتدائي
حافنة مطار الخرطوم
إدارة مدارك مطار الخرطوم

الدفیر : ٢٩/٧/١٤٣٦
الشمسیة : ١/٨/١٤٣٦

شهادة

1. تشهد إدارة مطار الخرطوم بأن الطالب / عبده عباس إبراهيم
احمد لله دورة تدريبية في الفترة من ٠٣/١٥/٢٠١٥ حتى ١٥/٧/٢٠١٥

2. للطعام بالعلم.

3. جزاكم الله خيراً.

مدير إدارة جمارك مطار الخرطوم

اسم الفقي روسي
مدير شرطة
السماحة حمدي محمد الحبشي

السماحة حمدي محمد الحبشي

التاريخ: 10/1/2020

شهادة


2. للنظام بالمغامرة.

3. جزاك الله خيراً.

فازم حمدي

مدير إدارة جمارك مطار الخرطوم