HAZARD IDENTIFICATION RISK ASSESSMENT AND RISK CONTROL IN MEDICAL DIVICE MANUFACTURING COMPANY DURING PANDEMIC OUTBREAK

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HAZARD IDENTIFICATION RISK ASSESSMENT AND RISK CONTROL IN MEDICAL DIVICE MANUFACTURING COMPANY DURING PANDEMIC OUTBREAK

ABSTRACT

The coronavirus, known as COVID-19, started in December of 2019. It started in Wuhan, China, then started spreading around the world till it became a global pandemic. Many people around the world are affected not only in terms of health but also in the economy due to COVID-19. Many industries are facing issues with operating their businesses during a pandemic. Because of a lack of resources, particularly manpower, industry is unable to function normally. They still need to operate the plant to fulfill customer demand. Due to the limitations that industry is facing in order to run a business during a pandemic outbreak, there will be new hazards from manufacturing activities. Lack of skilled workers, attendance issues due to COVID-19, employee's motivation, and workplace configuration to meet COVID-19 Standard Operating Procedure (SOP) regulated by National Security Council (NSC) becomes a limitation for industries. Details of hazard assessment are required to review past activities and processes in each department of an organization during a pandemic outbreak. Risk analysis needs to be performed immediately once a hazard is identified to find an effective control measure to prevent any unexpected incident from happening. Instead of controlling the spread of COVID-19 in the workplace, industries still need to focus on preventing accidents and occupational health issues to ensure employees come to work safe and healthy. Every employee must be aware of the hazards in their workplace and understand how to overcome the hazards using the control measures discovered during the risk assessment. Employees must be trained on how to work within the new norm in order to protect their safety and health. Even during pandemic season, incidents can be avoided if a proactive assessment is performed to identify new hazards and effective control measures. Assessment needs to be effective and comprehensive in order to cover every angle and situation of a pandemic. The risk assessment needs to be conducted regularly based on the pandemic situation. An industry can operate smoothly if an effective assessment has been conducted. It can minimize the limitations due to a pandemic outbreak. Support from each employee and management is important to ensure it can be done effectively. All countries are facing the same pandemic situation. The only difference is how they manage it, either proactively or not. Proactive countries will accelerate their growth and improve their economies when their industries can operate normally while meeting safety and health standards. From the study, the COVID-19 pandemic had an impact on a medical company's device manufacturing. It can be measured by using the Hazard Identification Risk Assessment and Risk Control method to indicate the level of risk rating for a company operating during the COVID-19 outbreak. Employees' perception of COVID-19 can also be evaluated, and most of them respond that the COVID-19 pandemic has an impact on their daily routine in medical device manufacturing companies.

Keywords: COVID-19, Pandemic, Hazard, Risk Assessment, Incident

PENGENALPASTIAN HAZAD PENILAIAN RISIKO DAN KAWALAN RISIKO DALAM SYARIKAT PEMBUATAN PERANTI PERUBATAN SEMASA WABAK PANDEMIK

ABSTRAK

Koronavirus, juga dikenali sebagai COVID-19, ianya bermula pada bulan Disember 2019. Ia bermula di daerah Wuhan, China, kemudian mula merebak ke seluruh dunia sehingga ia menjadi pandemik global. Penduduk di seluruh dunia terjejas bukan sahaja dari segi kesihatan mereka tetapi juga dari segi ekonomi akibat penularan COVID-19. Banyak industri menghadapi masalah bagi menjalankan perniagaan mereka semasa wabak pandemik ini. Oleh kerana kekurangan sumber, terutamanya dari segi tenaga kerja, industri tidak dapat beroperasi secara normal. Walaubagaimanapun mereka masih perlu meneruskan operasi syarikat bagi memenuhi permintaan dari pihak pelanggan. Disebabkan oleh halangan yang dihadapi oleh pihak industri untuk menjalankan perniagaan semasa wabak pandemik, terdapat bahaya baharu daripada aktiviti pembuatan. Kekurangan pekerja mahir, isu kehadiran akibat COVID-19, motivasi pekerja, dan susunatur tempat kerja untuk memenuhi Prosedur Operasi Standard (SOP) COVID-19 yang dikuatkuasakan oleh Majlis Keselamatan Negara Malaysia (MKN) menjadi halangan bagi pihak industri. Butiran penilaian bahaya diperlukan untuk menyemak setiap aktiviti dan proses di setiap jabatan sesebuah organisasi semasa wabak pandemik. Analisis risiko perlu dilakukan dengan segera sebaik sahaja bahaya dikenal pasti untuk mencari langkah kawalan yang berkesan untuk mengelakkan sebarang kejadian yang tidak dijangka berlaku. Selain mengawal penularan COVID-19 di tempat kerja, pihak industri perlu memberi tumpuan untuk mencegah kemalangan dan isu kesihatan pekerjaan untuk memastikan pekerja datang bekerja dengan selamat dan sihat. Setiap pekerja mestilah mempunyai kesedaran tentang bahaya di tempat kerja mereka dan memahami cara untuk mengatasi bahaya tersebut dengan menggunakan langkah kawalan yang ditemui semasa penilaian dilakukan. Pekerja mesti dilatih tentang cara bekerja dalam norma baharu untuk melindungi keselamatan dan kesihatan mereka. Walaupun semasa musim pandemik, insiden boleh dielakkan jika penilaian risko dilakukan secara proaktif untuk mengenal pasti bahaya baharu dan langkah kawalan yang berkesan. Penilaian perlu berkesan dan menyeluruh untuk merangkumi setiap sudut dan situasi pandemik. Penilaian perlu dilakukan secara berkala berdasarkan situasi semasa pandemik. Sesebuah industri boleh beroperasi dengan lancar sekiranya penilaian yang berkesan dapat dijalankan. Ia boleh meminimumkan halagan akibat wabak pandemik. Sokongan setiap pekerja dan pengurusan adalah penting bagi memastikan ia dapat dilakukan dengan berkesan. Semua negara menghadapi situasi pandemik yang sama. Satu-satunya perbezaan ialah cara mereka menguruskannya, sama ada secara proaktif atau tidak. Negara yang proaktif akan mempercepatkan pertumbuhan mereka kembali dan meningkatkan ekonomi apabila industri boleh beroperasi secara normal sambil memenuhi piawaian keselamatan dan kesihatan. Daripada kajian dijalankan, COVID-19 pandemik memberi impak kepada syarikat pembuatan peranti perubatan. Impak ini ditentukan mengunakan kaedah Pengenalpastian Hazad Penilaian Risiko dan Kawalan Risiko bagi mengukur aras risiko untuk syarikat beroperasi semasa COVID-19 merebak. Persepsi pekerja terhadap COVID-19 dapat dinilai, dan kebanyakkan mereka respon bahawa COVID-19 pandemik memberi impak kepada rutin harian di syarikat pembuatan peranti perubatan.

