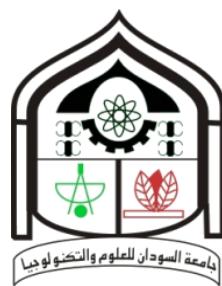


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SUDAN UNIVERSITY OF SCIENCE AND TECHNOLOGY



College of post graduate studies



Development of protocol for Inspecting Imported Medical device

تطوير بروتوكول فحص الأجهزة الطبية المستوردة

Thesis Submitted in partial fulfillment for M.Sc.(honor) Degree in :

Biomedical Engineering

by:

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الله

بسم الله الرحمن الرحيم

{**قَالُوا سَبَّانَكَ لَا عِلْمَ لَنَا إِلَّا
مَا عَلِمْتَنَا إِنَّكَ أَنْتَ الْعَلِيمُ
الْحَكِيمُ**}

صدق الله العظيم

الأية 32 سورة البقرة

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ABSTRACT

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.

المستخلص

تلعب الأجهزة الطبية دوراً مهماً في صحة الإنسان، لذا من الاهتمام بمكان أن تكون هناك طريقة لتفتيش موحدة للأجهزة الطبية المستوردة وتوحيد فريق العمل من كل الجهات الرقابية بالبلاد.

أعد بروتوكول لتفتيش الأجهزة الطبية المستوردة موضح في شكل مخطط تدفقي وذلك بواسطة الإستبيان وجهاً للمعنىين بتنظيم وتفتيش الأجهزة الطبية المستوردة وتحليل المعلومات باستخدام نظام إحصائي (SPSS) ومقارنة واستناداً على تجارب دول أخرى.

من خلال الدراسة تم الوصول لضرورة العمل كفريق لتفتيش وضمان جودة الأجهزة المستوردة بواسطة مختبرات التأكيد من جودة الأجهزة المستوردة.

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CHAPTER ONE

Introduction

Introduction

The Medical Devices Inspection Program, adopted in March 2004, was directed towards medical devices manufacturers, importers and distributors. For most of the companies and establishments that were inspected at least for some issues of noncompliance were cited. However, the majority of the compliance issues were related to the documentation of risk-management procedures. Whereas noncompliance associated with a potential direct risk to health and safety was observed, the ministry of health worked together with companies involved to immediately resolve the issue.

The aims of the study are to identify and address risks for health and safety. In addition, the inspections achieved further benefits. Through this process, the companies gained better understanding of regulations and inspection procedures. Furthermore, the Inspectorate was able to determine the regulatory areas that need more clarification. To address this, the Inspectorate will continue to develop compliance promotion activities which aimed at achieving greater regulatory compliance. These efforts including a pre-inspection package help establishments to prepare for the inspection process.

1-1 General view:

Sudanese standard and metrology organization approved many standards for different equipment and devices but they have not been implemented in the inspection of imported medical equipment. And the actual population of the study consists of all Sudanese standards and metrology organization (SSMO) in all branches Port Sudan, Soba containers, Khartoum Air port, and other regulatory parts.

1-2 Problem statement:

Lack of proper inspection procedure for imported medical equipment.

1-3 Objectives:

1-3-1 General objectives:

Reduce and manage the risks of medical equipment by placing a proper inspection procedure for the imported medical equipment.

1-3-2 Specific objectives:

- Implement approved Sudanese standards.
- Regulate the clearance of imported medical equipment.
- Develop guide lines for inspection.
- Prevent the economy of our country.
- Ensure safety in medical device use.

1-4 Methodology:

The research used the questionnaire to survey all organizations and inspectors of medical device. And the data was analyzed by using computer-based program Statistical Package for Social Sciences (SPSS) version 21. Flow chart for inspection procedure protocol was designed.

1-5 Thesis layouts:

This research includes six chapters. Chapter one is an introduction that contains the general review, problems and objectives of the research. Theoretical, fundamental and background studies were reviewed in chapter two. Chapter three contains data analysis. Design and inspection protocol was explained in chapter four. Chapter five includes discussion. Chapter six contains conclusion and recommendations.

CHAPTER TWO

Theoretical fundamental and back ground studies

Theoretical fundamental and back ground studies

2-1 Theoretical fundamental:

For the purpose of this research, the following definitions are used:

2-1-1 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.

2-1-2 Medical device: An article, instrument, apparatus or machine that uses in prevention, diagnosis, treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purposes. Typically, the purpose of medical device is not achieved by pharmacological, immunological or metabolic means. [2]

2-1-3 Medical equipment: Medical devices require calibration, maintenance, repair, 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 excluding implantable, disposable or single-use medical devices. [3]

2-1-4 Clinical Engineering: A specialty within Biomedical Engineering responsible primarily for managing and maintaining medical equipment/devices and related systems. The scope and location (within the health service) of Clinical Engineering vary from country to country, region

to region and depend on historical, organizational, related-service- and economic factors, amongst others. CE functions typically include: Asset management; Risk management; Technology specification, evaluation & commissioning; Inspection/preventive maintenance (IPM); Repairs, modifications and limited R&D; Spares inventory management; Contract/service provider management; In-service training; Liaison with users and suppliers, etc.[3]

2-1-5 Inspection: A procedure used to verify that the physical integrity, safety, and performance of a device meet the necessary requirements. [3]

2-1-6 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]

2-1-7 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]

2-1-8 Benchmark: A reference value for an indicator; it may be established by using internal or external benchmarking or regulation. [4]

2-1-9 CE mark: CE markings indicate that a product meets European Union directive standards of performance and safety. [4]

2-2 Classification of 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 in each class, type and technology of medical device.

2-2-1 classification of general medical devices

Medical devices may be classified into 4 classes Class 1 (low risk). II and III (medium risk) or IV (high risk). Refer to annex 2 for classification rules of general medical devices [5].

2-2-1-1 Class I Devices –Those need 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 by the legal manufacturer.

2-2-1-2 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

2-2-1-3 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.

2-2-1-4 Class IV devices are of high risk and require design/clinical trial reviews, product certification and quality assessment system involving

clinical trials. These devices affect the functioning of vital organs and/or life-support systems. The devices are usually invasive, life-sustaining, life-supporting, or that used "in preventing impairment of human health or in case that 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 3 for their classification rules [7].

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

2-2-2-1 Class A: (Low Individual Risk and Low Public Health Risk).

2-2-2-2 Class B: (Moderate Individual Risk and/or Low Public Health Risk).

2-2-2-3 Class C: (High Individual Risk and/or Moderate Public Health Risk).

2-2-2-4 Class D: (High Individual Risk and High Public Health Risk).

2-2-3 General Consideration in classification

In terms of further interpretation of the decision rules, the following should be considered [8]:

- A.** It is intended, not accidental use of the device that determines the class of the device. If a medical practitioner uses the device in a manner not intended by the company that will not change the class of the device for purpose of conformity assessment.
- B.** It is the intended purpose assigned by the company to the device that determines the class of the device and not the class assigned to other similar products.
- C.** As an alternative to classify the system as a whole, the determination of the class of a particular device may be made with respect to the simplest configuration that can still be considered, in view of its proper functional features, as a device in its own right. A device that is part of a system may be classed as a device in its own right rather than classifying the system as a whole. Similarly, combination devices with parts that have different functional purpose may be analyzed separately with respect to each of these parts, for instance, a drainage device will have an invasive tube and non-invasive collections device. These components may be classified separately.
- D.** Accessories must be classified separately from their parent device.
- E.** If a given device can be classified according to several rules, then the highest possible class applies.
- F.** If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

The classification of the device will have to be determined on the basis of claims contained in the information provided with the device. The company and its manufacturing site must be sufficiently precise in that regard. If the company and its manufacturing site want to avoid the particular higher classification, then it must clearly label the intended purpose in such a way

that device falls into the lower class. The company and its manufacturing site must provide as a minimum requirement either appropriate positive or negative indications for the use.

G. As for a device to be "specifically intended" for the purpose referenced in a particular classification rule, the company and its manufacturing site must clearly indicate that the device is intended for such a specific purpose in the information accompanied the device. Otherwise, it is deemed to intend to be used principally for the purpose that is accepted in general medical practice.

H. Multi-application equipment such as laser printers and identification cameras, which may be used in combination with medical devices, is not medical devices unless their company and its manufacturing site display them in the market with specific intended purpose as medical devices.

I. Stand-alone software, for instance, software which is used for image enhancement is regarded as driving or influencing upon the use of a device and so falls automatically into the same class.

Other stand-alone software, which is neither driving nor influencing upon the use of a device is classified in its own right.

2-3 Responsibility and regulation In Sudan:

2-3-1Sudan National Medicines & Poisons Board

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 (www.nmpb.gov.sd)

- Medical devices range:

Medical devices range from simple tongue depressors, syringes, catheters and surgical instrument to complex programmable pacemakers with micro-chip technology, medical laser devices, patient monitors and rehabilitation devices and prostheses. In addition, medical devices include in vitro-diagnostic products, such as general purpose lab equipment, reagents, and test kits. Radiation emitting device including diagnostic ultrasound products, x-ray machines and radio therapy equipment are considered as medical devices as well [9].

