INCORPORATION OF SAFETY, HEALTH AND ENVIRONMENTAL ASPECTS FOR MEDICAL DEVICES IN MALAYSIA

DINESH A/L MURGIS

FACULTY OF ENGINEERING
UNIVERSITY OF MALAYA
KUALA LUMPUR

2018

INCORPORATION OF SAFETY, HEALTH AND ENVIRONMENTAL ASPECTS FOR MEDICAL DEVICES IN MALAYSIA

DINESH A/L MURGIS

RESEARCH PROJECT REPORT SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF ENGINEERING (SAFETY, HEALTH AND ENVIRONMENT)

FACULTY OF ENGINEERING
UNIVERSITY OF MALAYA
KUALA LUMPUR

2018

UNIVERSITY OF MALAYA

ORIGINAL LITERARY WORK DECLARATION

Name of Candidate: Dinesh A/L Murgis

Matric No: KQD160014

Name of Degree: Master of Safety, Health and Environmental Engineering

Title of Project Paper/Research Report/Dissertation/Thesis ("this Work"):

Incorporation of Safety, Health and Environmental aspects for medical devices in Malaysia

Field of Study: Hazard and Risk Management

I do solemnly and sincerely declare that:

(1) I am the sole author/writer of this Work;
(2) This Work is original;
(3) Any use of any work in which copyright exists was done by way of fair dealing and for permitted purposes and any excerpt or extract from, or reference to or reproduction of any copyright work has been disclosed expressly and sufficiently and the title of the Work and its authorship have been acknowledged in this Work;
(4) I do not have any actual knowledge nor do I ought reasonably to know that the making of this work constitutes an infringement of any copyright work;
(5) I hereby assign all and every rights in the copyright to this Work to the University of Malaya ("UM"), who henceforth shall be owner of the copyright in this Work and that any reproduction or use in any form or by any means whatsoever is prohibited without the written consent of UM having been first had and obtained;
(6) I am fully aware that if in the course of making this Work I have infringed any copyright whether intentionally or otherwise, I may be subject to legal action or any other action as may be determined by UM.

Candidate's Signature Date:

Subscribed and solemnly declared before,

Witness's Signature Date:

Name:

Designation:

ABSTRACT

Generally the life expectancy of Malaysian population has increased over the years. This is partly due to availability of medicines and medical devices. However, the medical devices can pose direct and indirect risks and hazards associated to safety, health and environment. Therefore in this study, risk and hazards associated to safety, health and environment are generally assessed by visit to a medical device establishment. The study was conducted to identify possible risk and hazards from the application and usage of common medical device. Data acquisition related to the possible risk and hazards were identified using a set of standard methodology. Personnel from the medical device establishment was interviewed with a set of question, observation during site visit and walk about in the manufacturing line also contributed in the data collection. Apart from that, review and verification of the medical device technical file was also conducted. The risk assessment was done using a standard risk evaluation matrix. Six main groups of risks were recognized and a total of 28 possible risks were identified under the main group. With reference to the risk and hazards identified, approximately 25 strategies that can be used to minimize or eliminate these risks are also presented accordingly and evaluated in terms of applicability and ease of implementation. Subsequently, a standard medical device checklist based on the technical and legal requirement was developed and proposed to be used to assess a medical device prior to usage in order to minimize or eliminate any possible risk and hazard that might arise.

Keywords: Medical device, Risk and hazards, Strategies

ABSTRAK

Secara umumnya jangka hayat rakyat Malaysia menunjukkan kadar peningkatan sejak beberapa tahun kebelakangan ini. Perkara ini boleh dikaitkan dengan kemudahan kesihatan yang dilengkapi dengan ubat-ubatan dan peranti perubatan. Walau bagaimanapun, peranti perubatan yang digunakan boleh membawa risiko dan bahaya secara langsung dan tidak langsung dari aspek keselamatan, kesihatan dan alam sekitar. Oleh yang demikian, dalam kajian ini risiko dan bahaya berkaitan dengan keselamatan, kesihatan dan alam sekitar dinilai secara am dengan menjalankan lawatan kerja ke sebuah kilang pembuatan peranti perubatan. Kajian telah dijalankan untuk mengenal pasti kemungkinan risiko dan bahaya dari penggunaan dan aplikasi peranti perubatan. Satu metodologi umum telah diguna pakai untuk memperoleh maklumat berkaitan dengan risiko dan bahaya yang boleh dikenal pasti daripada penggunaan peranti perubatan. Personel dari kilang pembuatan telah ditemu ramah dengan satu set soalan. Pemerhatian semasa lawatan tapak di bahagian pembuatan dan pengeluaran kilang tersebut turut menyumbang kepada pengumpulan maklumat yang dikehendaki. Selain itu, pengesahan fail teknikal peranti perubatan turut menghasilkan input yang diperlukan. Seterusnya, risiko yang dikenal pasti dinilai menggunakan matriks penilaian risiko. Dengan berpandukan risiko yang dikenal pasti, beberapa strategi telah dibangunkan agar boleh digunakan untuk mengurangkan serta menghapuskan risiko-risiko tersebut. Strategi ini turut dinilai dari segi kebolehgunaan dan kemudahan pelaksanaan. Sejurus itu, satu senarai semak berdasarkan keperluan teknikal serta regulatori telah dibangunkan dan penggunaannya dicadangkan untuk menilai peranti perubatan dengan tujuan mengurangkan serta menghapuskan risiko yang mungkin timbul.

Kata kunci : Peranti perubatan, Risiko dan bahaya, Strategi

ACKNOWLEDGEMENTS

First and foremost, I am very thankful to my supervisor, Professor Ir. Dr. Abdul Aziz Bin Abdul Raman whose encouragement, support and guidance in conducting the project which has enabled me to understand and successfully completing it.

I also wish to express my gratitude to my family members and friends who had helped and guided me significantly throughout this project completion and my study in University of Malaya.

I would like to thank all University of Malaya lecturers who had taught and guided me during the study duration and towards completing this course. I am also thankful to my course mates who have helped me throughout the study period.

Last but not least, I would like to thank God for giving me this opportunity of pursuing Masters and successfully completing it.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF SYMBOLS AND ABBREVIATIONS

GNI	:	Gross National Income
MRI	:	Magnetic Resonance Imaging
ECG	:	Electrocardiogram
BAI	:	Biomaterial associated infections
IMD	:	Implantable medical device
MDA	:	Medical Device Authority
FMEA	:	Failure Modes and Effects Analysis
FTA	:	Fault Tree Analysis
SME	:	Small and Medium Enterprise
QMR	:	Quality Management Representative
DNA	:	Deoxyribonucleic Acid

LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

1.1 Background of Study

In Malaysia, medical device industry has been identified as one of the high potential growth sector under the Eleventh Malaysia Plan (RMK-11). The sector is targeted to contribute RM 17.1 billion in revenue and RM 11.4 billion in gross national income (GNI) by 2020.

Medical device usually refer to any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article intended to be used for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease and injuries. The increasing complexity of medical devices and the variability of usage environments have posed risk and hazard associated to safety, health and environment lately.

Apart from the strict regulatory framework to ensure safety of patients and healthcare providers, continuous monitoring and information collection are necessary to evaluate the safety and risks posed by the medical devices in the market. Malaysian Medical Device Act and Regulation has been established to regulate the medical device and the industry.

This work is aimed to assess risk and hazard associated to safety, health and environment in the usage of medical devices. Recommendations in term of strategies that can be used to minimize or eliminate these risks will be discussed. It is expected that this work will be able to assist the implementation of legal and technical requirements to minimize and eliminate possible risks in the future.

1.2 Problem Statement

The Medical device industry is becoming highly regulated lately as it causes hazard to clinical user and patients in case of improper usage. All this while, the direct and indirect risk which compromises the health and environment has not been a major concern in the society. These risks, if not properly handled can lead to fatal implications in the prolonged period. The life expectancy of population has increased over the years and it is due to the advancement in healthcare including medicines and medical devices. Therefore in this study, possible risks due to application and usage of medical device are identified and also the strategies to reduce and eliminate these risks are presented. The problem being addressed in this work can be represented by following research questions:

a) What are the possible safety, health and environmental risks associated with common medical devices ?

b) What are the strategies to minimize or eliminate the safety, health and environmental risks ?

1.3 Aim and Objectives

The study aims to reduce the possible risks in application and usage of medical devices.

To achieve the aim, the following objectives were defined:

a. To identify possible safety, health and environmental risks associated with common medical devices.

b. To generate possible strategies to minimize or eliminate the safety, health and environmental risks.

c. To develop an appropriate checklist based on technical and legal requirement.