Kata kunci: COVID-19, Pandemik, Bahaya, Penilaian Risiko, Insiden

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LIST OF SYMBOL AND ABBREVIATIONS

%	Percentage
ºC	Degree Celsius
HIRARC	Hazard Identification, Risk Assessment and Risk Control
PPE	Personal Protective Equipment
SOP	Standard Operating Procedure
WI	Work Instruction
WHO	World Health Organization
DOSH	Department of Occupational Safety and Health
NSC	National Security Council
MCO	Movement Control Order
SDS	Safety Data Sheet
ALARP	As Low As Reasonably Practicable
UPS	Uninterruptible Power Supply
HSO	Home Surveillance Order
WFH	Work From Home
EHS	Environment Health Safety
HVAC	Heating Ventilation Air Conditioning
HT	High Tension
LT	Low Tension
PM	Preventive Maintenance
OSH	Occupational Safety and Health

LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

1.1. Background of Study

There will be a variety of effects on workplace health and safety in the medical device manufacturing industry as the number of COVID-19 cases increases during the pandemic outbreak. To guarantee the safety and health of workers in a medical device manufacturing company, a safety management system (SMS) must be in place. In the safety management system, techniques for risk analysis are chosen along with their outcomes based on how frequently they occur and how severe their effects are. (Demichela et al., 2004). Therefore, it is essential to comprehend the risks associated with pandemic operations in the workplace in order to create efficient control measures. A useful tool or model for Occupational Health and Safety Assessment is Hazard Identification, Risk Assessment, and Risk Control (HIRARC).

1.2. Problem Statements

Since the Coronavirus, also known as COVID-19, became a global pandemic, many people have been affected not only by health but also by the economy. This is because many industrials are not able to operate as normal since they have many limitations. One limitation that is always faced by many industrial, especially in Malaysia, is human resources. Due to the fast spread of COVID-19, many people have gotten infected and need to undergo quarantine either at home or at a quarantine center. Due to this situation, industries lack manpower to operate their plants. The situation will become worse when their skilled and trained workers are involved. To hire new employees is not easy since the Malaysian government has developed Standard Operating Procedures (SOP) that will make industries face problems in hiring new employees, such as Movement Control Order (MCO). The total number of confirmed COVID-19 cases and

fatalities in Malaysia from December 2020 to June 2022 are shown in Figure 1.0 below from the World Health Organization (WHO).

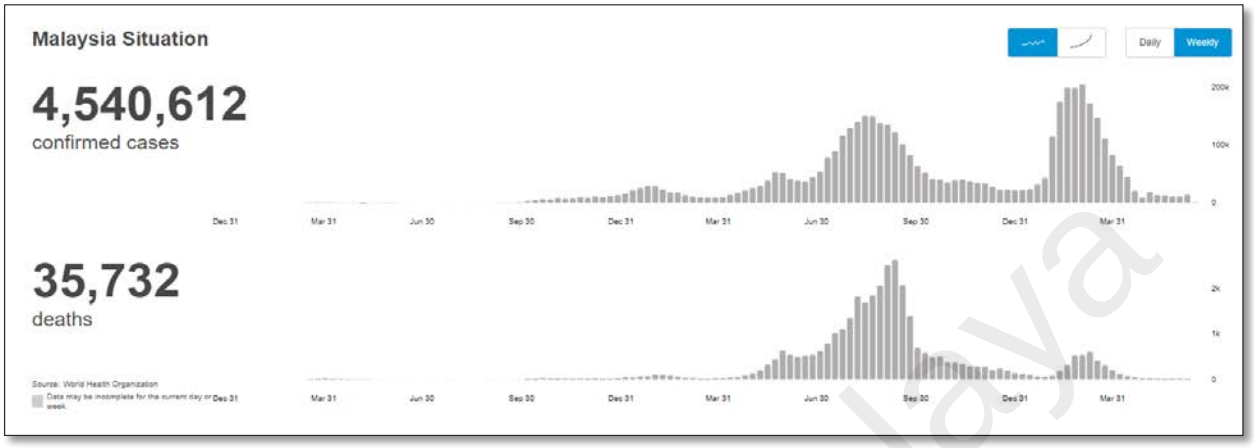

Figure 1.0: WHO Data for Malaysia COVID-19 Confirmed Cases and Death from Dec 2020 till June 2022 (Source: https://covidnow.moh.gov.my/)

Medical device manufacturing company is a company categorized under essential industrial in Standard Operating Procedure (SOP) created by Malaysia National Security Council (NSC) to operate during a Movement Control Order (MCO). Even though they have special approval to operate during pandemic, this type of industry is still facing problems like other industrials in Malaysia. Lack of manpower due to their employees' getting infected with COVID-19 and need to undergo quarantine. Other than that, by referring to Malaysian government Standard Operating Procedure (SOP), workstations layout also needs to be re-arranged to meet the requirement of physical distancing to prevent the spread of COVID-19. In addition, due to COVID-19 spreading widely, some skilled and trained employees get involved. The company is not able to operate smoothly due to some issues related to a lack of skilled and trained employees. In some cases, the quarantine period may be extended beyond 14 days, depending on the individual's health condition. From Ministry of Health Malaysia (MOH) statistics, the age

group that gets infected is always between 18 and 49 years old. The distribution of COVID-19 cases by age category for those who are typically infected with the COVID-19 is shown in Table 1.0. Most of this age group are working and supporting industrial growth in Malaysia.

Table 1.0: Distribution of Cases by Age Group in Malaysia

(Source: https://covidnow.moh.gov.my/)

Cases

Distribution of Cases by Age Group

Data for Malaysia

Data as of 20 Jun 2022, 11:59 pm

	0 - 4	5 - 11	12 - 17	18 - 29	30 - 39	40 - 49	50 - 59	60 - 69	70 - 79	80+
This week	2.9%	4.4%	5.9%	26.6%	24.2%	17.5%	9.9%	4.6%	2.7%	1.3%
1 week ago	3.3%	3.9%	5.0%	26.2%	25.0%	17.8%	9.6%	5.1%	2.5%	1.5%
2 weeks ago	3.0%	4.9%	8.4%	24.5%	23.7%	17.0%	9.7%	5.1%	2.7%	1.1%
3 weeks ago	3.4%	5.2%	8.4%	25.1%	23.5%	15.9%	9.0%	5.4%	2.7%	1.4%
4 weeks ago	4.0%	5.4%	7.9%	25.0%	23.5%	15.5%	9.0%	5.2%	2.8%	1.7%
5 weeks ago	4.1%	5.4%	7.2%	26.1%	23.5%	16.3%	8.6%	4.9%	2.8%	1.3%
6 weeks ago	4.6%	6.8%	5.6%	23.4%	23.0%	15.5%	9.0%	6.9%	3.7%	1.6%
7 weeks ago	4.6%	6.3%	9.8%	23.0%	22.9%	15.1%	8.5%	5.7%	2.7%	1.4%
8 weeks ago	4.5%	8.0%	11.9%	22.0%	22.7%	13.8%	8.0%	5.3%	2.6%	1.1%
9 weeks ago	5.6%	8.2%	10.5%	21.6%	23.8%	13.5%	8.3%	5.1%	2.4%	1.2%
10 weeks ago	6.0%	8.7%	5.7%	23.3%	24.5%	14.2%	8.7%	5.3%	2.5%	1.2%
11 weeks ago	6.3%	8.4%	4.5%	24.1%	24.2%	14.0%	9.0%	5.7%	2.7%	1.2%

Operating within this restriction will present a problem in terms of health and safety. The new workplace hazards will come out and the risk rating may be different compared to normal operation without a pandemic. For example, a limitation of manpower will cause some tasks not be able to be performed as normal. It may take longer than expected, or the finished product may not meet expectations. In terms of safety element, a hazard that an employee may face is not being familiar with the task due to not normally having a buddy to guide them on how to do it. The risk rating will also increase if it involves heavy machinery. Operating machines without skilled and trained employees may lead to an incident happening. Workplace stress is another risk that employees may face during a pandemic season.