- Medical devices Safety:

Risk is the measure of likelihood and severity of hazard; according to the risk medical devices are classified into 3 classes. The degree of regulation imposed on devices is proportional to its potential hazard. In the past, medical devices were received and viewed by a committee which was responsible for product entry in principle, until the examination through the initial invoices and approve incoming and verification only be through logo and stamp contained identifying Is it new or used without the work of the specific test of the device. But now companies are registered supplied and approved as a proxy for specific products , despite the difficulties faced by

the ports by not provide sufficient details of the product , which makes it difficult to know there is the most sought species and until the inspection process.

2-3-2 Sudan Federal Ministry of Health

IMPORT OF MEDICAL DEVICES

Donated Medical devices can be issued a temporary import license if they are accepted as a donation in the donor country or, they are given with respect to the recipient wishes or, they should benefit the recipient and based on need assessment. All donations should respond to an expressed need by the recipient and should never arrive unannounced.

Samples; Urgent needed devices; Home/Personal used devices can be issued temporary import license provided submitting a logical documented justification for the import.

The import of used devices into Sudan should not be permitted. This is due to the fact that an adequate replacement or other immediate action cannot be ensured in case of device failure; in addition to concerns about the quality of used medical devices, specifically in relation to areas like disinfection.

MOH develops donation guidelines and standards for donation of medical devices.

However, the donated medical devices should meet general criteria required for the quality of equipment, safety, compliance with specifications and standards, non-obsolescence, and appropriateness of the medical device for the user's environment.

There should be an effective communication between the donor and the recipient prior to donation, according to plan formulated by both.

Donations should be treated in the same way as paid procurement in terms of preparation, installation requirements, human resources, maintenance and calculation of cost of the used equipment throughout its lifespan. There should be no double standard in quality. If the quality of an item is unacceptable in the donor country or for any other reason, it is also unacceptable as a donation [3].

2-3-3 Sudan Atomic Energy Commission (SAEC)

-Historical Background

Sudan became a member of the International Atomic energy Agency in 1958; one year after it had come into being. In 1962 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 "Atomic Energy Committee Act, 1973" established a committee, under the supervision of the chairman of National Research Council, with the mandate to promote the use of nuclear techniques in the country as well as overseeing safety in all activities involving the use of ionizing radiation (www.saec.gov.sd/home.html)

-Objectives of SAEC

- Establish such facilities and infra-structure, as may be necessary for training and conducting scientific research, in the field of the peaceful applications of atomic energy and develop the same.
- Prepare, train and raise the efficiency of workers in the fields of nuclear technology and sciences,
- Render services in the field of peaceful uses of atomic energy,
- Monitor the environment and exported and imported materials to assess the levels of their contamination by radioactive substances according to national and international regulations made in this respect, in coordination with other competent bodies; therefore the issue of certificates are necessary
- Organize scientific activities, and support the same, in the field of nuclear and atomic applications, and in all such, as may be connected therewith of sciences, through scientific courses, workshops, conferences and seminars, in coordination with the competent institutions, inside and abroad,
- Employ the aid rendered by the International Atomic Energy Agency and otherwise of international or regional institutions, and rationalize the same for the service of the research and development projects, in the field of atomic energy.
- Lay down the bases of cooperation, with the similar scientific institutions, outside the country and entrench the same,
- Facilitate conduction of scientific researches, in the field of atomic energy and applications thereof, by presenting the necessary support,

for conducting the same, and participate in scientific activities inside and abroad,

- Establish a central library to provide scientific materials for researchers, in the field of atomic energy and applications thereof.
- Take such measures, as may be necessary for protection against the deleterious effects of radiation and treatment of being affected thereby, in coordination with other competent bodies.

2-4 Issue scientific publications and periodicals, pertaining to the activity of the commission.

2-4-1 Quality management system (QMS):

The manufacturer should implement, document and maintain a QMS that ensures the medical devices, designs, manufactures and supplies to the market are safe, perform as intended and comply with the international standard. The scope and complexity of the QMS are influenced by the range of different medical devices that are under QMS control, the processes employed the size and structure of the organization [11].

Conformity assessment of the manufacturer's QMS is influenced by the class of the medical device, as follows:

- Manufacturers of Class A devices should implement and maintain the basic elements of a QMS but have the option of excluding design and development controls from it.

- Manufacturers of Class B devices should implement and maintain an effective QMS but may have the option of excluding design and development controls from it.
- Manufacturers of Class C and D devices should implement and maintain an effective QMS that includes design and development controls.

2-4-2 System for post market surveillance

Prior to placing the product on the market, the manufacturer will put in place as part of its QMS, a process to assess the continued conformity of the device to the Essential Principles of Safety and Performance throughout the medical device lifecycle. This process will include, at a minimum, complaint handling, vigilance reporting, and corrective and preventive action.

2-4-3 Technical documentation

Manufacturers of all classes (except class A) of device are expected to demonstrate conformity of the device to the essential principles of safety and performance of medical devices through preparation and holding of summary of technical documentation (STED) that shows how each medical device was developed, designed and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity. This technical documentation is updated as necessary to reflect the current status, specification and configuration of the device.

The extent of evidence on the STED is likely to increase with the class of the medical device and its complexity.

2-4-4 Conformity assessment:

Conformity Assessment Elements:

The conformity assessments elements include conformity assessment systems as follows:

1. Quality Management System
2. System for Post-Market Surveillance
3. Summary Technical Documentation
4. Declaration of Conformity
5. Registration of Establishments & Their Medical Device

The conformity assessment elements that appear in this section describe the tasks of the manufacturer and all five elements that applicable to the medical device according to their classification.

Active medical devices and devices connected to them:

- 1) As for active medical devices, in the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.
- 2) Devices where the safety of patients depends on an internal power supply should be equipped with a means of determining the state of power supply.
- 3) Devices where the safety of patients depends on an external power supply should include an alarm system to signal any power failure.
- 4) Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of patient's

state of health

- 5) Devices should be designed and manufactured in such a way to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this device, other devices or equipment in the usual environment.
- 6) Devices should be designed and manufactured in such a way to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.
- 7) Devices should be designed and manufactured in such a way to avoid as far as reasonably practicable the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided that the device is installed and maintained as indicated by the manufacturer.

Protection against mechanical risks:

- 1) Devices should be designed and manufactured in such a way to protect patient and user against mechanical risks that connected with, for example, resistance to movement, instability and moving parts.
- 2) Devices should be designed and manufactured in such a way to reduce the lowest practicable level, the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations; particularly at source unless the vibrations are part of the specified performance.
- 3) Devices should be designed and manufactured in such a way to reduce the lowest practicable level, the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce

noise; particularly at source unless the noise emitted is part of the specified performance.

- 4) Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way to minimize all possible risks.
- 5) Devices should be designed and manufactured in such a way to reduce the lowest practicable level, the risk of error when certain parts within the device are intended to be connected or reconnected before or during the use.
- 6) Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal conditions of use.

2-5 Back ground studies

Several studies on regulation of imported medical equipment were carried out in other country.

1-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.

2-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.

3- Medical Device Regulatory Requirements for Egypt (2007) (The MOH is responsible for the registration and approval of medical devices in Egypt. It does this through the Drug Policy and Planning Center (DPPC) and the Central Administration of Pharmaceutical Affairs (CAPA). The DPPC controls and sets the strategic rules for drug policy, but it also regulates the importation and manufacture of medical devices and instruments. It furthermore controls the registration of medical devices through a specialized committee for study of manufactured and imported medical devices and equipment. This committee comprises leading medical professors (approximately 10) from the specialties of ophthalmology, orthopedics, surgery and cardiology; in addition to professors in medical engineering. Moreover, the committee includes pharmacist managers from CAPA, DPPC and the National Organization for Drug Control and Research (NODCAR).

This committee is responsible for reviewing and approving applications for the manufacture or importation of medical devices and equipment in Egypt. Applicants may be importing companies, manufacturing companies, physicians or individuals. The committee evaluates an application in the light of existing status of device or equipment in question, and whether there is a real need and benefit for Egyptian patients. It then makes a decision regarding the application before the equipment is released from customs or manufactured. As explained below, one further evaluation by another body is often required. CAPA is responsible for registration and issue of final marketing approval for Class III medical devices).

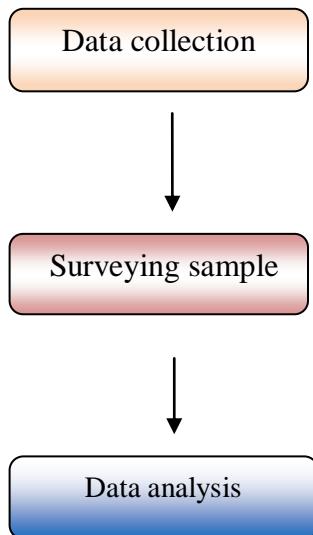
CHAPTER THREE

Methodology and data analysis

Methodology and Data analysis

This chapter explains the steps that followed on this research.

This research is qualitative and quantitative which describes specific current situation by using questionnaire.



The document, Guidance on the Medical Devices Inspection Program (GUI-0064), provides guidelines on the interpretation of regulations pertaining to inspections of medical device companies.

It is important to note that most of the noncompliance citations did not involve a direct health risk, but rather they represented deficiencies in the documentation of risk management procedures. For instance, almost one-third of the compliance issues involved incomplete or erroneous attestations made on establishment license renewal submissions. As indicated earlier,

this noncompliance is not associated with a direct risk to health. However, the proper documentation of risk management procedures is essential for Health in Sudan to ensure that medical device companies can investigate potential risks and respond appropriately to risks when identified.