1.4 Scope of the study

This study was carried out on risk analysis of common medical device based on ISO 14971- Application of risk management to medical devices. Basically common medical devices can be categorized into four types which is :

i. Diagnostic
ii. Therapeutic
iii. Laboratory
iv. Radiology and Imaging

1.5 Report Layout

This study report consists of five main chapters. The chapters are explained as following :

a. Chapter 1 : Introduction

This chapter addresses brief introduction to medical device scenario, the background and significance of the study. This chapter also covers the research questions aim, objectives of the study and the scope.

b. Chapter 2 : Literature Review

In this chapter, details on subject related to medical device, the categories and classification of medical device are covered. Apart from that, information related to relevant regulatory requirements and possible risks from application and usage of medical device are also elaborated.

c. Chapter 3 : Methodology

Based on the objective defined, a methodology was designed to be implemented to fulfill the aim of the study. The methodology was constructed to properly identify possible risks resulting from the application and usage of medical device. Besides that,

methodology also enables identification of suitable strategies to reduce and eliminate the possible risks present in medical device application.

d. Chapter 4 : Result and Discussion

This chapter presents the results obtained from the study and discusses the risk identification and possible strategies that can be practiced in order to minimize and eliminate the risks present in the usage of medical device.

e. Chapter 5 : Conclusion and Recommendation

In this chapter, conclusion is drawn using the result obtained from the study based on the predefined objectives. Few recommendations for future work and suggestion for improvement are also covered in this chapter.

CHAPTER 2: LITERATURE REVIEW

2.1 Definition of medical device

According to Malaysian Medical Device Act 2012 (Act 737), medical device is defined as :

(a) any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of –

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii. diagnosis, monitoring, treatment, alleviation, of or compensation for injury;

iii. investigation, replacement or modification, or support of the anatomy or of a physiological process;

iv. support or sustaining life;

v. control of conception;

vi. disinfection of medical device; or

vii. providing information for medical or diagnostic purpose by means of in-vitro examination of specimens derived from the human body, which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means (ISO, 2003); and

any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a medical device by order published in the Gazette.

2.2 Previous studies on risk of medical devices

The human population constantly come into contact with natural and man-made sources of non-ionizing and ionizing radiations, non-ionizing radiation in this case includes, electric and magnetic fields. Significant sources of man-made radiation or electromagnetic usage are mostly utilized in diagnostic tests. It was said that the radiation from medical sources contributed nearly one fifth compared to the natural source in the year 1987. The number of people exposed to electromagnetic radiation has increased gradually since the introduction of Magnetic Resonance Imaging method in diagnostic test. We are yet to find out any significant effects that can be caused by electromagnetic radiation from Magnetic Resonance imaging (MRI) whereas it is proven that ionizing radiation is capable of affecting the human health and environment. Lately, MRI has been widely used as an diagnostic technique in cardiology. (Hartwig et al., 2009)

Recognizing, investigating, controlling, and monitoring dangers always begin in the development stage, start right on time in the advancement procedure. As client needs are evaluated, dangers related with possible misuse or gadget failure should be recorded. Design input prerequisites should be built up, checked, and approved to guarantee all risks are minimized to a level that is as low as sensibly practicable. As the advancement continues, the device and assembling process should be fundamentally analyzed to set up proper controls. There is no real way to totally wipe out risks related to usage of a medical device. Each exertion ought to be made to moderate risks by outlining the item and process used to manufacture the device. (Kinsel, 2012)

General medical waste which is disposed of from hospitals and clinics is able to present a huge health risk through infection. The United Nation estimated that nearly half of the world's population is at risk from effect that might arise due to healthcare waste. Design of medical products is a high risk field, whereby any potential reduction

in the medical device functionality or increase in risk could endanger patients' safety, health or even lives. (Kane, Bakker, & Balkenende, 2017)

There have been a few reported cases of infusion pumps where the design was not relevant to the operation method. Few examples of reported cases consist of unexpected rebooting of the pump, key skip or numeric entry mistakes which lead to infusion error, and pumps that is preprogrammed with an incompatible module which could not integrate with the hospital system and ease of physicians' usage. (C. Vincent & Blandford, 2011)

Studies uncovered that the mobile phone is one of the potential cause of disturbance to the functionality of numerous medical devices. The radiation from mobile phones will either cause the close-by medical device to be out of order or alter the parameters estimated. Besides that, it could interfere with screen displays. It was found that, most medical devices are susceptible against the mobile phone radiations. They include the mechanical ventilators, implantation pumps, Electrocardiogram (ECG) recorder, defibrillators, patient monitors and pacemakers. Therefore, the modification of estimated parameters may change the diagnostic results and lead to irrelevant treatment. (Mariappan, Raghavan, Aleem, & Zobaa, 2016)

Medical devices by their extreme nature are expected to offer patients considerable advantage. An inevitable truth is that therapeutic devices have the ability to cause huge harm in case of improper execution or device failure. With regards to the implanted devices, there are configuration issues identified such as the biocompatibility and its sturdiness. For an example, the unforeseen vulnerability of implanted pacemakers to stray electrical obstruction from devices such as microwave broilers that could make the implant giving wrong stimulus to the heart. Electromagnetic obstruction from microwave stoves and different devices could lead to serious patient injury or even passing. (Citron, 2012)

Biomaterial associated infections (BAI) intrinsically linked to implant use, have plagued patients and clinicians over the entire history of implant and device use. This is a consequence of the invasive nature of implant or device placement: almost every implant or device placement creates a wound or tissue irritation. (Grainger et al., 2013)

Although current insulin pumps have gone through so much of evolutions, possibilities of error in insulin infusion can still occur. This is basically due to set blockage, pump failure, user blunder or the combination of all possibilities. Patients are in this way presented to huge and possibly fatal hazards: intrusion of insulin infusion can bring about hyperglycaemia and ketoacidosis; on the other hand, administration of excess insulin can cause extreme hypoglycaemia. (Heinemann et al., 2015)

Developing from a normal electromechanical implantable medical device (IMD) to one with further developed processing and correspondence capacities has numerous advantages. At the same time, it also involves various security and protection dangers for the patient. The significance of such dangers is generally common in computing and processing fields. However, the consequences are more critical in term of implants. Assaults against an IMD can put in danger the security of the patient who conveys it, with fatal outcomes in specific cases. Examples of such IMD's are heart implantable devices, neurostimulators and biosensors. (Camara, Peris-Lopez, & Tapiador, 2015)

Innovation, equipment and medical devices are key for efficient health services all around the world yet it still poses significant risks. These dangers incorporate failure of a device, improper utilization, lacking user training and awareness also inefficient assessment and support. Additionally hazards that are present in current situation includes various states of temperature and moisture, poor framework, inadequately prepared healthcare facilities, restricted assets and supervision, and supply of complex devices without proper usage, application instruction and support. (Newton et al., 2010)

Infectious risk is one of the most frequent complications related to the use of indwelling medical devices such as cardiac prostheses, urinary catheters, endotracheal tube and vascular catheters. Medical device-related infections are a public health concern and an economic burden (Desrousseaux, Sautou, Descamps, & Traoré, 2013)

Medical practitioners and staffs are generally at a high risk of exposure to infections at workplace, the healthcare facilities. They are very prone to infections due to blood borne pathogens. These infections are possible whenever a needle stick injury occurs during administration of medicine or drawing out blood from the patient. (Fukuda & Yamanaka, 2016)

Besides the possible risks discussed above, complication with regards to the various energies used and delivered to medical device in the hospital environment are not well established. This risk is potential in causing danger to the patient as well as to the medical practitioners. (Borie et al., 2017)

2.3 Review on strategies to mitigate risks present in the usage of medical device.

Several strategies have been identified in previous studies. For an example, training and awareness on the task support, and utilization of the medical device might be required. The last safety measure that can be taken by medical device producers to avert unfriendly results is to give the clinician clear signs and instructions to utilize, contraindications, alerts, and notices in device packaging (Kinsel, 2012). Healthcare management teams should be responsible to train their staffs, users and exposure to the patients on correct usage method of devices and possible risk due to misuse. (Heinemann et al., 2015)

In particular, the incorporation of human factor techniques in the design and development of medical device offers benefits that encourage more secure and more

user friendly devices that are more qualified to current needs. As devices are discharged for utilization, risk managers can upgrade persistent security by adopting human factor criteria amid the assessment of another innovation. (Privitera, Evans, & Southee, 2017). A crucial aspect of medical device design is human factors. It is the study and evaluation of how people apply and interact with technology. (Heinemann et al., 2015)

The advancement potential due to the postmarket information for medical device establishment is evident. It creates device related hazard data and in this way, specialized user knowledge and motivations for research and development with reference to how new restorative devices or officially existing therapeutic devices and procedures can be composed more productively and successfully, bringing about ergonomical, more secure, and better device utilization and risk minimization. (Zippel & Bohnet-Joschko, 2017)

Patient safety and risk minimization can be achieved through reporting system whereby it provides a mechanism of learning from failures reported and leads to a progress of achieving safety culture in healthcare facilities. (Newton et al., 2010)