Hazard identification, risk assessment and risk a control (HIRARC) is a systematic procedure for identifying risks and specifying mitigation strategies for tasks or job activities that includes controls. Hazard Identification, Risk Analysis, and Risk Control (HIRARC) is the fundamental method for re-evaluating each department's activities and processes. The risk assessment process provides a way to determine the likelihood of negative effects on health, safety, and the environment from potential operating risk events. It provides an integrated method for managing and prioritizing risks. It is possible to identify and immediately execute appropriate control measures based on the study. By this way, the medical device manufacturing industry can operate smoothly by ensuring each employee understands hazards and knows what their roles are to mitigate them. Instead of eliminating or substituting hazards in the workplace, engineering and administrative controls should focus on preventing incidents from occurring.

This research will focus on the re-assessment of the workplace hazards in the medical device manufacturing industry operating during a pandemic outbreak. It will be targeted to reduce the risk rating for each new hazard found during the re-assessment of the workplace activities. Existing Hazard Identification, Risk Analysis, and Risk Control (HIRARC) for each hazard during normal operation must be reviewed and updated to reflect the current pandemic condition. The COVID-19 outbreak is still ongoing, but industry must train their employees and set up workplaces to allow them to carry out their daily routine tasks with new norms practice. This study can help medical device manufacturing company to operate smoothly as an essential industrial but still maintain and taking care employees' safety and health elements as a priority. The company will benefit from it when employees feel safe coming to work. A company can achieve their target even while operating during the COVID-19 outbreak.

1.3. Aim and Objectives

The objectives of the study are:

1. To study the impact of COVID-19 pandemic outbreak to a medical device manufacturing company in term of occupational safety and health aspect.

2. To perform the Hazard Identification, Risk Assessment and Risk Control (HIRARC) method in a medical device manufacturing company when operating during COVID-19 pandemic outbreak.

3. To identify the risk rating from Hazard Identification, Risk Assessment and Risk Control (HIRARC) of work activities in a medical device manufacturing company during normal operation and COVID-19 pandemic outbreak.

4. To evaluate perception of COVID-19 among employee in term of Occupational Safety and Health (OSH) aspect

The main objective of this study is to compare the risk rating levels when a medical device manufacturing company operates under normal operating conditions and COVID-19 pandemic outbreak conditions. This study will focus on medical device manufacturing company in Malaysia and St. Jude Medical Operations (M) Sdn. Bhd. (Known as Abbott) as a reference for this study. St. Jude Medical Operations (M) Sdn. Bhd. (known as Abbott) is a medical device a business that makes pacemakers and supplies its products around the world. This company is

considered an essential company based on the classification of industrial in COVID-19 Malaysia Standard Operating Procedure (SOP) set up by Malaysia National Security Council (NSC).

1.4. Research Question

i. How does COVID-19 Pandemic impact the Occupational Safety and Health (OSH) elements in the workplace.

ii. What is the main challenge facing by a medical device manufacturing company operating during the COVID-19 pandemic?

iii. What is the most suitable method to help a company to rectify the problem and identify control measures in a systematic approach?

iv. What is the ideal control measure to ensure a company can operate smoothly during a COVID-19 pandemic outbreak?

1.5. Scope of Research

The scope of the study will be based on the risk rating level from hazard identification, risk assessment, and risk control (HIRARC) to the work activities of a medical device manufacturing company operating during the COVID-19 pandemic outbreak. From the risk rating level, it can determine the action level need to be taken and to make a company operate smoothly during a pandemic outbreak. The risk rating level is determined using the risk matrix from the 2008 Hazard Identification, Risk Assessment, and Risk Control (HIRARC) Guideline from the Department of Occupational Safety and Health (DOSH). Feedback from employees was also collected through a survey questionnaire. From the survey, we can gather details of employees' perception while working during the COVID-19 pandemic outbreak. Feedback from

employees also important to measure level of their understanding to COVID-19 pandemic, workplace hazards and how to mitigate it.

1.6. Research Limitation

This research study is based on the situation and activities that happened during the COVID-19 pandemic outbreak in a medical device manufacturing company located in Bayan Lepas, Pulau Pinang. Since a company-related document is confidential, the data to be included in the report is only general.

CHAPTER 2: LITERATURE REVIEW

2.1 COVID-19 as Global Pandemic

The COVID-19 virus was discovered in medical laboratories in Wuhan, Hubei Province, China, in early December 2019 (Huang et al., 2020). On January 7, 2020, when Chinese authorities identified a novel coronavirus as the virus, it was temporarily renamed "2019 nCoV". Based on Johns Hopkins University (2020), with approximately 6,309,107 tainted individuals and over 376,445 passing records, the pandemic affects 200 countries and regions. Furthermore, after witnessing all of these calamities, the WHO has designated COVID-19 as the sixth worst global disaster of the twenty-first century. This pandemic wreaked havoc on many economies, killed several people, and caused countries to lose billions of dollars in business in a matter of months, all of which had a direct impact on long-term environmental, social, and industrial production (Allocati et al., 2016; Gorbalenya, 2020; Kumar et al.). After a few months, the virus became a global outbreak around the world. The World Health Organization announced COVID-19 as a pandemic by May 2021.

Southeast Asia (SEA) was not exempt from the novel coronavirus's effects, and several SEA nations have been hard-hit by the illness since late February (WHO, 2020), though with significantly fewer fatalities than in Europe and the US. As of May 16, there were 66,140 confirmed cases and 2078 deaths, with Singapore, Indonesia, the Philippines, and Malaysia accounting for 94% of the cases and 97% of the deaths overall, respectively (WHO, 2020). Chinese tourists from Singapore were the first to be exposed to Malaysian cases on January 25, 2020, and until March 2020, when numerous local clusters first appeared, there were only a small number of imported cases (Sipalan and Holmes, 2020). On March 18, 2020, in response to

the increasing number of cases, the Malaysian government, under the leadership of Prime Minister Muhyiddin Yassin, imposed a nationwide lockdown known as the Movement Control Order (MCO) (Aziz, 2020). The MCO imposed six main restrictions, including the ban on large gatherings for religious, social, sporting, and cultural events; the requirement that visitors to Malaysia undergo a 14-day self-quarantine and a medical examination upon arrival; the restriction of entry for all tourists and foreign visitors; the closure of all types of educational facilities, from kindergartens to universities; and, finally, the closure of all premises save for necessities like a hospital.

Despite the expanding number of sufferers, there is no viable cure or therapy for the virus. The pandemic's impact not only on human health but also on the long-term economic effects for all countries worldwide. As a result, precautions are taken across the world to minimize the spread of sickness. Because of these difficult conditions, worldwide societies have been driven to seek new methods of controlling the virus's spread. Thus, early identification and effective prevention of fast transmission are critical difficulties confronting many nations impacted by the pandemic (Gilbert et al., 2020).

2.2 Importance of Workplace Hazards Risk Assessment

The Medical Device Manufacturing Company is one of the industries impacted by the COVID-19 pandemic. In Malaysia, this type of industry is considered essential industrial that can run a business even during the early phase of the COVID-19 pandemic outbreak. However, this company encountered challenges in operating a business during a pandemic outbreak. Due to limitations imposed by Malaysia's Standard Operating Procedure (SOP) to prevent the spread of

viruses, medical device manufacturing companies were not able to achieve 100% of their target. A manpower issue due to the requirement for quarantine if infected with COVID-19 is one of the limitations that create a challenge for this industrial. Aside from that, manpower issues created another issue: a lack of skilled and trained employees. One employee may need to multitask in order to support employees who are under quarantine due to COVID-19 infection. All of the challenges had an impact not only on the final product, but also on the organization's occupational safety and health.