3-1data collection:

All information and literature reviews regarding this research were collected from international organizations, national port of Sudan, reference and internet

3-1-1 Study design:

The study used a descriptive approach

3-1-2Study duration:

The duration of the study was 5 month (November2014 to 30 March 2015)

3-1-3 Study population:

The actual population of the study consists of all Sudanese Standards and Metrology Organization (SSMO), its subsidiaries, and other regulatory authorities.

3-2 surveying samples:

Includes National Medicines and Poisons Board, Sudanese Standards and Metrology Organization, Ministry of health and Central Medical Supplies Public Corporation.

3-2-1 Interviews guided by questionnaires:

The questions directed to those work in inspection of import medical equipment, investigate as well as manage or regulate the medical devices in Sudan.

Questionnaires are composed of two parts; the first being about the general information of respondents.

The second part is the assessment of depression by using basic axes of the search that focus on legislative regulations, procedures status of medical devices and importing inspection procedures in the Sudan.

The questions covered the term of policy documented and applied and responsibilities of national regulation bodies.

The questions covered the term of regulation of reprocessing and used medical device as well.

Finally the questions covered current procedure and whether there is a calibration lab works in accurate goodness of importing medical device.

3-2-2 The study limitation:

- Time limitation considering the period of research which was just 5 month.
- Source limitation.

3-3 Data analysis:

Data analysis was conducted by using (SPSS) version 21.

3-3-1 Gender

Through the analysis we found that 60% of study sample is male, and 40% female that shows through the table and figure below:

Table (3-1) shows the gender

	Frequency	Percent	Cumulative Percent
Male	15	60.0	60.0
Female	10	40.0	100.0
Total	25	100.0	

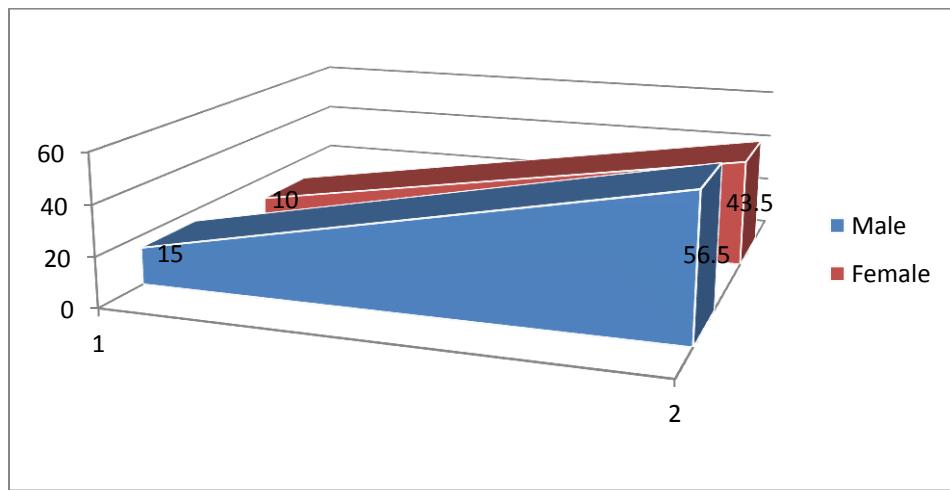


Figure (3-1) shows the gender

- The majority of study sample is male

3-3-2 Qualifications:

4% of respondents are holders of diploma degree, 16% holders of post graduate degree, 72% holders of bachelor degree while 8% represents other specialties.

Table (3-2) shows the qualifications

	Frequency	Percent	Cumulative Percent
Diploma	1	4.0	4.0
Post-graduate	4	16.0	20.0
Bachelor	18	72.0	92.0
Other	2	8.0	100.0
Total	25	100.0	

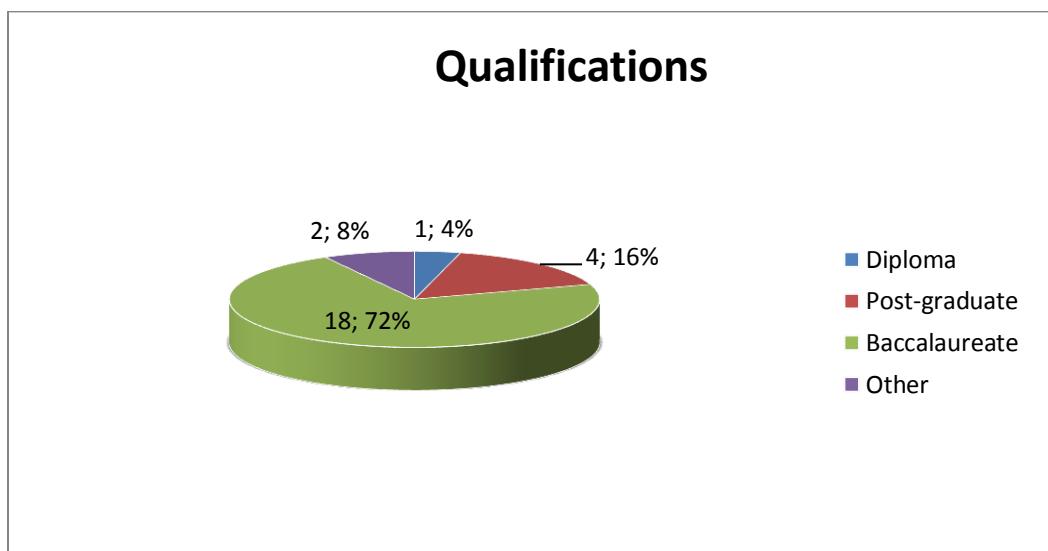


Figure (3-2) shows qualifications

- The majority of respondents are holders of bachelor degree by 72%

3-3-3 Responsible for development of laws and regulations for the control of imported medical devices

Through the analysis we found that 52% for National Medicines and Poisons Board and 40% for Sudanese Standards and Metrology Organization and 8% for other authorities as shown in table and figure below:

Table (3-3) shows the responsible in development of law

	Frequency	Percent	Cumulative Percent
N MP B	13	52.0	52.0
S SMO	10	40.0	92.0
Other authority	2	8.0	100.0
Total	25	100.0	

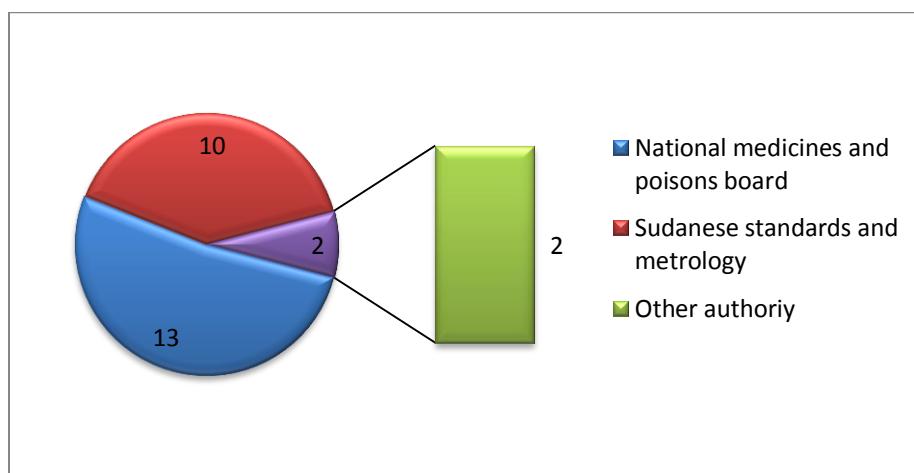


Figure (3-3) showing the responsible in development of law

- The majority respondents indicates that National Medicines and Poisons Board is responsible for the development of laws and regulations for the control of imported medical devices

3-3-4 The entity responsible for granting a certificate of quality of imported medical device

Through the analysis, it turned up that 20% of respondents indicate that the National Medical and Poisons Board is responsible for granting a certificate of quality of imported medical device and 72% of respondents indicates that Sudanese Standards and Metrology Organization is responsible for granting certificates while 8% of respondents indicate that other authorities are responsible for that.

Table (3-4) shows responsible for granting a certificate of quality of imported medical device

	Frequency	Percent	Cumulative Percent
NM P B	5	20.0	20.0
S S MO	18	72.0	92.0
Other authority	2	8.0	100.0
Total	25	100.0	

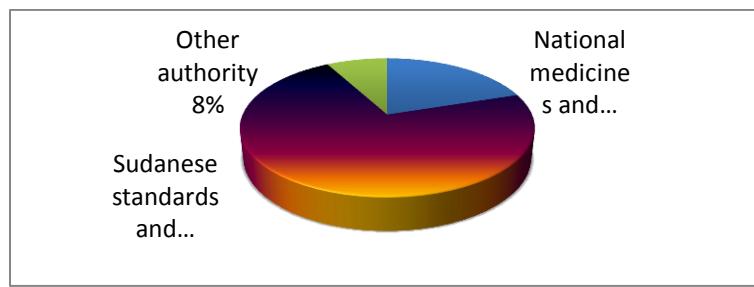


Figure (3-4) indicates responsible for granting a certificate of quality of imported medical device

- The majority of respondents indicate that Sudanese Standards and Metrology Organization is responsible for granting a certificate of quality of imported medical device

3-3-5 The availability of other authorities in charge of importing of medical equipments

The study shows that 40% of respondents indicate that there are other authorities in charge of importing of medical equipments while 60% of respondents indicate that there are no other authorities in charge of imported medical devices.