Training and awareness of staff in the utilization of medical device should be ensured as an important requirement by the management of healthcare facilities. This can be put into realization with generation of proper strategies and training courses to ensure the competency levels of the users are suitable for the medical devices being handled. (Clarkson, 2017)

An alternative way of preventing invasive device-related infections is the realization of medical devices with surfaces or materials that have an action against microbial viability or adhesion (Desrousseaux et al., 2013) (Menezes et al., 2014)

2.4 Regulatory requirements for medical device in Malaysia

Medical Device Authority (MDA), a statutory body under the Ministry of Health Malaysia is established and given the powers to control and regulate medical devices,

related industries and the activities. MDA is also responsible to enforce the medical device laws and related matters. Basically, medical device is regulated to address public health and safety issues. Apart from that, it is also to facilitate the medical device trade and industry. The structure of medical device regulatory system established as below;

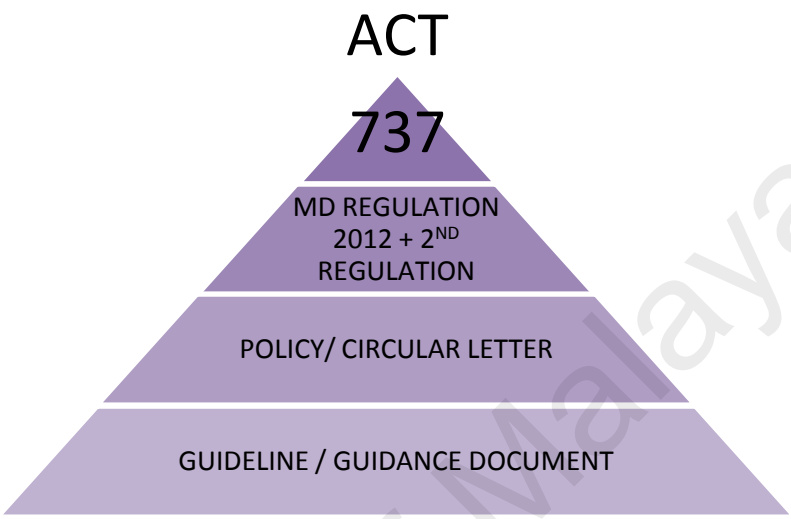

Figure 2.1: Medical device regulatory structure in Malaysia

2.4.1 Regulatory framework in Malaysia

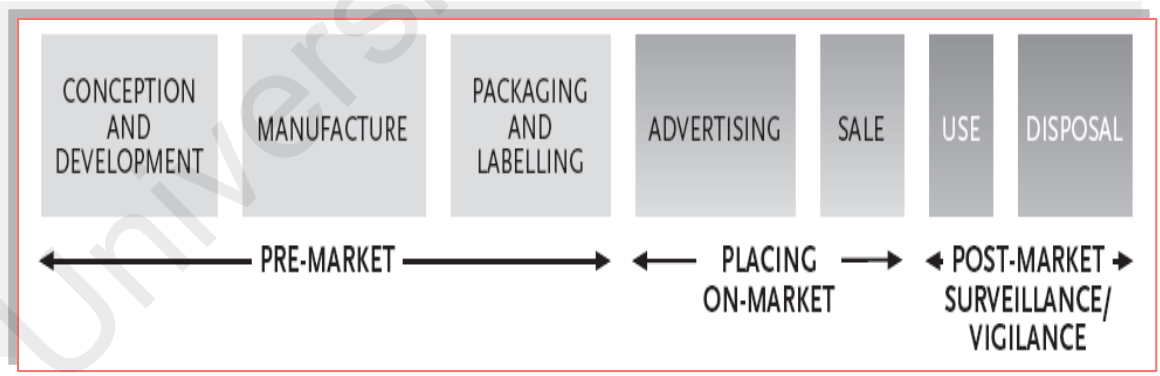

Figure 2.2 : Stages of Regulatory control throughout the life cycle of medical device.

2.5 Risk based classification of medical device in Malaysia.

The classification of medical device is usually determined by the intended purpose of a medical device set by the manufacturer based on a set of classification rules. Risk based classification of medical device is done in order to :

i. Ensure the regulatory control is equivalent to the risk of medical device.

ii. Aid manufacturer to classify the medical device appropriate to the risk.

Medical device classification is based on the risk associated to it at the point of usage which considers the risk to patients, users and other persons. Risk posed by a particular device relies on the :

a. Intended purpose of the medical device.
b. Effectiveness of the risk management applied throughout the life cycle of the medical device (design, manufacture and usage)
c. Intended users of medical device.
d. Mode of operation of the device.

2.5.1 Factors determining the medical device classification.

Few factors that may influence the medical device classification include :

i. Contact duration of the device with the human body. Medical devices can be meant for transient use which is usage lower than 60 minutes, short term use within 60 minutes to 30 days and long term use which exceeds 30 days of continuous use.

ii. The site of and degree of invasiveness into the body. The site administered for example cardiac symbolizes that the device carries a higher risk classification and surgically invasive devices pose higher risk compared to device which is invasive through body orifice.

iii. Whether the device delivers energy or medicine to the patient. Devices which are meant to deliver energy or substance might be of higher risk as there is a possibility of a different interface which function together with the medical device. Such example is syringe pump, although the intended use is to deliver

medicines to the patient, the electrical energy used to power the pump do influence the risk classification of the device.

iv. Whether the device is intended to cause any biological effect on the body. Certain devices naturally might initiate biological reactions when comes into contact with patient. For an example, synthetic heart valves can cause biological effect to the patient if it is not compatible with the patient's body system

v. The intended action on the human body. Risk class of device also depends on the intended use of the device. For example, thermometer can be of a lower risk class as it poses less significant risk compared to a ventilator.

vi. Local *versus* systemic effects. Medical device causing significant effects to the systemic part of the human body can be considered having a higher risk compared to the devices with effects towards local system.

vii. Whether the device comes into contact with injured skin. In the event of a device coming in contact with the injured skin, it is posing a higher risk as it has a direct contact to the body as the primary defense which is the skin is already breached.

viii. Whether for diagnosis or treatment. Medical devices can be used for diagnostic purpose and also for treatment. Most of the time, diagnostic devices pose lower risk compared to the treatment devices unless the diagnostic devices do have other systems or device attached to be used together.

ix. The ability to be reused or not. Single use devices usually pose less significant risk as devices that are subject to be reused can cause infections if not properly sanitized.

x. Combination of devices. Medical devices which are combined have the possibilities of being a higher risk device. Physiologic monitoring system which incorporates monitoring of blood oxygen saturation, blood pressure and also

heart rate can be of higher risk class compared to a stand-alone blood pressure monitor.

Table 2.1 : Risk based classification of medical device

Class	Risk Level	Device Examples
A	Low Risk	Tongue depressors / surgical retractors
B	Low-moderate Risk	Suction equipment / hypodermic needles
C	Moderate-high Risk	Orthopaedic implants / lung ventilator
D	High Risk	Implantable defibrillator / heart valves

The regulatory control of the medical device increases as the risk class of the device is higher. Figure 2.3 shows the correlation between the regulatory control and risk classification of the medical device.

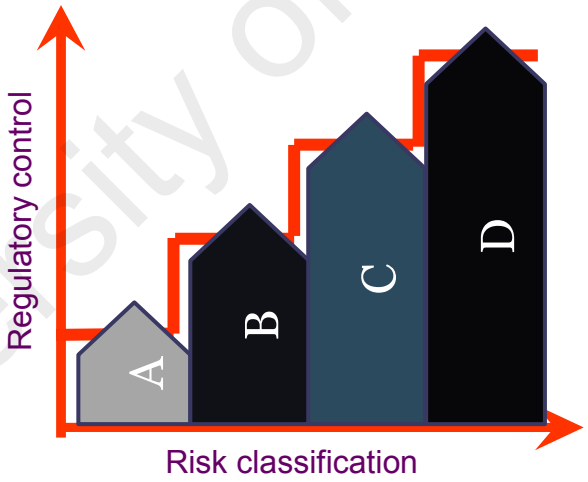

Figure 2.3 : Correlation between the regulatory control and risk classification of a medical device.

2.6 Risk Management techniques

Risk management serves as the cornerstone for guideline, regulation, and compliance development for any device that interacts with the body and should be performed continuously throughout the product lifecycle - spanning from the device prototype stage through the end of the device lifecycle. Risk management is defined as the

application of various practices to analyze, evaluate, and control risk. (Bikson et al., 2018). There are few techniques that can be adopted to conduct the risk analysis of a particular medical device. The main principle of the assessment is that the chain of events is considered and analyzed step by step.