The workplace hazards in medical device manufacturing company are different between operating during pandemic and no pandemic. The risk rating will higher based on the limitations that company facing. Proper assessments on the hazards needed to ensure it prevent any incident from happen. HIRARC (Hazard Identification, Risk Assessment, and Risk Control) have become essential. Hazard identification and risk assessment are processes that are used to identify and evaluate existing and potential hazards on a worksite, as well as the methods used to control or eliminate the hazards. Details of risk assessment are needed to cover all of the work activity in the company. It is not just for documentation but must implement all of the control measures suggested during the assessment. This is due to the fact that risk assessment is frequently only done for compliance and to satisfy the NLI (in the event of an audit) and is not used effectively for the management of OSH and the reduction of incident and occupational health diseases (Baldock et al., 2006). Since the risk will not only be evaluated, but it is crucial that all levels of the organization understand and respond to it, understanding the impact of a potential hazard is as important as agreeing to a tactical response prior to an incident (Buang, 2014). A successful safety culture practice can also lessen the effects of particular accidents and advance the risk

assessment process, according to Mearns and Yule (2009) and Wahlström and Rollenhagen (2014).

2.3 Hazard Identification, Risk Assessment and Risk Control (HIRARC) Model

According to Malaysian law, it is the employer's responsibility to ensure the worker's and the workplace's safety and health under the OSHA 1994 regulations. Employers must "ensure, to the extent that is practicable, the safety, health, and welfare at work of all his employees," according to OSHA's Section 15. Employers must "conduct his undertaking in such a manner as to ensure, so far as is practicable, others person not affected," according to another Subsection 17 of OSHA. To be in compliance with this requirement, the employer must be dedicated to OSH planning, implementation, and evaluation to guarantee that all safety and health risks in the business are taken care of. The word "hazard" refers to aspects of the workplace (physical, psychosocial, or both) that have the potential to cause harm or unfavorable outcomes (Agwu, 2012). Risk is when a human is exposed to a hazard. In other words, the probability and impact of a specific hazardous event occurring are combined to determine it. A risk is a source or circumstance that has the potential to cause harm to people or their health, damage to property, harm to the workplace environment, or any combination of these. Risks and hazards associated with work activities can be categorized as high, medium, or low.

Hazard identification, risk assessment, and risk control are abbreviated as HIRARC. It is the process of controlling risks that have been identified as potentially causing or contributing to accidents in order to manage related work risks. The advantage of HIRARC is that it will allow organizations to continuously assess, monitor, and manage their occupational safety and health

risk. Accidents at work will decrease as risk is reduced. HIRARC also covers risks involved in both new and existing processes, allowing for comprehensive risk identification and control implementation. HIRARC is classified as a "Planning and Implementation" activity in the OSH Management System Guideline published by DOSH Malaysia (Barahim, 2010). This meant that it needed to be put into practice in addition to being included in the management planning. According to a previous study by Agwu (Agwu,2012), adhering to risk assessment (HIRARC) will remove the third domino (unsafe acts or physical hazard factor) from the series and stop accidents/incidents from occurring, improving safety procedures, boosting productivity, and boosting profitability. To safeguard the health and safety of the workforce as well as the environment, it is necessary to identify and assess all potential risks and hazards. Risk management is therefore seen as a formal process that will be very effective in managing risks. It entails hazard identification, risk assessment, identification of risk control options, as well as evaluation, monitoring, and review of risk in the workplace (Bahari et al., 2013). In the safety and risk management system, it has also been noted that risk assessment plays a significant role in determining probability, consequences, and hazard control. In order to develop managerial decisions that minimize risks and protect the lives and health of employees, occupational risk assessment is only a necessary first step (Kuletskiy et al., 2020; Filimonov and Gorina, 2019). In this regard, it is important to realize that risk encompasses more than just the likelihood of an unfavorable event occurring and the resulting harm; it also includes a number of variables that describe the circumstances surrounding the implementation of an unfavorable event. Therefore, it is necessary to incorporate somewhat more complete data in the analysis than what an occupational risk assessment matrix can provide in order to determine a package of occupational risk management measures. Comprehensive hazard identification might take a lot of work and

time. To ensure its effectiveness, it may also need to be repeated frequently. To identify and concentrate on a specific area, it is most effective to divide the workplace into a number of distinct areas. According to this hazardous plant, substances, processes, or environment, priority should be given to the most hazardous area and high exposure level (F. Al-Bahar et, al. 1991).

CHAPTER 3 RESEARCH METHODOLOGY

3.1 Research Framework

The HIRARC process recommended by DOSH Malaysia is primarily followed in this study. Only this research will explicitly and practically explain every step of the process; all other activities and planning involved in the study strictly adhere to the DOSH methodology. The research was primarily divided into three stages:

Step 1

The initial framework created in accordance with DOSH guidelines will be examined and analyzed. The analysis will provide a clear understanding of the DOSH requirements that must be met in order to guarantee that the carried-out process complies with the rules and regulations.

Step 2

The present-day practical approaches suggested by earlier research and practices will be examined. This will paint a clear picture of the viability and common practice used to carry out the HIRARC process. This will also provide us with a wealth of knowledge about how the rules and the industrial practical are typically carried out.

Step 3

A comprehensive methodology for carrying out HIRARC processes will be created by combining the guidelines with real-world industrial practices. It will be suggested to follow some basic practical guidelines when performing the entire process.

There are primarily three stages in the HIRARC process (Figure 3.0). The process of identifying the risks associated with the work activity is the first step. The second step is to carry out the risk assessment as soon as it is clear. Here, the risk can be estimated and compared to the level of risk that is acceptable. The final step is to think about how to reduce the risk effect. The third stage of the process is risk control, which makes sure that the source of the hazard won't hurt the workers.

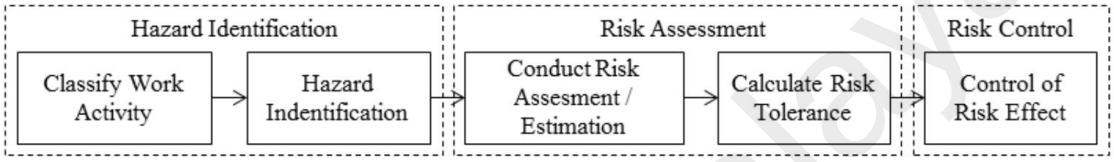

Figure 3.0: HIRARC Assessment Process

3.1.1 Study Area

The hazard identification, risk assessment and risk control (HIRARC) will address the following:

1. The hazards from work activities and processes in different department in medical device manufacturing company.
2. Semi-quantitative assessment of any potential occupational health and safety impact due to hazards changing due to operating during the COVID-19 pandemic outbreak.
3. Effective risk control based on the consideration of Risk Hierarchy of Control as per stated in Figure 3.1 and proposed percentage effectiveness hierarchy control in Figure 3.2 below.