Table (3-5) shows that there are other authorities in charge of importing of medical equipments

	Frequency	Percent	Cumulative Percent
Yes	10	40.0	40.0
No	15	60.0	100.0
Total	25	100.0	
1			

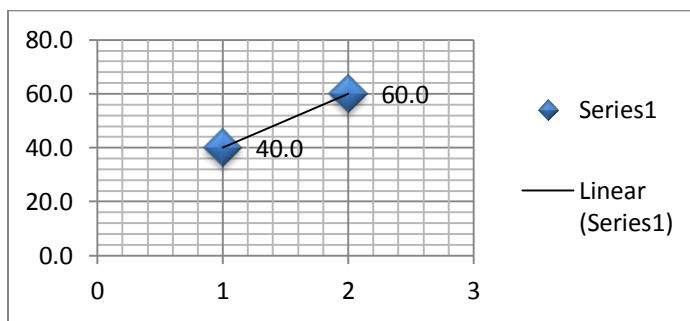


Figure (3-5) shows that there are other authorities in charge of importing of medical equipments

- The majority of respondents indicate that there are no other authorities in charge of importing of medical equipments 60%.

3-3-6 The detection of medical devices within imported consignments or commodities follows regulatory law procedures

The study shows that 60% of respondents indicate that the detection of medical devices follows regulations and procedures while 40% of respondents indicate that the detection of medical devices does not follow regulations and procedures.

Table (3-6) shows the detection of medical devices follows regulations and procedures

	Frequency	Percent	Cumulative Percent
Yes	15	60.0	60.0
No	10	40.0	100.0
Total	25	100.0	

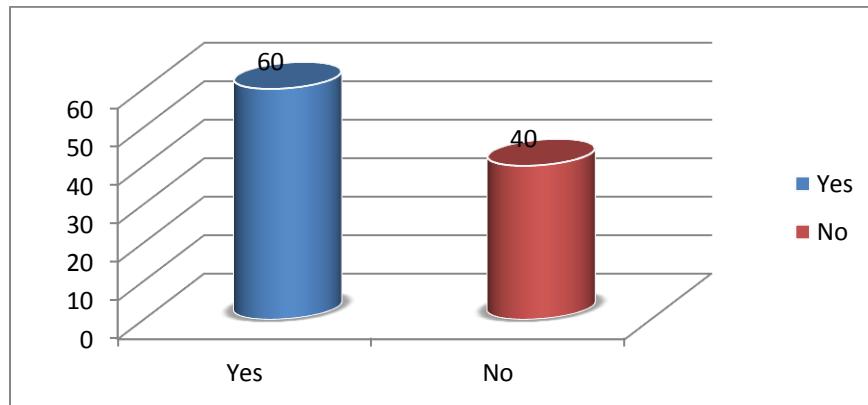


Figure (3-6) shows the detection of medical devices follows regulations and procedures

- The majority of respondents indicate that the detection of imported medical devices follows regulations and procedures by 60%.

3-3-7 The Follow-up after premised entrance of imported devices

Through the study it turned up that 32% of respondents indicate that medical devices are subject to follow-up by regulations and procedures after being permitted while %68 of respondents indicate that medical devices are not being followed up by law and procedures after being permitted.

Table (3-7) shows the follow-up for medical devices by law & procedures

	Frequency	Percent	Cumulative Percent
Yes	8	32.0	32.0
No	17	68.0	100.0
Total	25	100.0	

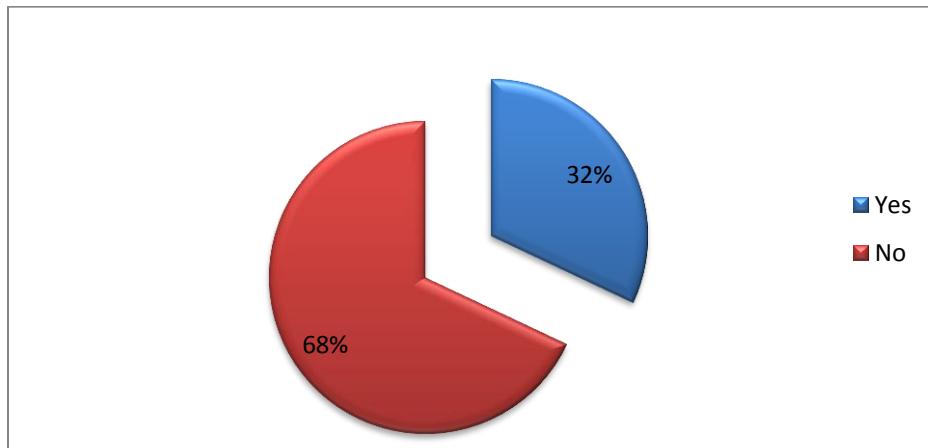


Figure (3-7) shows the follow-up for medical devices by law & procedures

- The majority of respondents indicate that there is no follow-up for medical devices follow-up after being permitted by 68%

3-3-8 Regulation procedures refurbished medical devices

The study shows that 24% of respondents indicate that refurbished medical devices are subjected to regulations and procedures while 76% of respondents indicate that refurbished medical devices are not subjected to regulations and procedures.

Table (3-8) shows regulation procedures of refurbished medical devices

	Frequency	Percent	Cumulative Percent
Yes	6	24.0	24.0
No	19	76.0	100.0
Total	25	100.0	

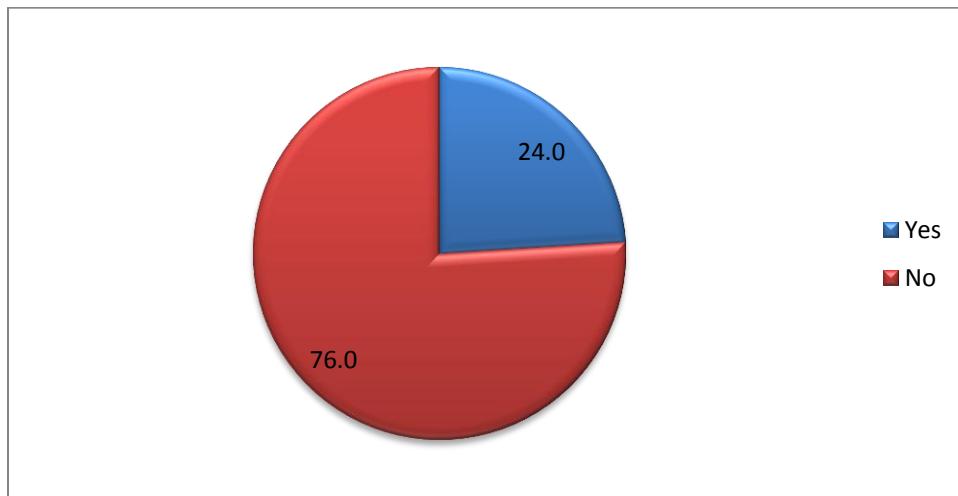


Figure (3-8) shows regulation procedures of refurbished medical devices

- The majority of respondents indicate that there are no regulations and procedures of refurbished medical devices by 76%.

3-3-9 Importing law banned of used medical device

The study shows that 60% of respondents indicate that there is a law that bans the importing of used medical devices while 40% of respondents indicate that there is no law that bans the importing of used medical devices.

Table (3-9) shows that there is a law banning the importing of used medical device

	Frequency	Percent	Cumulative Percent
Yes	15	60.0	60.0
No	10	40.0	100.0
Total	25	100.0	
	1		

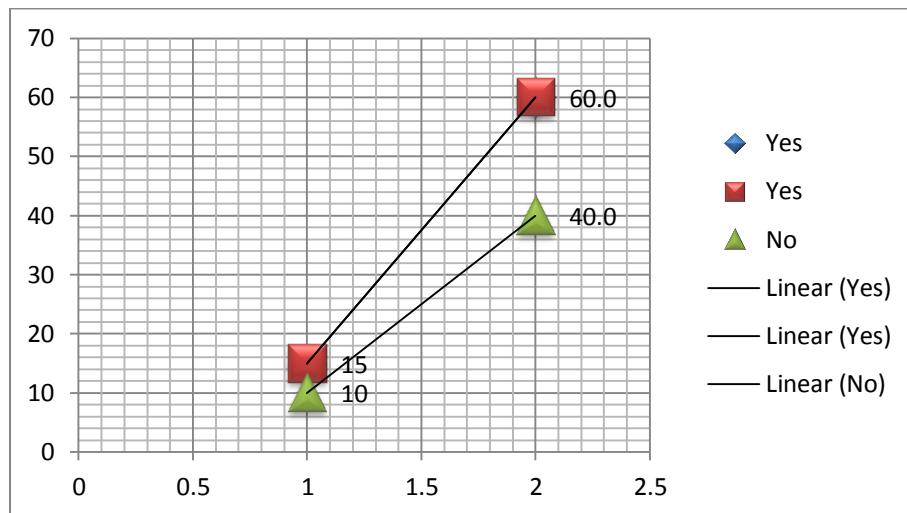


Figure (3-9) shows that there is a law banning the importing of used medical device

- The majority of respondents indicate that there is a law banning the importing of used medical devices by 60%

3-3-10 Relationship of medical device with national medicines and poisons board

The study shows that 52% of respondents indicate that there is no relationship between medical device and national medicines and poisons board and 44% respondents indicate that there is a relationship while 4% of respondents indicate that they are not aware of that.