Risk analysis techniques received increasing attention in health care sector in the last 15 years. This is due to the increased attention on safety of both users and patients and to the development and diffusion of risk assessment standards. The analysis of risk associated with the device can be accomplished in different ways. Failure Modes and Effects Analysis (FMEA) (Onofrio, Piccagli, & Segato, 2015), fault tree analysis (FTA) (Kabir, 2017), and HAZOP (Taylor, 2017) technique are the most relevant, as described in ISO 14971 (Standardization, 2000)

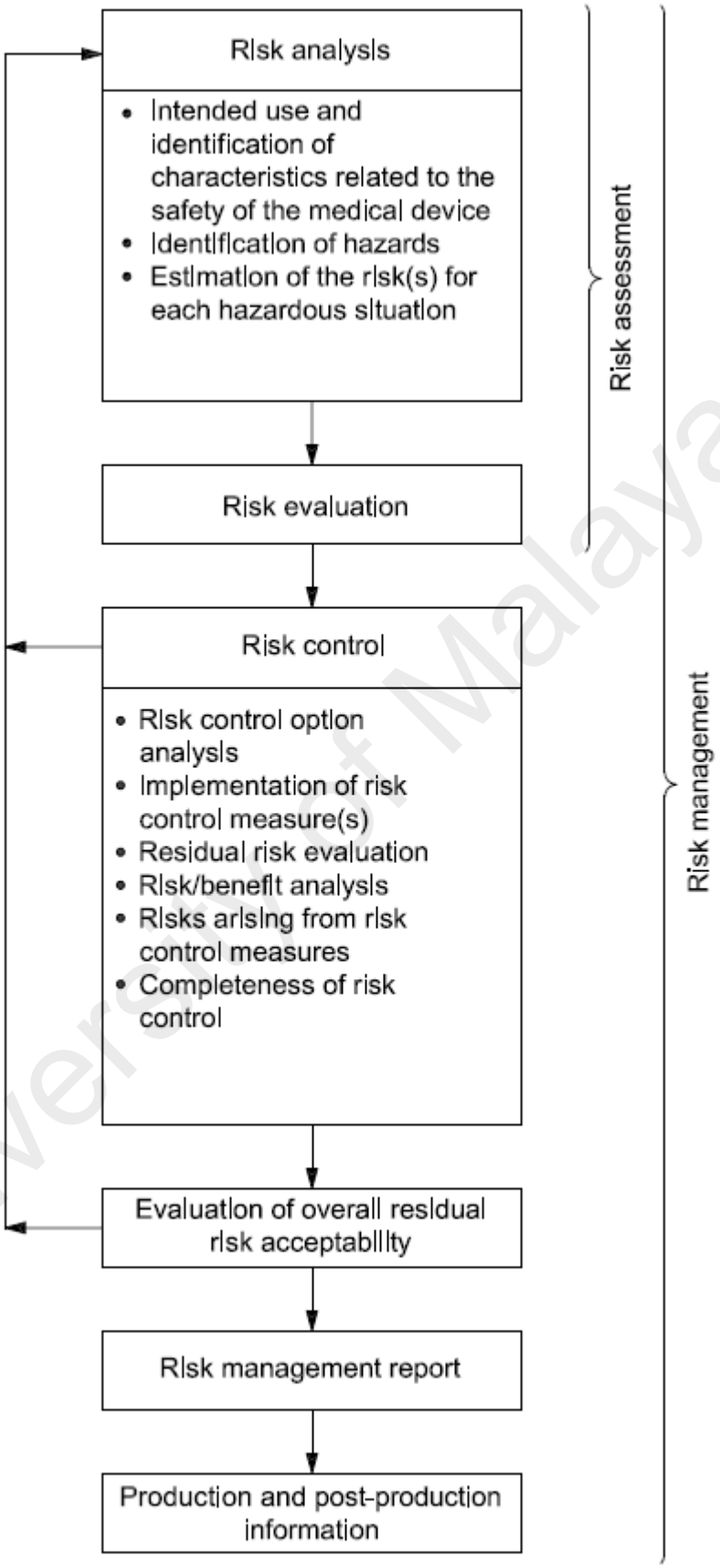

Figure 2.4 : Overall risk management process flowchart for common medical device. (Standardization, 2000)

2.7 Summary of literature review

The literature review explains how the medical device scenario in Malaysia is regulated. It also states how does a medical device is being classified according to the risk based on factors and a set of rules. The few factors that determines device risk classification was also elaborated for better understanding with examples. The risk identified in the usage of medical device in the previous studies was also highlighted and referred as a guide to the work. Apart from that, previous studies which describes possible ways of mitigating risk in medical device usage was also included in the literature review. Therefore it is expected that the part of objectives covered in the literature review will be beneficial in achieving the aim of the study which is to reduce the possible risks in application and usage of medical device. Literature review also elaborates few risk management techniques that will be appropriate in order to analyze and assess risks posed by medical device in general.

CHAPTER 3: METHODOLOGY

The research methodology applied in this study is elaborated in this chapter. This chapter highlights study planning, medical device manufacturer selection, sample size data acquisition process and analysis method used in the study.

3.1 Overall Methodology Flow Chart

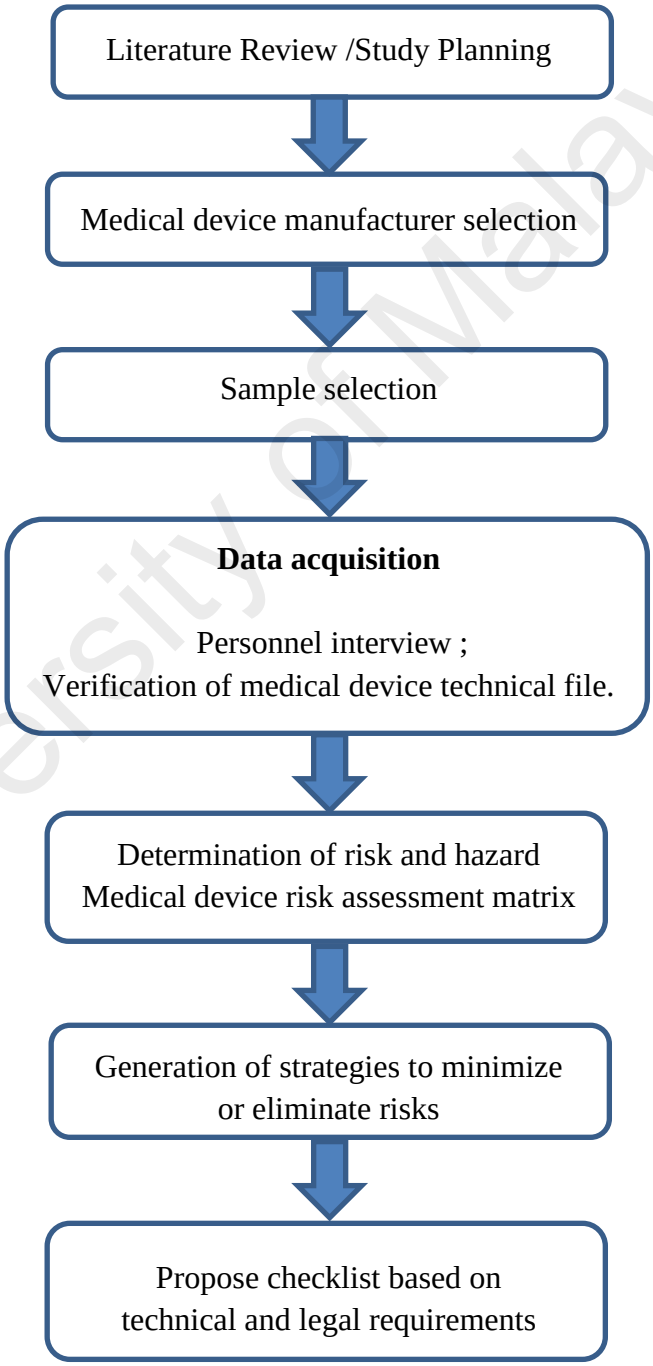

Figure 3.1 : Methodology flow chart

3.2 Study Planning

The planning was initiated by identifying the problem statement of the study. This is to ensure an effective progress throughout the study and to acquire the expected output from the study. Review of literature was conducted initially to familiarize the related topics and identify possible gaps in the study. Literature review was also done to determine suitable methods for data acquisition and analysis. The scope and objective of the study was also set in order to achieve the desired output.

3.3 Medical device manufacturer selection

Medical devices industry in Malaysia is basically composed of more than 190 companies including small and medium enterprises (SMEs). Out of this number, most of the manufacturers, manufacture rubber based products such as medical gloves, probe covers and condoms. Apart from rubber based products, Malaysian medical device manufacturers are also active in producing consumables such as various catheters and tubings. The medical device related industry has been identified as one of the key growth areas. For the purpose of this study, a medical device manufacturer was identified for a surveillance visit. Site visit to the manufacturing line was also part of the visit but no photographs were allowed as it was part of the confidentiality policy of the establishment. Basic information of the manufacturer is stated in the table below.