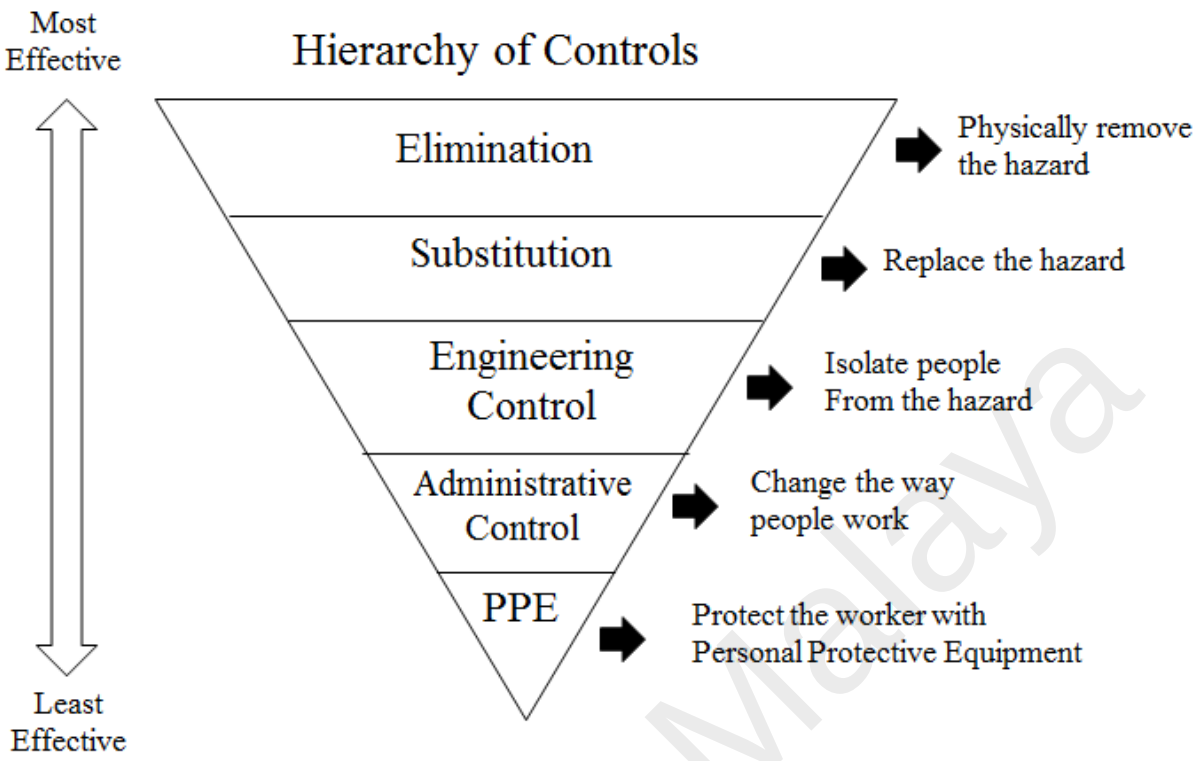

Figure 3.1: A Hierarchy of Risk Control based on Effectivity

Source: Stephen Williams, (2006)

Method	Risk reduction or effectiveness
Elimination	100%
Substitution	75%
Separation	50%
Administration	30%
Training	20%
PPE	5%

Figure 3.2: Proposed Percentage Effectiveness of Control

3.1.2 Study Setting

The study was carried out in medical device manufacturing company located in Bayan Lepas, Pulau Pinang from December 2021 till March 2022. The company known as St. Jude Medical Operation Sdn Bhd (Known as Abbott). This company operating 24 hours with 1308 employees (As of 1st June 2022). Company was categorized as essential industry from Standard Operating Procedure (SOP) by Malaysia National Security Council (NSC) and was allowed to operate during pandemic outbreak but need to comply the requirements as per stated in SOP. To comply these requirements, there have some limitation and workplace setting in company that contribute to new hazards especially due to limited resources during COVID-19 pandemic.

3.1.3 Study Design

The study used a semi-quantitative data collection method. Inspection of the work environment, interaction between employees about potential hazard, primary data was gathered using Standard Operating Procedures (SOP), Work Instruction (WI), and report of incident, while gathered using Safety Data Sheet (SDS), Near Miss case record, First Aid case record, employee's health records, journal, and literatures as secondary data. All of this is part of the risk management proposed plan, as shown in Figure 3.3 below.

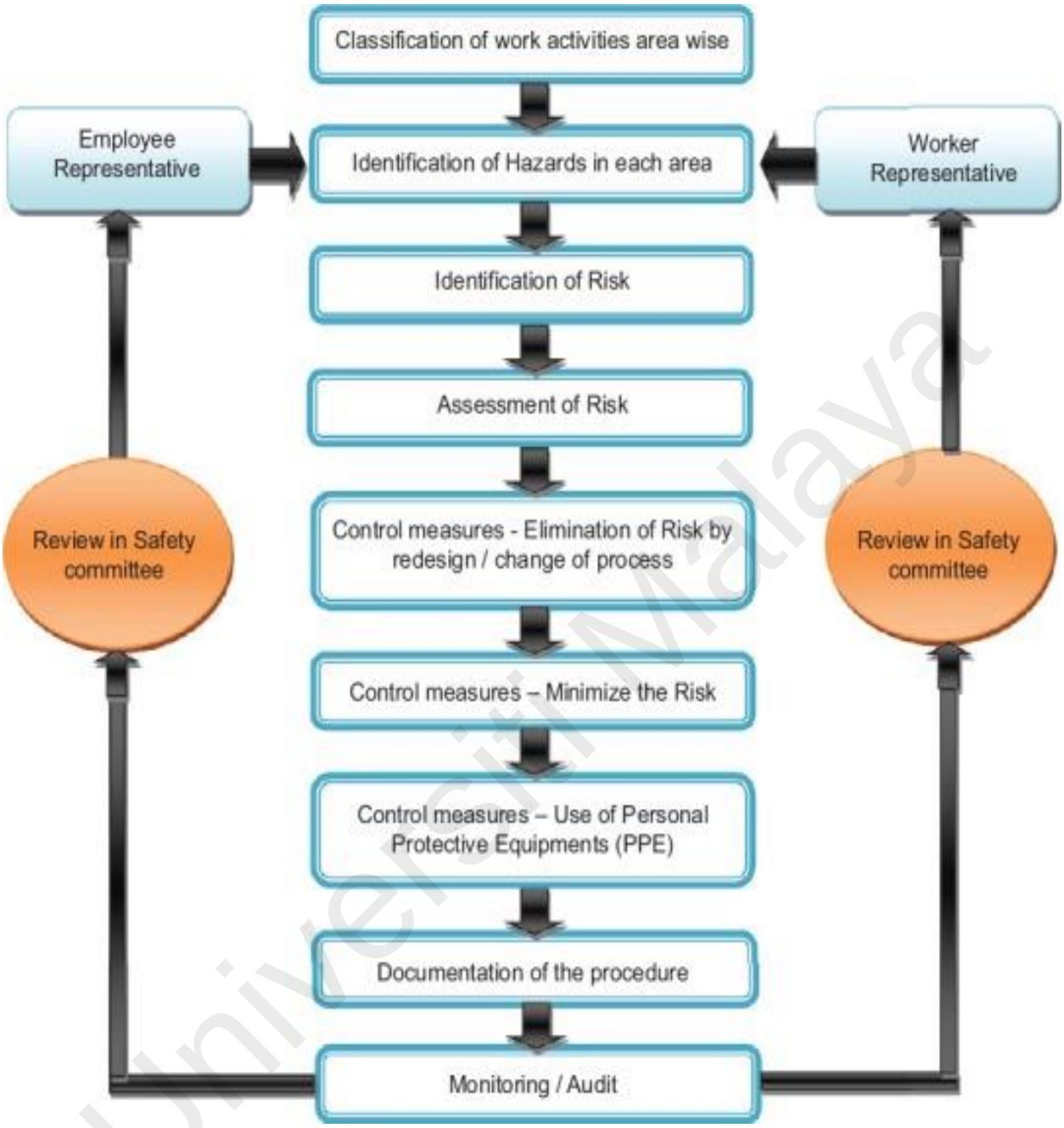

Figure 3.3: Process Flow for Risk Management Proposed Plan

(Source: DOSH, HIRARC Guideline 2008)