Table (3-10) shows the relationship between medical device and NMPB

	Frequency	Percent	Cumulative Percent
No relation	13	52.0	52.0
There is relation	11	44.0	96.0
Not aware	1	4.0	100.0
Total	25	100.0	

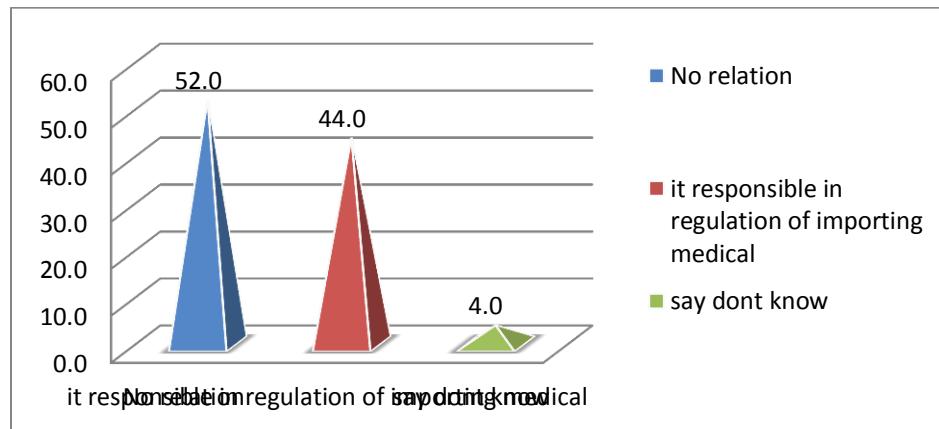


Figure (3-10): reveals the relationship between medical device and NMPB

- The majority of respondents indicate that there is no relationship between medical device and national medicines and poisons board

3-3-11 Relationship of medical device with laboratories administration

Through the study, it turned up that 40% respondents indicate that there is no relationship between medical device and laboratories administration and 52% of respondents indicate that there is a relationship between medical devices and laboratories administration while 8% of respondents indicate that they are not aware of that.

Table (3-11) shows the relationship between medical device and laboratories administration

	Frequency	Percent	Cumulative Percent
No relation	10	40.0	40.0
There is a relationship	13	52.0	92.0
Not aware	2	8.0	100.0
Total	25	100.0	

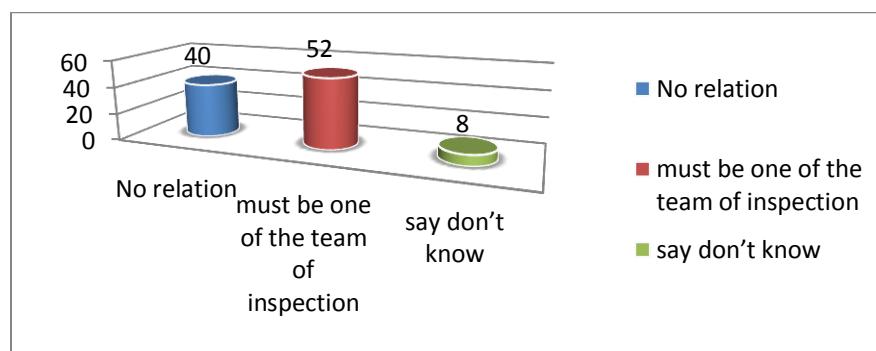


Table (3-11) shows the relationship between medical device and laboratories administration

- The majority of respondents indicate that there is relationship between medical device and laboratories administration.

3-3-12 Checking of medical device need a team work

The study shows that 84% of respondents indicate that the checking of medical device needs a team work while 16% of respondents indicate that the checking of medical device does not need a team work

Table (3-12) shows that the checking of medical device needs a team work

	Frequency	Percent	Cumulative Percent
Yes	21	84.0	84.0
No	4	16.0	100.0
Total	25	100.0	

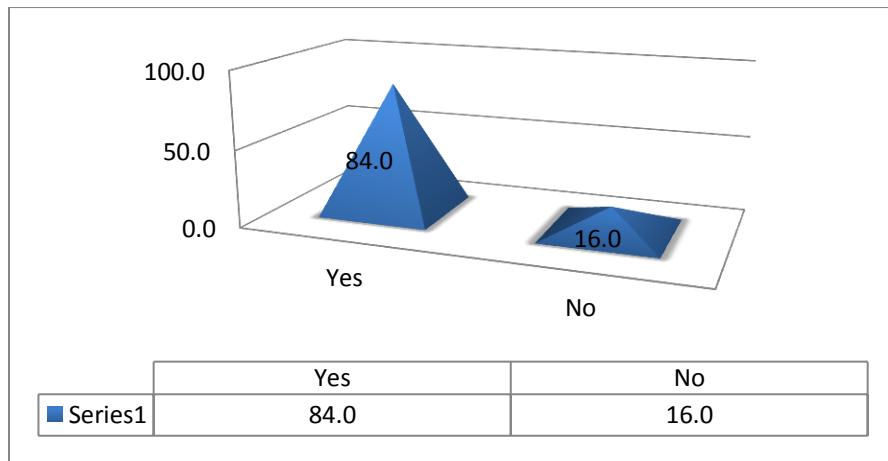


Figure (3-12) shows that the checking of medical device needs a team work

- The majority of respondents indicate that the checking of medical device needs a team work

3-3-13 Importance of calibration the medical devices

Through the study, it turned up that 64% of respondents indicate that it is important to calibrate the medical devices before entry and 36% of respondents indicate that it is not important to calibrate the medical devices

Table (3-13) shows the importance of calibration the medical devices before entry

	Frequency	Percent	Cumulative Percent
Yes	16	64.0	64.0
No	9	36.0	100.0
Total	25	100.0	

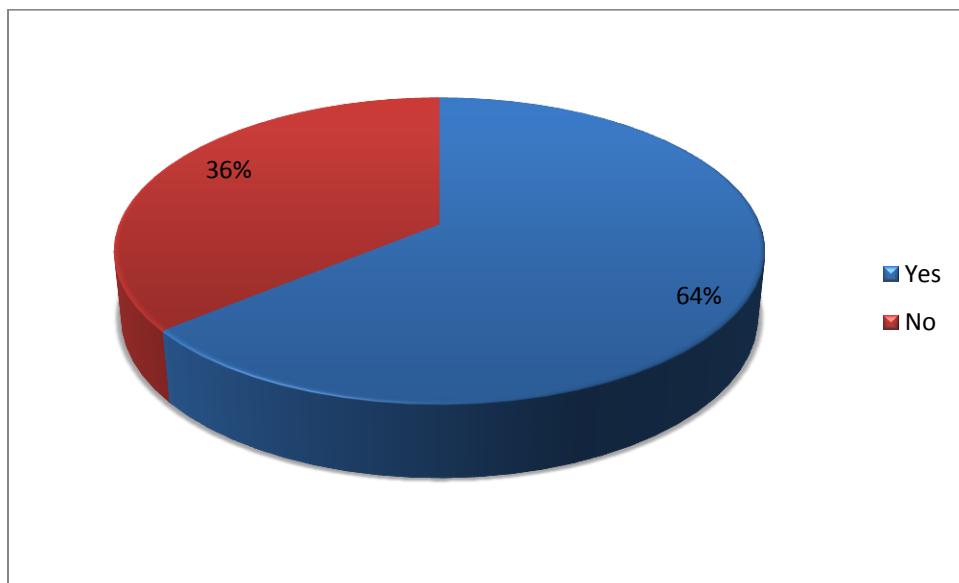


Figure (3-13) shows the importance of calibration the medical devices before entry

- The majority of respondents indicate that it is important to calibrate the medical devices before entry.

3-3-14 Availability of professional calibration laboratory

Through the study, it turned up that 36% of respondents that there is a professional calibration laboratory while 64% of respondents indicate that there is no a professional calibration laboratory.

Table (3-14) shows the availability of professional calibration laboratory

	Frequency	Percent	Cumulative Percent
Yes	9	36.0	36.0
No	16	64.0	100.0
Total	25	100.0	

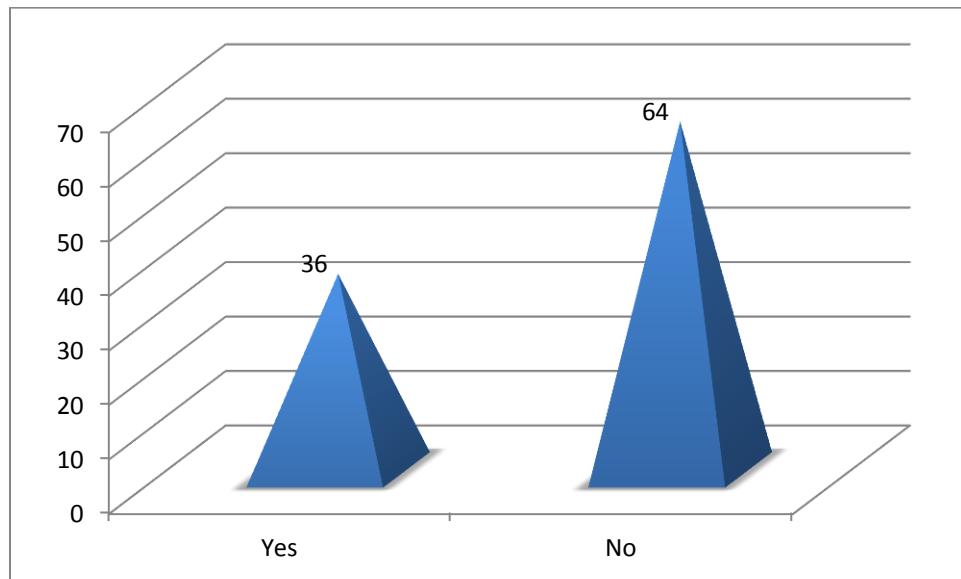


Figure (3-14) shows the availability of professional calibration laboratory

- The majority of respondents indicate that there is no professional calibration laboratory.