Table 3.1 : Manufacturer's information

No	Item	Information
1	Establishment name	SME Sdn Bhd
2	Medical device range	Disposable medical devices such as extension tubes, infusion sets, scalp vein sets, feeding sets, catheters and urinary tubes
3	Manpower	400 – 500 employees
4	Head quarters	Subang Jaya
5	Manufacturing site	Central

3.4 Sample selection

In this study, samples involve the quality management representative (QMR), line operators, laboratory officers and also technical file of selected medical devices. Samples are selected such because, these individuals know better about the medical device production and risks associated to the application and usage of it. Technical files on the other hand provide all the necessary information including the specification of the device, material used and also risk analysis result of the medical device. This information will be crucial in determining the prevalent risk posed by application and usage of medical devices.

3.5 Data acquisition

Data and related information that will be elaborated in the Chapter 4 were obtained through number of methods, by informal interviews, observation and verification of the medical device technical file.

3.5.1 Personnel interview

The informal interview was a details and information sharing session with the quality management representative (QMR) of the establishment, personnel from the quality assurance and control department, laboratory officers and the line operators. During the interviews, details of medical devices manufactured were shared, standards used in manufacturing and maintaining the quality management systems were elaborated. Besides that, type of test conducted on finished product to ensure the quality was also described. The line operators shared the common faulty and defects encountered in the production line. These faulty and defects sometimes might lead to risk if it is not captured by the quality assurance and control department in the manufacturing site. The list of questions asked to the personnel during interview is enclosed in **Appendix A**

3.5.2 Observation

Observation was conducted during the visit to the manufacturing plant. The management led by the QMR gave a full cooperation during the site and production line visit of the manufacturing plant. Other than the production lines, visit also covered the raw material storage area where incoming inspection for raw material is done before it can be channeled to the production line for further processing into finished goods. Guidance and assistance was provided throughout the visit. Relevant explanations were given on the processes undertaken from the acquisition of materials, into processing and finished product as a medical device.

3.5.3 Verification of the medical device technical file

Under the international standard relevant to quality management system of medical devices and the medical device regulatory framework, it is a requirement for the medical device manufacturers to prepare a medical device technical file for the devices that is being manufactured. This technical file consists of the technical specification of the device, testing criteria's, instruction for use, risk classification of device, risk analysis of the device, post market records, standards applicable to the device, material used and other relevant details. This file is very crucial as it contains details of the device since its conceptualization, marketed, put into usage and finally disposed.

3.6 Risk Evaluation Matrix

In order to determine if a risk is acceptable or not, it should be subjected to the risk evaluation matrix as specified in the ISO 14971, Application of risk management to medical device. The combination of probability of harm and severity of harm is referred to the risk evaluation matrix as in Table 3.3 to determine if the risk is acceptable or unacceptable. The **darker grey** area in the matrix portrays that the risk is unacceptable whereas the **clear area** portrays an acceptable risk.

The severity level with reference to the risk evaluation matrix can be described as follows ;

Table 3.2 : Description of severity levels

Terms	Description
Negligible	Temporary discomfort or inconvenience
Minor	Causing temporary injuries, does not require medical intervention
Serious	Injury or impairment requiring professional medical intervention
Critical	Permanent impairment and life threatening injury
Catastrophic	Resulting in death

As for the probability, it is more accurate to be related to the application of a device as the usage probability of devices varies according to their purpose.

Table 3.3 : Risk evaluation matrix

		Severity levels				
		Negligible	Minor	Serious	Critical	Catastrophic
Probability levels	Frequent					
	Probable					
	Occasional					
	Remote					
	Improbable					

3.7 Generation of strategies to minimize or eliminate risks

Based on the various risks identified using the data acquisition methods, possible strategies to minimize or eliminate the risks were identified and shortlisted by applying the risk management process. The strategies generated will be further used in proposing a checklist that can be used to conduct an initial assessment and checking on a particular

medical device before it can be put into operation and usage. The strategies are expected to meet the objective in reducing the prevalent risks from usage of medical devices (Christopher J Vincent & Blandford, 2015). The implementation of the strategies may involve various parties which will include the manufacturers, authorized representatives, importers, distributors, clinicians, patients and also the regulatory authorities (Hass & Berlin, 2013).

3.8 Propose checklist based on technical and legal requirements.

An appropriate checklist incorporating the technical and legal requirement is aimed to be developed at the end of the study. The checklist is expected to cover the technical criteria's emphasized by a general medical device manufacturer and regulatory requirements that should be adhered to according to the applicable law and guidelines binding to it. This checklist development will take into consideration the risks identified from the usage of medical device and at the same time accentuate the possible strategies which will be useful in minimizing and eliminating the risks identified.

CHAPTER 4: RESULT AND DISCUSSION

In this chapter, the result of the study will be discussed. Result of this study is obtained through the method described in the methodology, via informal interview of the relevant parties namely the quality management representative (QMR), personnel from quality assurance and control department, laboratory officers and also the line operators. Apart from that, information was also obtained through observations during walk about in the production line site visit. The verification of medical device technical file also contributed to the details and information obtained.

4.1 Possible risks and hazards associated with common medical devices.

There are several risks and hazards that can be associated to the application and usage of medical devices. The possible risks identified are listed in the table below.

4.1.1 Energy related risks and hazards

Energy related risks and hazards can be further divided into :

a. **Electrical** : Electrical risk is related to the line voltage of the device from the supply which might have fluctuations in the long run that could damage the medical device. Apart from that, various leakage current that might be present in an active medical devices has the potential of causing danger to the user if not properly operated. For an example, possibility of leakage current in an electrocardiogram could lead to electrocution of the patient if it is not monitored prior to usage.

b. **Heat** : Heat generation can be due to the operation principle of the device or could be due to usage duration of the device. Example of devices with operation principle using heat is blood warmers and bedside warmers. As for the heat generated due to usage, too much heat accumulation could damage the device and cause harm to the patient at certain instance.

c. **Mechanical force** : This includes force that may be exerted by certain devices in use. Vibration from the device, torsion and tensile forces that may indirectly cause harm to the user. Moving parts of a particular device can injure users indirectly if proper monitoring is not administered. For example, C-arm X-ray machine has an extended arm that can injure the user as the extended arm is a movable part.

d. **Radiation** : Radiation in medical device industry is basically used in radiology and nuclear medicine application. Radiation is potentially dangerous if necessary precaution is not taken. Radiation can damage living tissue by causing damage to the DNA and altering the cellular structure.

e. **Acoustic energy** : Acoustic energy application is used in imaging and curing certain medical conditions. For example, Doppler flow meter uses the acoustical energy principle where it senses using transmitting and receiving elements placed on the skin. This energy transfer may have effects at the cellular level.

4.1.2 Biological risks and hazards

a. **Biocompatibility** : Medical devices are manufactured using diverse range of materials due to various usage and intended purpose. However, it should be made sure that the medical device is biologically compatible to wide range of users in order to reduce the rate of rejection due to compatibility issues. During the conception phase of a medical device, material to be used should be subjected to compatibility studies and test before it can be confirmed safe for usage.

b. **Contamination** : Improper usage practice and failure to adhere to the intended purpose can lead to contamination. This is due to the presence of contaminants around the treatment or procedure area. In certain instance,

general medical device are sometimes exchanged in the wards without prior sanitization.

c. **Toxicity** : Is due to the toxical risk present in the usage of medical device. Toxical risk can be due to harmful compounds that are misused during application of the device.

d. **Degradation** : Certain reagents or consumables having shelf life may degrade as time passes by. Therefore proper attention is necessary during administration of a medical apparatus.

4.1.3 Environmental risks and hazards

a. **Electromagnetic interference** : Electromagnetic fields from surroundings may cause safety and health hazards. For example, electromagnetic field has significant effects on patients with active implantable medical devices as the electromagnetic field can alter the functionality of the particular device in the body. The electromagnetic fields present elsewhere in the environment may be potential in altering the functionality of the medical device. Implantable devices are very susceptible to the interference. Emission of electromagnetic interference can interfere with the radiofrequency spectrum and cause other implication towards the user and also the environment.

b. **Cooling system** : This phenomenon usually can implicate the functionality of magnetic resonance imaging (MRI) equipment. MRI basically uses helium as its cooling agent as it produces tremendous heat during operation. Insufficient coolant can lead to greater consequences.

c. **Storage or operation outside prescribed environmental conditions** : Most medical devices do have its ideal operating conditions as specified in the user an operational manual. Any major deviation from the prescribed condition

can alter the proper functionality of devices and lead to adverse incidence if not properly monitored.

d. **Incompatibility with other devices with which it is intended to be used** : Certain medical devices can lead to adverse incidence if it is not compatible to the device it was intended to be used with. For an example, the oxygen flow meter and regulator is meant to be used together but under certain circumstances, it may become incompatible when used together and may cause unwanted events.

e. **Contamination due to waste products and / or medical device disposal** : Waste discharge from the usage of medical device can pose indirect risk and harm if not properly managed. Once a device has reached end of its usage life, proper disposal should be implemented to avoid repercussion to the surrounding environment. For an example, medical devices that contain mercury should be disposed in a proper manner to prevent any kind of contamination. Contamination risk could also occur in the event of leakage or leach out of substances from the medical device, such as infusion/syringe pump during operation. This could possibly cause danger to the user and the patient themselves.