Classification of work activities and processes

Hazards from each of activities and processes from each of department need to identify (Table 3.0). Once hazards have been identified, further assessment needed to identify the potential risk from the hazards. The methods using to identify hazard in workplace as per below:

Table 3.0

Department – Work activities and processes

Departments	Work Activities and Processes
Operation (Production)	Device Production Activities Leads Production Activities
Mechanical Maintenance	Preventive Maintenance for Machineries and Equipment Preventive Maintenance for Heating Ventilation Air Conditioning (HVAC) System
Electrical and Instrumentation	Preventive Maintenance for LT Feeder Preventive Maintenance for HT Feeder Preventive Maintenance for Transformer Preventive Maintenance for Lighting Panel Preventive Maintenance for UPS Preventive Maintenance for Generator
Civil and Facilities Maintenance	Building Maintenance
Laboratory Operation	Sampling for Quality Testing

	Operation of instruments for laboratory analysis Chemical Management and Storage
Warehouse	Loading and Unloading Material Manual Carrying and lifting Forklift Operation Material Storage
Logistic	Truck movement inside plant premised
Office (Finance, Human Resource, Purchasing and Administration	Working at office for long time without taking break Working on Computer for long time Maitenace of Printer and Catridge
In-house contractor	Security daily patrolling Janitor – Cleaning activity (e.g. Chemical cleaning, mopping) Caterer – Café Activity (e.g. Cooking, Cleaning)

Identifying of the Workplace Hazards

Once work activities and processes have been classify, hazard identification needs to be conducted. The main objective of hazard identification is to ensure all potential workplace hazards are recognized. The classification of hazard as per stated in Table 3.1. They might choose to use sources for hazard identification as their most basic strategy. This approach is used by performing three fundamental tasks: observing the environment, reviewing the past, and getting advice from an expert. These seven sources can be used to determine the risk (Garrido et al. 2011, 2011):

1. A workplace assessment

2. An examination of the accident

3. Consultant knowledge sharing

4. Reports of incidents involving injuries or illnesses

5. Safety audit

6. Complaints and observations from employees

7. Environment and health surveillance

Table 3.1: Hazard Classification

Category	Examples
Physical	Noise, Radiation, Ventilation, heat stress, lighting, electrical
Chemical	Pesticides, Solvents and Heavy metals
Biological	Dangerous creatures, virus (e.g. COVID-19), bacteria, and parasite
Ergonomic	Human and machine interface, work position or work posture
Psychological	Work Stress, employee's interaction within organization, long hours work, shift work

Risk Assessment

The risk was evaluated using a semi-quantitative approach based on the two key factors listed in Table 3.2 below:

Table 3.2: Risk Assessment Using a Semi-Quantitative Approach

Risk rating (RR) = CL × LL	Likelihood level (LL)					Risk rating (RR)
	1	2	3	4	5	
Consequence level (CL)	Rare (practically impossible)	Unlikely (once in a year)	Possible (once in a month)	Likely (once in a week)	Almost certain (continuously occurring)	
5 Severe (Potential fatality or injury or illness with permanent disability)	5	10	15	20	25	Extreme (16-25)
4 Major (Potential lost time injury or injury of multiple persons irrespective of lost time but not permanent disability)	4	08	12	16	20	High (1115)
3 Moderate (Potential medical treatment injury or illness but no lost time)	3	06	09	12	15	Medium (6-10)
2 Minor (Potential first aid injury)	2	04	06	08	10	Low (1-5)
1 Minimal (Hazard and near miss requiring reporting and follow-up action)	1	02	03	04	05	

Control of Risk

By ranking hazards according to their likelihood and severity as per shown in Table 3.3 and Table 3.4, the most dangerous ones may be removed first. The action level need to be taken based on risk matrix in Table 3.5 and risk rating level as per stated in Table 3.6.

Table 3.3: Likelihood Level and Values
(Source: DOSH, HIRARC Guideline 2008)

Likelihood (*L*)	Example	Rating
Most likely	The most likely result of the hazard/event being realized	5
Possible	Has a good chance of occurring and is not unusual	4
Conceivable	Might be occur at sometime in future	3
Remote	Has not been known to occur after many years	2
Inconceivable	Is practically impossible and has never occurred	1

Table 3.4: Severity Indication
(Source: DOSH, HIRARC Guideline 2008)

Severity (*S*)	Example	Rating
Catastrophic	Numerous fatalities, irrecoverable property damage and productivity	5
Fatal	Approximately one single fatality major property damage if hazard is realized	4
Serious	Non-fatal injury, permanent disability	3
Minor	Disabling but not permanent injury	2
Negligible	Minor abrasions, bruises, cuts, first aid type injury	1

Table 3.5: Risk Matrix
(Source: DOSH, HIRARC Guideline 2008)

	Severity (S)				
Likelihood (L)	1	2	3	4	5
5	5	10	15	20	25
4	4	8	12	16	20
3	3	6	9	12	15
2	2	4	6	8	10
1	1	2	3	4	5

High
Medium
Low

Table 3.6: Action Level according to Risk Rating Level
(Source: DOSH, HIRARC Guideline 2008)

RISK	DESCRIPTION	ACTION
15 - 25	HIGH	A HIGH risk requires **immediate** action to control the hazard as detailed in the hierarchy of control. Actions taken must be documented on the risk assessment form including date for completion.
5 - 12	MEDIUM	A MEDIUM risk requires a planned approach to controlling the hazard and applies temporary measure if required. Actions taken must be documented on the risk assessment form including date for completion.
1 - 4	LOW	A risk identified as LOW may be considered as acceptable and further reduction may not be necessary. However, if the risk can be resolved quickly and efficiently, control measures should be implemented and recorded.

For risk management, the following steps were taken:

- Prompt response in dangerous or urgent circumstances
- Effective short-term solutions while permanent ones are being implemented
- Long-term remedy for the risk of chronic illness
- Long-term solutions to the risks with most serious consequences
- Training of employees on risk factors still present and preventative measures
- Repeated checks to ensure that control measures are being used.

Procedure documentation

When the process is documented, it is simpler to ensure the risk control measures are used as intended. It will also aid in the management of additional risks and hazards that are comparable

to those that have already been identified. The proper execution of the risk management process should be shown by adequate record keeping. Included in these details should be:

- Hazard discovered
- Assessment of hazard associate risk
- Making a choice regarding risk management controls
- When and how the measures are put in the place
- Evidence of control effectiveness monitoring and evaluation

Review and Monitoring

The risk is reevaluated to see if it can be reduced from critical and high risk to a level deemed As Low as Reasonably Practical (ALARP).

3.2. Collection Data thru Survey

In order to learn more about how the COVID-19 pandemic outbreak has affected employees who were chosen at random, a questionnaire survey was conducted. Questionnaire survey content 11 questions distributed via Google form to all levels of employees in medical device manufacturing company. An employees need to answer the questions based on their experiences working during COVID-19 pandemic outbreak.

3.3. Statistical Analysis

One aspect of statistical analysis is determining the mean of a group of values in an observational sample. Hypothesis testing is used to make conclusions about a population that is being studied. The null hypothesis states that the mean will be equal to zero. The paired t-test is a

technique for testing hypotheses when two sets of data are observed. Because each value in the first sample is paired with a value in the second sample, the data in a paired t-test are dependent. The parameter between the two sets of data is the mean difference, which is used to derive the conclusion.