3-3-15 The ideal inspection procedure or program to inspect the imported medical devices

The analysis proved that 44% of respondents indicate that there is an ideal inspection procedure or program to inspect imported medical devices while 56% of respondents indicate that there is no an ideal inspection procedure or program to inspect imported medical devices

Table (3-15) shows the ideal inspection procedure or program to inspect imported medical devices

	Frequency	Percent	Cumulative Percent
Yes	11	44.0	44.0
No	14	56.0	100.0
Total	25	100.0	

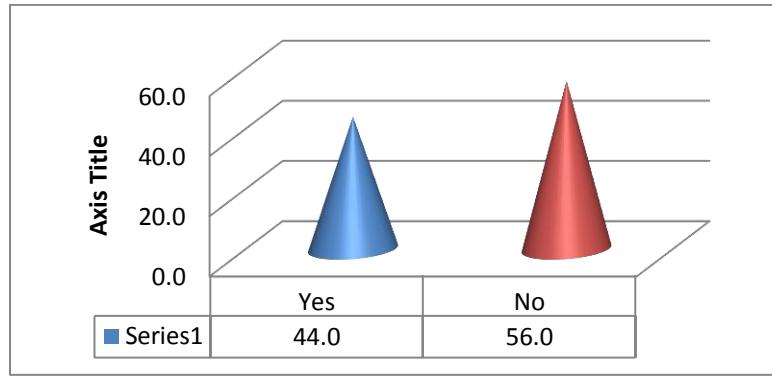


Figure (3-15) shows the ideal inspection procedure or program to inspect imported medical devices

- The majority of respondents indicate that there is no ideal inspection procedure or program to inspect imported medical devices

3-3-16 The current procedures sufficient to ensure the quality and validity of medical device.

The analysis proved that 20% of respondents indicate that the current procedures are sufficient to ensure the quality and validity of medical device and 80% of respondents indicates that the current procedures are not sufficient to ensure the quality and validity of medical device.

Table (3-16) shows the current procedures are not sufficient to ensure the quality and validity of medical device.

	Frequency	Percent	Cumulative Percent
Yes	5	20.0	20.0
No	20	80.0	100.0
Total	25	100.0	

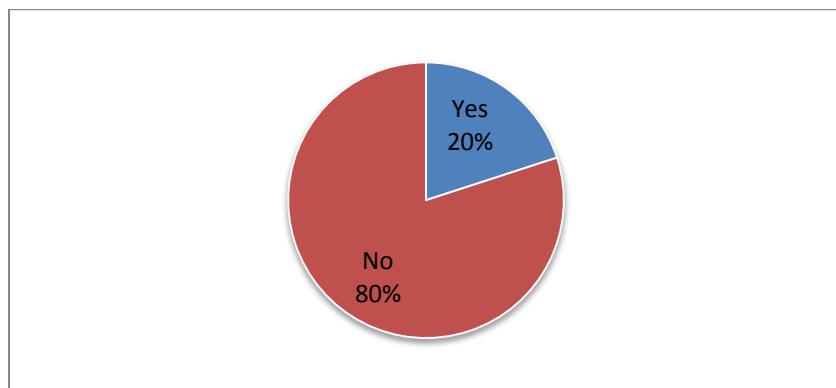


Figure (3-16) shows the current procedures are not sufficient to ensure the quality and validity of medical device.

- The majority of respondents indicate that the current procedures are not sufficient to ensure the quality and validity of medical device.

3-3 Correlations:

Table (3-17) showing relation of question 12 & 17 in questionnaire.

		Are current procedures sufficient to ensure the quality and validity of medical device?	Is there a professional calibration laboratory?
Spearman's	Are current procedures sufficient to ensure the quality and validity of medical device	Correlation Coefficient Sig. (2-tailed)	1.000 -.167
	N	.	.426 25
	Is there a professional calibration laboratories	Correlation Coefficient Sig. (2-tailed)	-.167 1.000
	N	.426 25	.

By measuring the Pearson and Spearman correlation, it was found out that there was a relationship between two variables degree of freedom which is 0.426 higher than the 0.05 level measurement of any two-way relationship, so we reject the hypothesis of non-acceptance and accept the hypothesis states that the current procedures sufficient to ensure the quality and validity of medical device and a professional calibration laboratories

Table (3-18) showing relation of question 6 & 13 in questionnaire.

		Is there an ideal inspection procedure or program to inspect the imported medical devices?	According to health adjacent effects of medical devices, are there a regulation procedures of remanufactured (Recycled) Medical devices and it's safe use?
	<p>Is there an ideal inspection procedure or program to inspect the imported medical devices?</p> <p>Spearman's</p> <p>According to health adjacent effects of medical devices, are there a regulation procedures of remanufactured (Recycled) Medical devices and its safe use?</p>	<p>Correlation Coefficient</p> <p>Sig. (2-tailed)</p> <p>N</p>	<p>1.000</p> <p>.</p> <p>25</p> <p>.257</p> <p>.216</p> <p>25</p> <p>1.000</p> <p>.</p> <p>25</p>

By measuring the Pearson and Spearman correlation we find that there is a relationship between two variables degree of freedom which is 0.216 higher than the 0.05 level measurement of any two-way relationship, so we reject the hypothesis of non-acceptance and accept the hypothesis states that current procedures sufficient to ensure the quality and validity of medical device and a professional calibration laboratories

CHAPTER FOUR

Design and inspection protocol

Design and inspection protocol

The import process, as shown in the "Import Procedures Flowchart" begins with the importer or filer submitting the necessary entry information to the local district office. For information not filed in electronically, it must be filled in a form; in addition to commercial invoice, entry forms and/or documentation that will need to be provided by the importer.

Entry information should identify the product and include appropriate information to demonstrate that the product is in compliance with regulations. Product information should include device's name and product code. Issued a letter which clarifies what type of entry information should be provided at the time of entry. The correct information will help expedite the entry review process and increase the probability that your shipment may be processed in term of import system screening and not held.

4-1 Inspection planning flowchart

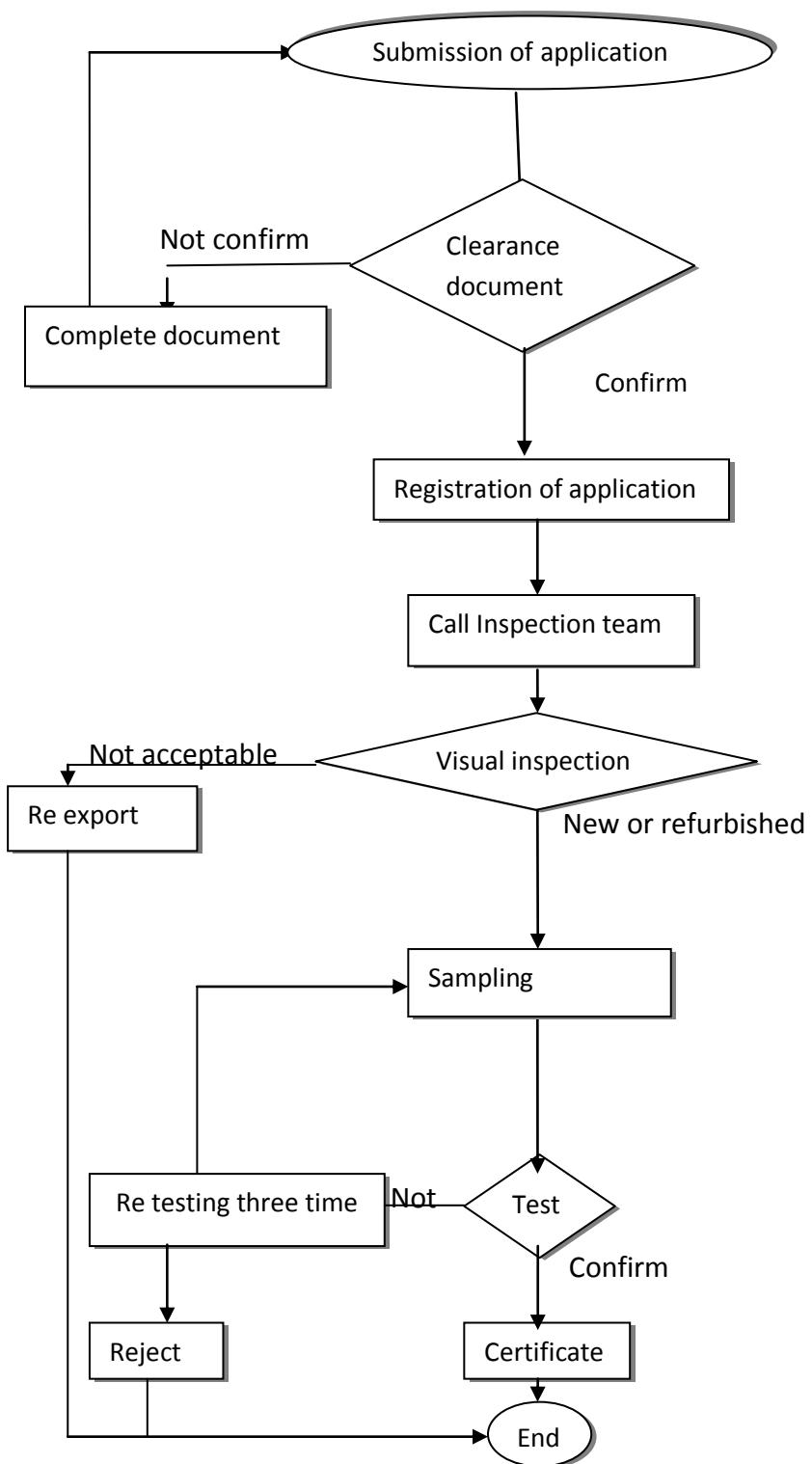


Figure (5-1): Inspection planning flowchart

4-2 Inspection planning description:

Inspection of medical device at the ports of Sudan must be in sequence as descript below:

- 1-** The importer should submit an application for incoming medical device.
- 2-** Verify the documents and certificates whether they are in compliance with regulations, otherwise the importer should be informed to complete documents.

Required documents are:

- Pre-conformity from national medicine and poison board.
- Bill of loading.
- Certificate of origin.
- Invoice.
- Backing list.
- International certificates for devices.

- 3-** The registration of application must be documented.
- 4-** Inspection team:

Inspection team should be perfect team work consist of:

- Biomedical engineers work in National Medicine and Poison Board (NMPB), Sudanese Standards and Metrology Organization (SSMO) and Sudan Atomic Energy Commission (SAEC).
- Medical device technician.

- 5-** Visual inspection:

Visual inspection by the shape of medical equipment and the label, the label is banded according to national medicine poison board annex 4.

According to visual inspection the medical equipment will classified:

- New or Refurbished medical devices must be in compliance with requirements that set by National Medicine and Poison Board. In case of compliance between medical devices and requirements, next step should be taken. If medical devices lack compliance with requirement, they should be re-exported.

6- Take samples from the import medical equipment according to specific standard.

7- Take samples to medical equipment test lap, the test should be carried in tow stage:

First: Electrical safety testing: If samples comply with the test, the second stage have to be taken, otherwise they must be rejected.

Second: Function performance calibration: if medical devices confirm that they should have a certificate and bass, otherwise they must be rejected.

Note:

When the test result is negative, it retests 3 times to insure the result and then writing the report.

CHAPTER FIFE

Discussion

Discussion

From the result of data analysis, the responsibility of regulation of medical equipment is shared between Sudanese Standard and Metrology Organization, National Medicine and Poison Board and Diagnostic and Therapeutic Radiation Council. According to the questionnaire and observation, it noticed that these corporations are working individually with poor coordination which allows many people to enter the field of importing medical devices. The interfere between the responsibility of the corporation create dependency situation which gave opportunity to enter many medical equipment into the country that not meet the specifications. That mean the need for one place to combine a representative from each regulatory authorities together at each ports in Sudan to regulate importing of medical device for easy team work is needed. The responsibilities must clearly marked and limit for each corporation while maintaining a high degree of coordination.

National Medicine and Poison Board must draw up a clear guide line for regulation importing of medical equipment.

The current inspection is not enough to accurate quality of medical equipment. And there is no clear requirement for importing of refurbished medical equipment; on the other hand, used medical devise must be banded by rule.

CHAPTER SIX

Conclusion and Recommendations

Conclusion and Recommendations

6-1 conclusion:

The study shows that the National Medicines and Poisons Board IS responsible for the development of laws and regulations for the control of imported medical devices.

The study indicates that Sudanese Standards and Metrology Organization are responsible of granting a certificate of quality of imported medical device.

The medical devices technology policy must consider four (4) basic principles:

Availability, Accessibility, Appropriateness, Affordability

All devices should carry a clear label that indicates the name of the company, responsible Manufacturer at country of origin, the local distributor's address or website that points to local distributor name, 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's information it will be liable for confiscation.

SSMO is responsible for specifying and establishing Sudanese standards for medical device and calibration test of medical device while NMPB is to regulate registration and pre-post marketing locally and international.

6-2 Recommendations:

- 1- A periodic calibration device after the operating one or two times per a year.
- 2- Inspection of medical device needs a team work consisting of all provisional inspectors.
- 3- We require from National Medicine and Poison Board to draw up a clear guideline in regulation of medical device.

Reference

Reference

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Appendices

Appendix (A)

Questionnaire

Dear Sir, I am hopefully inviting you with your precious time and information to participate in this questionnaire, which focus on the legislative regulations procedures status of medical devices importing inspection procedures in The Sudan. So I am gratefully hope that you complete its two divisions and return it back.

First division:

- Gender: male female
- Discipline:
 - Major.....
 - Specialization:
- Experience:
- Qualifications:
 - Diploma Post-graduate
 - Baccalaureate other

Second division:

1. Who is responsible in development of laws and regulations for the control of imported medical devices?
 - a. National medicines and poisons board
 - b. Sudanese standards and metrology organization (SSMO)
 - c. Other authority
2. What is the entity responsible of granting a certificate of quality of imported medical device?
 - a. National medicines and poisons board
 - b. Sudanese standards and metrology organization (SSMO)
 - c. Other authority

3. Are there other authorities in charge of the importing of medical equipments?

Yes no

4. Did the detection of medical devices within imported consignments or commodities follow regulatory law procedures?

Yes no

5. Medical devices as bio-vital equipments, did it have approved law procedures to follow-up after premised entrance of imported devices?

Yes no

6. According to health adjacent effects of medical devices, are there a regulation procedures of refurbished Medical devices and its safe use?

Yes no

7. Is there a law banned importing of used medical device?

Yes no

8. What is the relationship of medical device with national medicines and poisons board?

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

9. What is the relationship of medical device with laboratories administration?

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

10. Is the check of medical device need a team work?

Yes no

11. Is it important to calibrate the medical devices before interring it?

Yes no

12. Is there a professional calibration laboratory?

Yes no

13. Is there an ideal inspection procedure or program to inspect the imported medical devices?

Yes no

14. Are current procedures sufficient to ensure the quality and validity of medical device?

Yes no

For more information, Please don't hesitate to contact as follow:

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Email: shr.khiri@gmail.com

Appendix (B)

Classification rules

♦ NON-INVASIVE DEVICES

1. All non-invasive devices are in Class I, unless Rule II, III or IV applies
2. All non-invasive devices intended for channeling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class I, unless they may be connected to an active medical device in Class II or a higher class, in which case they are Class II; unless they are intended for use of storing or channeling blood or other body liquids or for storing organs, parts of organs or body tissues, in which case they are Class II
3. All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class III, unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class II.
4. All non-invasive devices which come into contact with injured skin: - are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates; unless intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class III.- are in Class II in all other cases, including devices principally intended to manage the microenvironment of a wound.

♦ INVASIVE DEVICES

5. All invasive devices with respect to body orifices

(Other than those which are surgically invasive) and which: a) are not intended for connection to an active such devices are invasive in body orifices and are not surgically invasive. Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynecology.

Classification depends on the time of invasion and the sensitivity (or vulnerability) of the orifice to such invasion. Medical device or b) are intended for connection to a Class I medical device

- are in Class I if they are intended for transient use;
- are in Class II if they are intended for short-term use unless they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I,
- are in Class III if they are intended for long-term use; unless they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class II.

All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class II or a higher class, are in Class II.

6. All surgically invasive devices intended for transient use are in Class II, unless they are reusable surgical instruments, in which case they are in Class I; unless intended to supply energy in the form of ionizing radiation, in which case they are in Class III; unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class III; unless intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class III. unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class IV.

7. All surgically invasive devices intended for short-term use are in Class II, unless they are intended to administer medicines, in which case they are in Class III; unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class III; unless they are intended to supply energy in the form or ionizing radiation, in which case

they are in Class III; unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class IV; unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class IV; unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class IV.

8. All implantable devices, and long-term surgically invasive devices, are in Class III,

unless they are intended to be placed into the teeth, in which case they are in Class II; unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class IV; unless they are intended to be life supporting or life sustaining, in which case they are in Class IV; unless they are intended to be active implantable medical devices, in which case they are Class IV; unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class IV; unless they are intended to administer medicines, in which case they are in Class IV; unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class IV. Unless they are breast implants, in which case they are in Class IV.

♦ ACTIVE DEVICES

9. All active therapeutically devices intended to administer or exchange energy are in Class II, unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class III

All active devices intended to control or monitor the performance of active therapeutically devices in Class III, or intended directly to influence the performance of such devices are in Class III.

10. Active devices intended for diagnosis are in Class II:

- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class I), or

- if they are intended to image *in vivo* distribution of radiopharmaceuticals, or

- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for:

- a) Monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac Performance, respiration, activity of central nervous system, or

- b) Diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class III.

Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class III.

11. All active devices intended to administer and/or remove medicines; body liquids or other substances to or from the body are in Class II,

unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application, in which case they are in Class III.

12. All other active devices are in Class I.

ADDITIONAL RULES

13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class IV.

14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class IV, unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class I. unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class I.

15. All devices intended specifically to be used for disinfecting or sterilizing medical devices are in Class II, unless they are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses, in which case they are in Class III.

16. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class III, unless they are implantable or long-term invasive devices, in which case they are in Class IV.

Appendix (C)

Classification Rules for In Vitro Diagnostic

Rule 1 - IVD medical devices intended for the following purposes are

Classified as Class D:

- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation, or
- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation

Rationale:

The application of this rule as defined above should be in accordance with the rationale that follows: Devices in this Class are intended to be used to ensure the safety of blood and blood components for transfusion and/or cells, tissues and organs for transplantation. In most cases, the result of the test is the major determinant as to whether the donation/product will be used. Serious diseases are those that result in death or long-term disability, that are often incurable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition.

Examples:

Tests to detect infection by HIV, HCV, HBV, HTLV. This Rule applies to first-line essays, confirmatory essays and supplemental essays.

Rule 2 - IVD medical devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as Class C, except for ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kell (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] determinations which are classified as Class D.

Rationale:

The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: A high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation places the device into Class D.

The rule divides blood grouping devices into two subsets, Class C or D, depending on the nature of the blood group antigen the IVD medical device is designed to detect, and its importance in a transfusion setting.

Examples:

1.) HLA, Duffy system (other Duffy systems except those listed in the rule as Class D are in Class C).

Rule 3 - IVD medical devices are classified as Class C if they are intended for use:

- In detecting the presence of, or exposure to, a sexually transmitted agent. Examples: Sexually transmitted diseases, such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*.
- In detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. Examples: *Neisseria meningitidis* or *Cryptococcus neoformans*.
- In detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested. Examples: diagnostic assay for CMV, *Chlamydia pneumoniae*, Methycillin Resistant *Staphylococcus aureus*.
- In pre-natal screening of women in order to determine their immune status towards transmissible agents. Examples: Immune status tests for Rubella or Toxoplasmosis.
- In determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient. Examples: Enteroviruses, CMV and HSV in transplant patients.
- In screening for selection of patients for selective therapy and management, or for disease staging, or in the diagnosis of cancer. Example: personalized medicine.

NOTE: those IVD medical devices where the therapy decision would usually be made only after further investigation and those used for monitoring would fall into class B under rule 6.

- In human genetic testing. Examples: Huntington's disease, Cystic Fibrosis.
- To monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient. Examples: Cardiac markers, Cyclosporin, Prothrombin time testing.
- In the management of patients suffering from a life-threatening infectious disease. Examples: HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping.
- In screening for congenital disorders in the fetus. Examples: Spina Bifida or Down Syndrome.

Rationale:

The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: Devices in this Class present a moderate public health risk, or a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation, or would have a major negative impact on outcome. The devices provide the critical, or sole, determinant for the correct diagnosis. They may also present a high individual risk because of the stress and anxiety resulting from the information and the nature of the possible follow-up measures.

Rule 4 - IVD medical devices intended for self-testing are classified as Class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.

IVD medical devices intended for blood gases and blood glucose determinations for near-patient testing would be Class C. Other IVD medical devices that are intended for near-patient should be classified in their own right using the classification rules.

Rationale:

The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: In general, these devices are used by individuals with no technical expertise and thus the labeling and instructions for use are critical to the proper outcome of the test.

Example for self-testing class C:

Blood glucose monitoring,

Example for self-testing class B:

Pregnancy self test, Fertility testing, Urine test-strips.

Rule 5 - The following IVD medical devices are classified as Class A:

- Reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination.
- Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures
- Specimen receptacles

Note: Any product for general laboratory use not manufactured, sold or represented for use in specified in vitro diagnostic applications are not deemed to be IVD medical devices, as defined in this document. However, in certain jurisdictions products for general laboratory use are considered to be IVD medical devices.

Rationale:

The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a low individual risk and no or minimal public health risk.

Examples:

Selective/differential microbiological media (excluding the dehydrated powders which are considered not to be a finished IVD medical device), identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.

Note 1: In certain jurisdictions there may be differences as to whether a device classified in this rule is considered an IVD medical device.

Note 2: The performance of software or an instrument that is specifically required to perform a particular test will be assessed at the same time as the test kit.

Note 3: The interdependence of the instrument and the test methodology prevents the instrument from being assessed separately, even though the instrument itself is still classified as Class A.

Rule 6 - IVD medical devices not covered in Rules 1 through 5 are classified as Class B.

Rationale:

The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a moderate individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on patient outcome or put the individual in immediate danger. The devices give results that are usually one of several determinants. If the test result is the sole determinant however other information is available, such as presenting signs and symptoms or other clinical information which may guide a physician, such that classification into Class B may be justified. Other appropriate controls may also be in place to validate the results. This Class also includes those devices that present a low public health risk because they detect infectious agents that are not easily propagated in a population.

Examples:

Blood gases, *H. pylori* and physiological markers such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers.

Rule 7 - IVD medical devices that are controls without a quantitative or qualitative assigned value will be classified as Class B.

Rationale:

For such controls, the qualitative or quantitative value is assigned by the user and not the manufacturer.

CLASS	RISK LEVEL	EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyzer , prepared selective culture media
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12, Pregnancy self testing, Anti-Nuclear Antibody, Urine test Strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self testing, HLA typing, PSA screening, Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood Diagnostic

Appendix (D)

Labeling:

General Principles

The primary purpose of labelling is to identify the medical device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on packaging or as instructions for use. The following principles are recommended:

- 1) The medium, format, content, legibility, and location of the label and instructions for use should be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may include separate information for the professional user and the lay person.
- 2) The information required on the label, should be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.
- 3) Where the manufacturer supplies multiple devices to a single user and/or location, it may be sufficient to provide only a single copy of the instructions for use. In these circumstances, the manufacturer should provide further copies upon request.
- 4) Instructions for use may not be needed or may be abbreviated for devices if they can be used safely and as intended by the manufacturer without any such instructions for use.
- 5) Labels should be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

- 6) Instructions for use may be provided to the user either in paper or non-paper format (e.g. electronic). They may be supplied by various means either with the medical device or separate from it. Examples of other means are information displayed on a screen incorporated into the device, information downloaded from the manufacturer's web site using the internet, and machine-readable sources. The means chosen should be appropriate for, and accessible to, the anticipated user population.
- 7) Where instructions for use are provided on a medium other than paper, the manufacturer should ensure the user has information on how to:
 - a) view the instructions for use;
 - b) access the correct version of the instructions for use; and
 - c) Obtain a paper version of the instructions for use.
- 8) Residual risks which are required to be communicated to the user and/or other person should be included as limitations, contraindications, precautions or warnings in the labelling.
- 9) The use of internationally recognised symbols should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the user. Where the meaning of the symbol is not obvious to the device user, e.g. for a newly introduced symbol, an explanation should be provided within the instructions for use.
- 10) Country-specific requirements for the content of the labelling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.
- 11) Provided that safe and correct use of the device is ensured, the labelling must be in Arabic and/or English language(s).

Content of the Label

The label should contain the following particulars which may appear on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

- a) The name of the medical device.

- b) The details strictly necessary for a user to identify the device and its use, e.g. 'cardiac ablation catheter 10 French / 20 cms' or 'pediatric thermometer' or 'tongue depressor', and a product catalogue code .
- c) The name and address of the manufacturer in a format that is recognisable and allows the location of the manufacturer to be established.
- d) For imported medical devices, the name and postal address of either the authorised representative, or importer or distributor established within the importing country/jurisdiction (if applicable). This information may be added by the authorised representative, importer or distributor, rather than be provided by the manufacturer, in which case, the additional label should not obscure any of the manufacturer's labels.
- e) Where appropriate, an indication that the device contains or incorporates a medicinal or biological substance, e.g. heparin coated catheter.
- f) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol.
- g) An unambiguous indication of the date until when the medical device may be used safely, expressed at least as the year and month (e.g. on reagents or consumables), where this is relevant.
- h) An indication of any special storage and/or handling condition that applies.
- i) If the medical device is supplied as sterile, an indication of its sterile state and, where appropriate, the sterilization method.
- j) Warnings or precautions to be taken that need to be brought to the immediate attention of the professional user, the lay person or other person (e.g. 'CAUTION – LASER' or 'CONTAINS POTENTIALLY INFECTIOUS MATERIAL'). This information may be kept to a minimum in which case more detailed information will appear in the instructions for use.
- k) If the medical device is intended for single use an indication of that fact.
- l) If the device is for use by a single individual and has been manufactured according to a written prescription or pattern (i.e. it is custom made), an indication of that fact.

- m) If the device is intended for premarket clinical investigation only, an indication of that fact.

Note: In this situation, some of the label content listed above may not apply.

- n) If the device is intended for non-clinical research, teaching or testing purposes only, an indication of that fact.

Note: In this situation, some of the label content listed above may not apply.

- o) If the device is intended for presentation or demonstration purposes only, an indication of that fact.

Note: In this situation, some of the label content listed above may not apply.