4.1.4 Risk and hazard due to incorrect output energy and substances

a. **Electricity** : Incorrect output energy could lead to failure of the device to function at an optimum level and could lead to damage of the electronic circuit boards. Leakage current in the circuit if not properly grounded could lead to electrocution potential towards the user and patients.

b. **Pressure** : Pressure application is common in blood pressure (BP) monitor. Failure to control the pressure during blood pressure monitoring could lead to occlusion of the blood vessel and cause unwanted incidents.

c. **Medical gases** : Common medical gases in patient wards are oxygen, medical air and nitrogen. Medical gas system should be maintained regularly as it is very crucial during any emergencies. The functionality should be monitored.

4.1.5 Risk and hazard related to usage of medical device.

a. **Inadequate labeling** : Labeling of the medical device is very crucial in providing basic usage and maintenance instruction. Effective labeling should include the storage conditions of device, instruction for use and also the precaution during usage of the device. Labeling of medical device also plays a vital role in communicating warnings and possible side effects that may arise if the device is not properly operated. Information of single use or reusable medical device should be provided in the labeling in order to prevent misuse of the device.

b. **Inadequate operating instructions** : Most medical device put in use is accompanied with user and operation manual which elaborates the instruction for usage of medical device. It is expected that user refers to this documents for proper and safe use of the device throughout. The operation manual also should enclose any pre-use check applicable to any particular device. Certain devices require pre-use checks and vital parameters set before it can be initiated for usage. Failure in conducting this may lead to distorted use of a device.

c. **Inadequate specification of accessories to be used with the medical device** : Certain medical device cannot be operated independently. It should be used together with applicable accessories and applied parts. Therefore, the user should be aware of the medical device and its accessories to ensure the usage can be optimized.

d. **Complicated operating instructions** : Certain devices are attached with complicated operation instructions. This can burden the user in understanding and putting into practice the instruction of usage. Operation instruction should be designed to provide easy understanding using layman terms instead of using scientific phrases.

e. **Unskilled / untrained personnel** : The personnel operating a medical device are made sure he/she has the understanding of the operation principle of the device. Any personnel to use a medical device are made aware of the proper usage and operation as per instruction manual. Lack of awareness on operation of the medical device can probably lead to misuse of the equipment which in turn could cause unwanted incidents.

f. **Ergonomics** : Medical devices may have its own properties. Not all the personnel can operate all the medical devices due to its dimensions and bulky properties. Therefore, ergonomical factor can pose risk in certain situation during usage of device.

g. **Incorrect measurement and other metrological aspects** : Certain medical devices incorporate measuring function. These devices should be periodically calibrated to ascertain the precise measurement value. For example, pulse oxymeter is used to measure the oxygen saturation percentage in blood. Calibration of this device is important as the value obtained will be a reference for the physicians to consult the patient.

h. **Sharp edges or points** : Presence of sharp edges and points may lead to physical injuries to the user and patient. Therefore, it is advisable that this edges and points are placed facing a safer place where there is no much movement and reduce the tendency of injuries.

i. **Complicated user interface** : Complicated user interface can lead to possibilities of mistake and judgement errors during usage of the device. Certain user interface uses abbreviation of instruction which affects the understanding of the users. Medical device with complex control system also may lead to improper or careless operation of the device. Certain user interface of devices have limited visibility of the screen and impaired audibility. This can indirectly affect the usage of the device.

4.1.6 Risk and hazard due to functional failure, maintenance and aging.

a. **Electrical / Mechanical integrity of device** : Medical device usually do have product useful life similar to the shelf life. As the device ages, the integrity of the device becomes questionable. The electrical and mechanical integrity is found to be important to ensure safe usage of the device all the time. Integrity of the device can be overseen by conducting periodical maintenance.

b. **Error in data transfer** : Data transfer error may happen in case of functional failure of device or the system is corrupted. This error is considered major as the data could be useful in diagnosis of a patient. Therefore, integrity of the data generated should also be monitored to prevent errors being committed.

c. **Deterioration** : Due to aging factor some medical devices may deteriorate in terms of functionality and also the integrity. Most of the time, deterioration effects the material and shape of the devices physically.

4.2 Generation of strategies to minimize or eliminate risks and hazards associated with common medical device.

With reference to the various risk and hazard identified during the data collection, possible strategies to minimize or eliminate the risks were generated accordingly.

4.2.1 Strategies on energy related risks.

Basically, there are quite a number of risks which can be placed under the energy related as described earlier. Following are some of the recommended strategies that can be implemented.

In order to mitigate the electrical risk mentioned in 4.1.1(a) and 4.1.4(a), it is best to pre check a device before and after usage. Normally periodical maintenance can be conducted where electrical safety test will be part of the maintenance routine to ensure the electrical functionality and integrity.

Heat generation 4.1.1(b) and exposure during device usage can be minimized by applying insulative layers to the areas that are prone to contact with users and patient.

Other than that, mechanical force 4.1.1(c) that can arise from freely moving parts of devices must be made sure secured before the device is being used. Ensure operator of the device is always aware of the surrounding before making any abrupt motion.

Radiation energy 4.1.1(d) is also a risk that has been identified. Monitoring frequency and dosage of radiation is crucial before subjecting the patient for diagnosis or treatment related to radiation. Apart from that, usage of radiation protection apparatus can be implemented during exposure to radiative devices. For example, radiation protection apparel can be used to minimize the effect of radiation exposure.

Patients who have been implanted with active implanted medical device such as pacemakers and drug delivery pumps should always be aware of their surroundings to ensure they are not in the range of strong electromagnetic interference which can alter the functionality of the implants.

4.2.2 Strategies related to biological risk

Biological risk 4.1.2(a) is identified to be one of the major risks in medical device industry. Requirements should be set to ensure all medical devices to undergo the biocompatibility testing protocol with reference to ISO 10993 which is comprehensive

for biological testing of medical device. There are series of test under the international standard and it should be proposed to be conducted during the premarket for the material used and before placement on the market for overall functionality and acceptance. Therefore, it is important to reduce the rate of rejection due to compatibility issues.

Method of usage of a medical device and its intended purpose should be always considered and studied before putting the device into usage. This is important to ensure usage does not cause any form of contamination 4.1.2(b) to the sample and also the patient under care.

Apart from contamination risk, toxicity risk 4.1.2(c) can also be minimized if proper usage of device is practiced. Degradation 4.1.2(d) of a medical device can be anticipated and taken out of use before it can harm the users and patient. This is possible by being aware of the lifespan of a particular device and referring to the user/operation manual in case of any doubt on the device and its application.

4.2.3 Strategies related to environmental risk

Electromagnetic interference in the environment could lead to alteration of functionality of the active implantable medical devices as per discussed in 4.1.3(a). Therefore, patients should be aware of their surroundings and avoid being in the electromagnetic field range.

Certain devices with cooling system 4.1.3(b) should be monitored periodically to ensure it is functional and efficient. For an example, cooling mechanism using helium in the MRI system should be monitored to ensure optimum function of the device. Basically, medical devices do have its ideal operating conditions 4.1.3(c) which is crucial for its optimum function. This condition should always be considered whenever usage is necessary.

Apart from that, prior to usage it is always best to take into account the compatibility of accessory devices 4.1.3(d) which is intended to be used with to prevent any undesirable events.

It is also important to ensure that no leakage or leaching is detected during usage of medical device which can lead to waste of medical benefit and also contamination 4.1.3(e) compromising safety of the user and patient.

4.2.4 Strategies related to incorrect output energy and substances.

Insufficient energy 4.1.4(a), 4.1.1(a) from supply towards the device can cause damage to the power supply board. Therefore, it is recommended to check and ensure correct output energy is being delivered from the supply before operating the medical device.

Besides that, certain device operates using pneumatic pressure 4.1.4(b). Such devices are non-invasive blood pressure monitor (NIBP). These devices should be calibrated and maintained using patient simulator circuits to ensure correct pressure value is applied to the patient during blood pressure measurement. Failure to monitor can cause occlusion of the blood vessel due to excessive pressure applied during diagnosis.

Medical gas system 4.1.4(c) is very crucial in hospital environment especially in emergency department and intensive care unit (ICU). In order to ensure its intended functionality, scheduled maintenance should be planned at suitable interval.

4.2.5 Strategies related to risk from usage of medical device

Prior to usage of medical device, it is best to be aware of the intended purpose of the medical device and method of operation. Therefore, it is important to enclose a proper labeling 4.1.5(a) which provides usage, maintenance instruction and also other crucial information such as the storage condition of the device, precaution that should be taken during usage.