CHAPTER 4: RESULT AND DISCUSSION

4.1 Hazard Identification, Risk Assessment and Risk Control (HIRARC) – Operating during COVID-19 Pandemic Outbreak

Table 4.0: Hazard Identification, Risk Assessment and Risk Control (HIRARC) - Production Device

Hazard Identification		Risk Assessment				Risk Control			
Work Activity/ Process	**Hazard**	**Existing Risk Control (If Any)**	**Likelihood**	**Severity**	**Risk**	**Recommended Control Measures**	**Likelihood**	**Severity**	**Risk**
Production - Device									
1.1. Work at station	Ergonomic	Ergonomic Chair	4	3	12	Job rotation/ Stagger Break	2	3	6
The majority of Device Production activities have the potential to be health hazard (COVID-19) due to workstation configuration.	Health (COVID-19)	Physical Distancing	4	4	16	Physical barrier/ Face shield/ Sanitation Scheduled/ Stagger break/ SWAB Test Program/ Health Declaration App	1	4	4
1.2. Assembly ICD Cell (machine inspection)	Electrical	Only trained operator allowed to do inspection	2	4	8	Only trained operator to do inspection	2	4	8
1.3. Using Nitrogen Gases for work	Fire or explosion	Only trained operator allowed to do inspection	2	4	8	Only trained operator allowed to do inspection	2	4	8
1.4. Using X-ray machine	Radiation exposure	Only trained operator allowed to do inspection	2	4	8	Only trained operator allowed to do inspection	2	4	8

1.5. Laser marking	Fire/ Explosion	Only trained operator allowed to do inspection	2	4	8	Only trained operator allowed to do inspection	2	4	8
1.6. Casting high voltage machine welding	Physical	Only trained operator allowed to do inspection / Wearing adequate PPE	2	3	6	Only trained operator allowed to do inspection / Wearing adequate PPE	2	3	6
1.7. Load and unload device into ICD Mold pre-heat (50 ºC)	Physical / Burn	Only trained operator allowed to do inspection / Wearing adequate PPE	2	3	6	Only trained operator allowed to do inspection / Wearing adequate PPE	2	3	6

Table 4.1: Hazard Identification, Risk Assessment and Risk Control (HIRARC) - Production Leads

Hazard Identification		Risk Assessment				Risk Control			
Work Activity/ Process	**Hazard**	**Existing Risk Control (If Any)**	**Likelihood**	**Severity**	**Risk**	**Recommended Control Measures**	**Likelihood**	**Severity**	**Risk**
Production - Leads									
2.1. Work at station	Ergonomic	Ergonomic Chair	4	3	12	Job rotation/ Stagger Break	2	3	6
The majority of Device Production activities have the potential to be health hazard (COVID-19) due to workstation configuration.	Health (COVID-19)	Physical Distancing	4	4	16	Physical barrier/ Face shield/ Sanitation Scheduled/ Stagger break/ SWAB Test Program/ Health Declaration App	1	4	4
2.2 Inspection on leads using microscopes manually	Ergonomic	Only trained operator allowed / Job rotation	2	2	4	Only trained operator allowed / Job rotation	2	2	4
2.3 Welding leads using machine laser welds	Electrical	Only trained operator allowed	2	4	8	Only trained operator allowed	2	4	8
2.4. Hand task on leads operations.	Ergonomic	Only trained operator allowed / Job rotation	2	2	4	Only trained operator allowed / Job rotation	2	2	4
2.5 Inspection on leads using machine test (Dielectric analyzer).	Electrical	Only trained operator allowed	2	4	8	Only trained operator allowed	2	4	8
2.6 Sterilization leads.	Chemical	Only trained operator allowed to do inspection /	2	4	8	Only trained operator allowed to do inspection / Wearing	2	4	8

		Wearing adequate PPE				adequate PPE			

Table 4.2: Hazard Identification, Risk Assessment and Risk Control (HIRARC) - Engineering

Hazard Identification		Risk Assessment				Risk Control			
Work Activity/ Process	**Hazard**	**Existing Risk Control (If Any)**	**Likelihood**	**Severity**	**Risk**	**Recommended Control Measures**	**Likelihood**	**Severity**	**Risk**
Engineering									
3.1 Preventive Maintenance (PM) for Production machineries and equipment *(Normal Practice and for safety purpose, PM job will be performed by applying the buddy system (2 pax of technician per shift pattern).*	Health (COVID-19)	Face mask	4	4	16	Face shield/ Regular SWAB Test Program/ Self-Health Declaration App	1	4	4
	Electrical	Only trained technician and engineer allowed	2	4	8	Only trained technician and engineer allowed	2	4	8
	Physical/ Mechanical (Rotation Part/ Sharp Edges)	Wearing adequate PPE	2	3	6	Wearing adequate PPE	2	3	6
	Chemical	Wearing adequate PPE	2	3	6	Wearing adequate PPE	2	3	6
	Ergonomic	Job rotation	2	2	4	Job rotation	2	2	4

Table 4.3: Hazard Identification, Risk Assessment and Risk Control (HIRARC) - Facilities

Hazard Identification		Risk Assessment				Risk Control			
Work Activity/ Process	**Hazard**	**Existing Risk Control (If Any)**	**Likelihood**	**Severity**	**Risk**	**Recommended Control Measures**	**Likelihood**	**Severity**	**Risk**
Facilities									
4.1 Preventive Maintenance Job for facilities machineries and equipment *(Normal Practice and for safety purpose, PM job will be performed by applying the buddy system (2 pax of technician per shift pattern).*	Health (COVID-19)	Face mask	4	4	16	Face shield/ Regular SWAB Test Program/ Self-Health Declaration App	1	4	4
	Electrical	Only trained technician and engineer allowed	2	4	8	Only trained technician and engineer allowed	2	4	8
	Physical/Mechanical (Rotation Part/ Sharp Edges)	Wearing adequate PPE	2	3	6	Wearing adequate PPE	2	3	6
	Chemical	Wearing adequate PPE	2	3	6	Wearing adequate PPE	2	3	6
	Ergonomic	Job rotation	2	2	4	Job rotation	2	2	4

Table 4.4: Hazard Identification, Risk Assessment and Risk Control (HIRARC) - Laboratory

Hazard Identification		Risk Assessment				Risk Control			
Work Activity/ Process	**Hazard**	**Existing Risk Control (If Any)**	**Likelihood**	**Severity**	**Risk**	**Recommended Control Measures**	**Likelihood**	**Severity**	**Risk**
Laboratory									
5.1 Laboratory activities *(Physical distancing is not possible to do in a laboratory since space is congested and employees normally move around to complete their daily task.)*	Health (COVID-19)	Face mask	4	4	16	Face shield/ Regular SWAB Test Program/ Self-Health Declaration App	1	4	4
	Chemical	Wearing adequate PPE	2	3	6	Wearing adequate PPE	2	3	6
	Ergonomic	Job rotation	2	2	4	Job rotation	2	2	4

Table 4.5: Hazard Identification, Risk Assessment and Risk Control (HIRARC) - Warehouse /Logistic