Besides that, it is also advisable for a user to always refer to the operation manual in case of any doubts before, during and after the usage of device. The operation manual 4.1.5(b) is expected to provide guide for safe and proper use of the device which may include the pre-use check of the device and basic setup before a medical device can be put into use.

User is also advised to ensure the accessories 4.1.5(c) to be used with the medical device is compatible in order to avoid undesirable incidents. This is because not all accessories can fit to be used with a medical device. For example, certain electrocardiogram (ECG) device requires the specific ECG leads to function as intended. This should be made sure by the user before device is put into operation.

In order to ease users in operating a medical device as intended, the manufacturer or authorized representative should consider developing an operation manual 4.1.5(d) which can be easily understood by the users. Usage of layman terms should be applied rather than complicated scientific phrases.

The management of the healthcare facility should ensure personnel operating a medical device to have the basic understanding and intended purpose of the medical device. Therefore, training and awareness 4.1.5(e) should be provided to the personnel to ensure they understand and gain the valuable skills in proper operation of the device and managing the patients.

Ergonomics factor 4.1.5(f) should also be given emphasis by manufacturer and the healthcare personnel (Christopher James Vincent, Li, & Blandford, 2014). As for manufacturer, they should design a device that can be used to majority of the population. As for the healthcare personnel, physical build of the user should be considered in operating a medical device as not all the user will be suitable in handling the medical devices as they come in various dimensions and different properties. So,

proper selection can reduce the risk and occurrence of incidents. (Christopher James Vincent & Blandford, 2017)

Devices which incorporate measuring functions 4.1.5(g) should be periodically calibrated and the user should be professionally trained to obtain the measurement values during the diagnosis and treatment of a patient. Lack of skill in obtaining the proper measurement may lead to misdiagnosis (Money et al., 2011).

Similar to the complicated operation manual as mentioned before, complicated user interface 4.1.5(i) should be avoided during manufacturing to reduce the number of mistake and judgement errors during device usage. Manufacturers can conduct a survey on the potential customers on the user friendliness of their medical device and ease of usage in order to produce an acceptable device (van der Peijl, Klein, Grass, & Freudenthal, 2012).

4.2.6 Strategies related to risk from functional failure, maintenance and aging

As a medical device ages, the integrity of the device becomes questionable 4.1.6(a). Therefore, it is important to ensure the electrical and mechanical integrity is always monitored before a device is being used. In order to make sure the device is fit to be use, planned preventive maintenance can be conducted and emphasis should be given to critical point of usage of the device. By this way, device can be confidently used.

Every device may be manufactured using various materials and due to aging 4.1.6(c), the materials might deteriorate and affect the functionality of the device. In order to avoid this scenario, the devices having tendency of deterioration upon aging should be put to stop from usage to avoid any further problems that might arise if its usage is continued.

4.3 Feasibility of strategies in terms of acceptability and ease of implementation

The feasibility of strategies is evaluated in term of applicability and ease of implementation as tabulated. The feasibility is described using three options, which is **high**, **medium** and **low**. High applicability conveys a message where the strategy is easily applicable without obstacles with the available sources. Medium applicability resembles additional resources may be needed to make the strategy implemented. Low applicability indicates that the strategy is not readily feasible and needs certain extent of interference from third party, for instance manufacturer of medical device or the Regulatory Authority. In terms of, ease of implementation, high ease of implementation indicates strategy is implementable with less financial burden.

Table 4.1 : Feasibility of the possible strategies

	Strategies on energy related risks		
	Strategies	**Applicability**	**Ease of implementation**
a.	Pre-check a device before and after use and periodical maintenance which includes the electrical safety test.	High	High
b.	Apply insulative layers to heat generating surfaces that are prone to come into contact with users and patient.	High	Medium
c.	Ensure device operator aware of the surrounding before making any abrupt motion.	High	High
d.	Monitoring frequency and dosage of radiation administration before subjecting patient for diagnosis / treatment	Medium	Medium
e.	Radiation protection apparatus to be used to minimize the effect of radiation exposure.	High	High
f.	Patients to ensure their surroundings not to be within the range of strong electromagnetic fields	Low	Low
	Strategies related to biological risks		

g.	Subject the medical devices to undergo the biocompatibility testing with reference to ISO 10993 testing protocol.	High	Medium
h.	Usage method and intended purpose of a medical device should always be considered before put into usage.	High	High
i.	Proper use of device is implemented to prevent occurrence of contamination.	High	High
j.	Refer to the user/operation manual to study on the application and lifespan of device.	High	High
	Strategies related to environmental risks		
k.	Periodical monitoring of cooling systems in certain devices to ensure optimum function.	High	Medium
l.	Ensure optimum operating condition prior to usage of device.	High	Medium
m.	Ensure compatibility of accessory devices to be used with medical device.	High	High
n.	Ensure no leakage or leaching is detected during usage of medical device.	High	High
	Strategies related to incorrect output energy and substances		
o.	Inspect and ensure correct output energy is being delivered from the supply.	High	High
p.	Pressure generating devices to be calibrated and maintained using relevant test equipment.	High	High
q.	Plan scheduled maintenance for gaseous system at suitable interval to ensure functionality.	High	High
	Strategies related to risk from usage of medical device		
r.	Being aware of the intended purpose and operation method of a medical device.	High	High
s.	Refer to the operation manual before, during and after usage of the device in case of any doubts.	High	High
t.	Manufacturers and authorized representatives to develop easily understandable user/operation manual.	High	High
u.	Ensure skilled and trained personnel to operate a medical device.	High	Medium

v.	Ergonomics factor in terms of lighting, reach and posture to be applied.	Medium	Low
w.	Measuring devices properly calibrated and user trained to operate and analyse the measurement.	High	Medium
	Strategies related to risk from functional failure, maintenance, aging		
x.	Planned preventive maintenance and emphasis given to critical usage points.	High	High
y.	Stop the usage of deteriorating / aged device.	High	Medium

4.4 Proposed Checklist

A checklist which covers the technical and legal requirements is proposed to be used in the healthcare environment by the users before a common medical device is put into usage. Elements included in the checklist is based on the risk identified and proposed strategies to minimize or eliminate the risks. The checklist is expected to cover important aspects that need to be assured before a medical device can be operated in a safe manner (Plogmann, Janß, Jansen-Troy, & Radermacher, 2013). Based on the checklist, risk was assessed for three medical devices and completed checklist enclosed in **Appendix B, B1, B2, and B3.**

4.5 Discussion

Based on the results obtained, there were total 28 risks that were identified from five main risk groups and a total of 25 strategies that can be proposed to minimize or eliminate the risks present on application and usage of the medical device. By using those risk and strategies details, a standard checklist was developed as mentioned in item 4.4. According to the developed checklist, assessment of a medical device indicates the classification, can lead to determination of risks present in the usage of medical device and possible strategies that can be adopted for a safe use. All the acquired information from the checklist can be presented in a coding system form which

facilitates the users and patients to be extra cautious in handling higher risk medical device. For instance, the format of coding can be represented as such :

[Classification of the device] : [Risk Identified] : [Possible strategies]

For an example, upon completing the checklist for digital thermometer in Appendix B1, the coding system for this device can be represented as follows:

[Class B] : [E,S,U,V,X,Y,Z,AA] : [f,r,s,t,u,w,x]

Therefore using this coding, a medical device user can estimate the possible risk and hazards arising from the digital thermometer. In this example, it was found out that the device is Class B. Possible risk or hazard that might be present include electromagnetic interference from surrounding, inadequate operating instructions, complicated instructions, unskilled/untrained personnel handling the device, possibilities of device producing an incorrect measurement of temperature, sharp points in term of geometry of the device, complicated user interface and also questionable electrical and mechanical integrity of the device. Proposed strategies in accordance to the risks include user to ensure their surroundings not to be within the range of strong electromagnetic fields. Besides that, user should be aware of the intended purpose and operation method of a medical device. User should also refer to the operation manual before, during and after usage of the device in case of any doubts. Device manufacturers and authorized representatives should develop easily understandable user/operation manual. Healthcare management must ensure skilled and trained personnel to operate a medical device. Measuring devices to be properly calibrated and user trained to operate and analyse the measurement. Conducting planned preventive maintenance and emphasis given to critical usage points.

CHAPTER 5: CONCLUSION AND RECOMMENDATION

In this chapter, the conclusion based on the result and discussion will be elaborated. Besides that, recommendation based on the observation and results will also be included here.

5.1 Conclusion

Medical device usage and application is anticipated to pose direct and indirect risks associated to safety, health and environment. Therefore it will be beneficial to study and identify the possible risks that may be present. Several strategies can be proposed based on the identified risks. It is expected that the strategies can be utilized to better manage the risks present. In this study, emphasis was given on identifying the risks and hazards associated to medical device usage and later generate possible strategies to manage those risks. The conclusion were drawn according to the objectives, with following details :

1. The risks and hazards associated to safety, health and environment from the application and usage of medical device had been identified and presented in a table form. Various risk had been included, which are categorized under six categories, energy related risks and hazards, biological risks and hazards, environmental risks and hazards, risk and hazard due to incorrect output energy and substances, risk and hazard related to usage of medical device and risk due to functional failure, maintenance and aging. A total of 28 possible risk and hazards was identified and discussed.
2. Several strategies to minimize or eliminate the risk and hazard associated to safety, health and environment has been proposed in the study. The proposed strategies were assessed in terms of applicability and ease of implementation

in a form of table. Therefore, feasibility of a strategy can be evaluated before implementation in order to minimize and mitigate the residual risk.

3. Subsequently, integration of both risk factors and strategies generated is later summarized and it is developed in a form of checklist which incorporates the technical and legal requirement. The checklist is proposed to be used to assess a medical device prior to usage in order to minimize or eliminate any possible risk and hazard that might arise. Based on the checklist, risk was assessed for three medical devices to ensure feasibility of the checklist to countercheck all the important aspects pertaining to risk before the medical device can be assured to be safe for operation.

5.2 Recommendation

Based on the study conducted and results collected, the three objectives defined in the earlier phase of the study had been covered to identify the possible risks and hazards, generation of possible strategies and checklist development. From the study, it can be recommended that future study should engage a broader perspective. This study was only limited to a medical device establishment that manufactures disposable medical devices which does not involved in active medical device manufacturing or assembly. Malaysian medical device manufacturers are more into consumables and disposable devices manufacturing rather than electronic medical devices. This indirectly limits the scope of exposure for conducting a more comprehensive study. This study was designed for application and usage of common medical devices, where the findings might be less relevant for implementation onto more specialized and developed medical devices. Therefore, it is recommended that future studies can cover devices based on their type so the application can be widely accepted.

REFERENCES

Bikson, Marom, Paneri, Bhaskar, Mourdoukoutas, Andoni, Esmaeilpour, Zeinab, Badran, Bashar W, Azzam, Robin, . . . Wingeier, Brett. (2018). Limited output transcranial electrical stimulation (LOTES-2017): Engineering principles, regulatory statutes, and industry standards for wellness, over-the-counter, or prescription devices with low risk. *Brain Stimulation: Basic, Translational, and Clinical Research in Neuromodulation, 11*(1), 134-157.

Borie, F, Mathonnet, M, Deleuze, A, Millat, B, Gravié, J-F, Johanet, H, . . . Gugenheim, J. (2017). Risk management for surgical energy-driven devices used in the operating room. *Journal of visceral surgery*.

Camara, Carmen, Peris-Lopez, Pedro, & Tapiador, Juan E. (2015). Security and privacy issues in implantable medical devices: A comprehensive survey. *Journal of biomedical informatics, 55*, 272-289.

Citron, Paul. (2012). Ethics considerations for medical device R&D. *Progress in cardiovascular diseases, 55*(3), 307-315.

Clarkson, Douglas M. (2017). Medical Device Guidebook: A browser information resource for medical device users. *Medical Engineering and Physics, 41*, 97-102.

Desrousseaux, C, Sautou, V, Descamps, S, & Traoré, O. (2013). Modification of the surfaces of medical devices to prevent microbial adhesion and biofilm formation. *Journal of hospital Infection, 85*(2), 87-93.

Fukuda, H, & Yamanaka, N. (2016). Reducing needlestick injuries through safety-engineered devices: results of a Japanese multi-centre study. *Journal of Hospital Infection, 92*(2), 147-153.

Grainger, David W, van der Mei, Henny C, Jutte, Paul C, van den Dungen, Jan JAM, Schultz, Marcus J, van der Laan, Bernard FAM, . . . Busscher, Henk J. (2013). Critical factors in the translation of improved antimicrobial strategies for medical implants and devices. *Biomaterials, 34*(37), 9237-9243.

Hartwig, Valentina, Giovannetti, Giulio, Vanello, Nicola, Lombardi, Massimo, Landini, Luigi, & Simi, Silvana. (2009). Biological effects and safety in magnetic resonance imaging: a review. *International journal of environmental research and public health, 6*(6), 1778-1798.

Hass, Chris, & Berlin, Dan. (2013). *Usability testing medical devices: a practical guide to minimizing risk and maximizing success.* Paper presented at the International Conference of Design, User Experience, and Usability.

Heinemann, Lutz, Fleming, G Alexander, Petrie, John R, Holl, Reinhard W, Bergenstal, Richard M, & Peters, Anne L. (2015). Insulin pump risks and benefits: a clinical appraisal of pump safety standards, adverse event reporting and research needs. A joint statement of the European Association for the Study of Diabetes and the

American Diabetes Association Diabetes Technology Working Group. *Diabetologia, 58*(5), 862-870.

ISO, BSEN. (2003). 13485: 2003 Medical devices-Quality management systems-Requirements for regulatory purposes. *International Organisation for Standardisation*.

Kabir, Sohag. (2017). An overview of fault tree analysis and its application in model based dependability analysis. *Expert Systems with Applications, 77*, 114-135.

Kane, GM, Bakker, CA, & Balkenende, AR. (2017). Towards design strategies for circular medical products. *Resources, Conservation and Recycling*.

Kinsel, David. (2012). Design control requirements for medical device development. *World Journal for Pediatric and Congenital Heart Surgery, 3*(1), 77-81.

Mariappan, Periyasamy M, Raghavan, Dhanasekaran R, Aleem, Shady HE Abdel, & Zobaa, Ahmed F. (2016). Effects of electromagnetic interference on the functional usage of medical equipment by 2G/3G/4G cellular phones: A review. *Journal of Advanced Research, 7*(5), 727-738.

Menezes, Jacqueline A, Bandeira, Carolina S, Quintana, Marcel, e Silva, Julio CA de Lima, Calvet, Guilherme A, & Brasil, Patrícia. (2014). Impact of a single safety-engineered device on the occurrence of percutaneous injuries in a general hospital in Brazil. *American journal of infection control, 42*(2), 174-177.

Money, Arthur G, Barnett, Julie, Kuljis, Jasna, Craven, Michael P, Martin, Jennifer L, & Young, Terry. (2011). The role of the user within the medical device design and development process: medical device manufacturers' perspectives. *BMC medical informatics and decision making, 11*(1), 15.

Newton, Richard C, Mytton, Oliver T, Aggarwal, Rajesh, Runciman, William B, Free, Michael, Fahlgren, Bjorn, . . . Locke, Gerad. (2010). Making existing technology safer in healthcare. *BMJ Quality & Safety, 19*(Suppl 2), i15-i24.

Onofrio, Rossella, Piccagli, Francesco, & Segato, Federica. (2015). Failure Mode, Effects and Criticality Analysis (FMECA) for medical devices: Does standardization foster improvements in the practice? *Procedia Manufacturing, 3*, 43-50.

Plogmann, Simon, Janß, Armin, Jansen-Troy, Arne, & Radermacher, Klaus. (2013). *Development and evaluation of a knowledge-based method for the treatment of use-oriented and technical risks using the example of medical devices.* Paper presented at the International Conference of Design, User Experience, and Usability.

Privitera, Mary Beth, Evans, Mark, & Southee, Darren. (2017). Human factors in the design of medical devices–Approaches to meeting international standards in the European Union and USA. *Applied ergonomics, 59*, 251-263.

Standardization, International Organization for. (2000). *ISO 14971: medical devices-application of risk management to medical devices*: ISO.

Taylor, JR. (2017). Automated HAZOP revisited. *Process Safety and Environmental Protection, 111*, 635-651.

van der Peijl, Jorien, Klein, Jan, Grass, Christian, & Freudenthal, Adinda. (2012). Design for risk control: the role of usability engineering in the management of use-related risks. *Journal of biomedical informatics, 45*(4), 795-812.

Vincent, Chris, & Blandford, Ann. (2011). *Designing for safety and usability: User-centered techniques in medical device design practice.* Paper presented at the Proceedings of the Human Factors and Ergonomics Society Annual Meeting.

Vincent, Christopher J, & Blandford, Ann. (2015). Usability standards meet scenario-based design: Challenges and opportunities. *Journal of biomedical informatics, 53*, 243-250.

Vincent, Christopher James, & Blandford, Ann. (2017). How do health service professionals consider human factors when purchasing interactive medical devices? A qualitative interview study. *Applied ergonomics, 59*, 114-122.

Vincent, Christopher James, Li, Yunqiu, & Blandford, Ann. (2014). Integration of human factors and ergonomics during medical device design and development: It's all about communication. *Applied ergonomics, 45*(3), 413-419.

Zippel, Claus, & Bohnet-Joschko, Sabine. (2017). Innovation for Safe and Effective Medical Devices: Contributions From Postmarket Surveillance. *Therapeutic Innovation & Regulatory Science, 51*(2), 237-245.