Hazard Identification		Risk Assessment				Risk Control			
Work Activity/ Process	**Hazard**	**Existing Risk Control (If Any)**	**Likelihood**	**Severity**	**Risk**	**Recommended Control Measures**	**Likelihood**	**Severity**	**Risk**
Warehouse and Logistic									
6.1. Warehouse and logistic activity *(Physical distancing and barrier not possible in warehouse/logistic. Employees move around for manual lifting, dealing with transporter, checking boxes at racking)*	Health (COVID-19)	Face mask	4	4	16	Face shield/ Regular SWAB Test Program/ Self-Health Declaration App	1	4	4
	Ergonomic	Job rotation	2	2	4	Job rotation	2	2	4
	Physical	Buddy system	2	2	4	Buddy system	2	2	4

Table 4.6: Hazard Identification, Risk Assessment and Risk Control (HIRARC) - Finance, Human Resource, Purchasing and Administration

Hazard Identification		Risk Assessment				Risk Control			
Work Activity/ Process	**Hazard**	**Existing Risk Control (If Any)**	**Likelihood**	**Severity**	**Risk**	**Recommended Control Measures**	**Likelihood**	**Severity**	**Risk**
Finance, Human Resource, Purchasing and Administration									
7.1 Office Activity *(Employees in the office have less potential exposure to COVID-19 if they follow company guidelines in terms of virtual meetings, no talk policy, WFH)*	Health (COVID-19)	Face mask	2	4	8	Face shield/ Regular SWAB Test Program/ Self-Health Declaration App/ WFH	1	4	4
	Ergonomic	Job rotation	2	2	4	Job rotation	2	2	4

Table 4.7: Hazard Identification, Risk Assessment and Risk Control (HIRARC) –Inhouse contractor

Hazard Identification		Risk Assessment				Risk Control			
Work Activity/ Process	**Hazard**	**Existing Risk Control (If Any)**	**Likelihood**	**Severity**	**Risk**	**Recommended Control Measures**	**Likelihood**	**Severity**	**Risk**
In-house contractor									
8.1. Security Activity *(High risk of COVID-19 exposure because they are considered front liner, meeting unknown status of visitor, contractor, transporter)*	Health (COVID-19)	Face mask	4	4	16	Face shield/ Regular SWAB Test Program/ Self-Health Declaration App	1	4	4
	Ergonomic	Job rotation	2	2	4	Job rotation	2	2	4
9.1. Janitor cleaning activity *(High risk of COVID-19 exposure since their work requires them to move around the plant and meet various employees, visitors, and contractors)*	Health (COVID-19)	Face mask	4	4	16	Face shield/ Regular SWAB Test Program/ Self-Health Declaration App	1	4	4
	Physical (Slip, Trip and Fall)	Wearing adequate PPE	2	3	6	Wearing adequate PPE	2	3	6
	Ergonomic	Job rotation	2	2	4	Job rotation	2	2	4
9.2. Caterer activities *(High risk of COVID-19 exposure since their work requires them to deal directly with employees, such as food serving activity)*	Health (COVID-19)	Face mask	4	4	16	Face shield/ Regular SWAB Test Program/ Self-Health Declaration App	1	4	4
	Ergonomic	Job rotation	2	2	4	Job rotation	2	2	4
	Chemical	Wearing adequate PPE	2	3	6	Wearing adequate PPE	2	3	6

	Physical (Slip, Trip and Fall)	Wearing adequate PPE	2	3	6	Wearing adequate PPE	2	3	6

4.2 Result of Survey

A Questionnaire was distributed randomly to all level of employees working in medical device manufacturing company thru google form. Received 130 responses from employees. The result of the survey was tabulated in the pie chart.

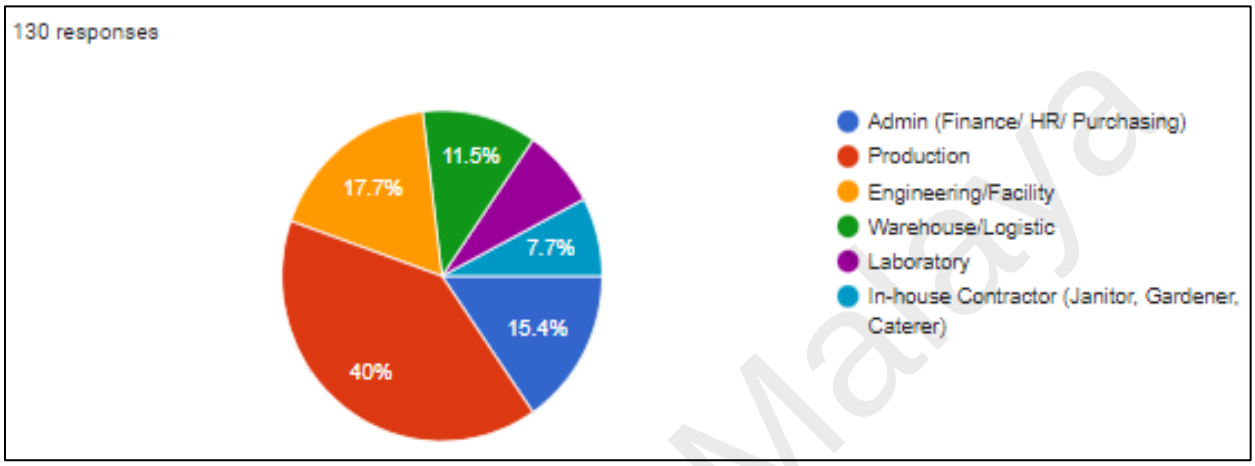

Figure 4.0: Roles of employees in Medical Device Manufacturing Company

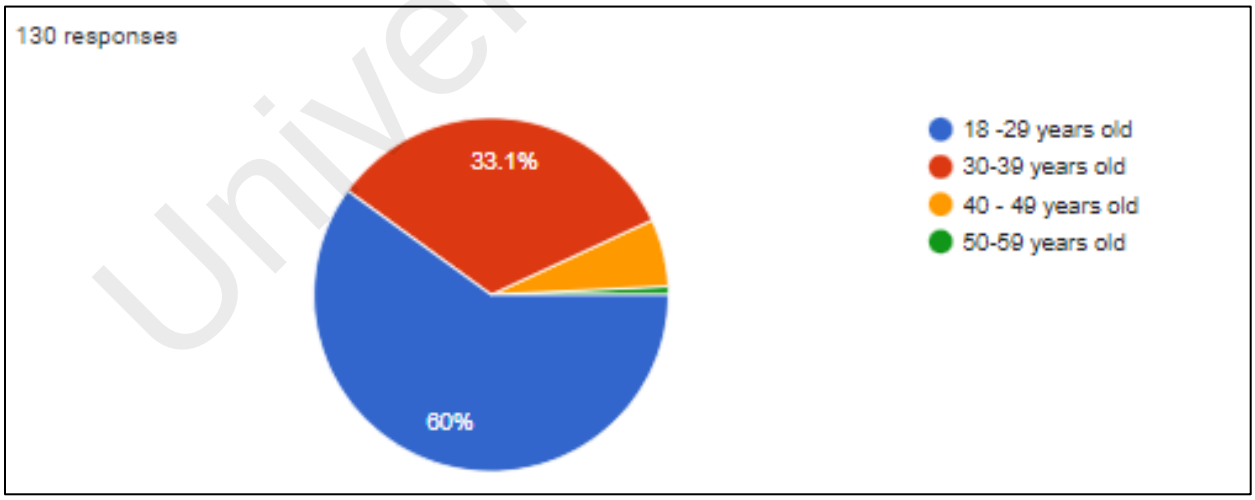

Figure 4.1: Age range of employees in Medical Device Manufacturing Company

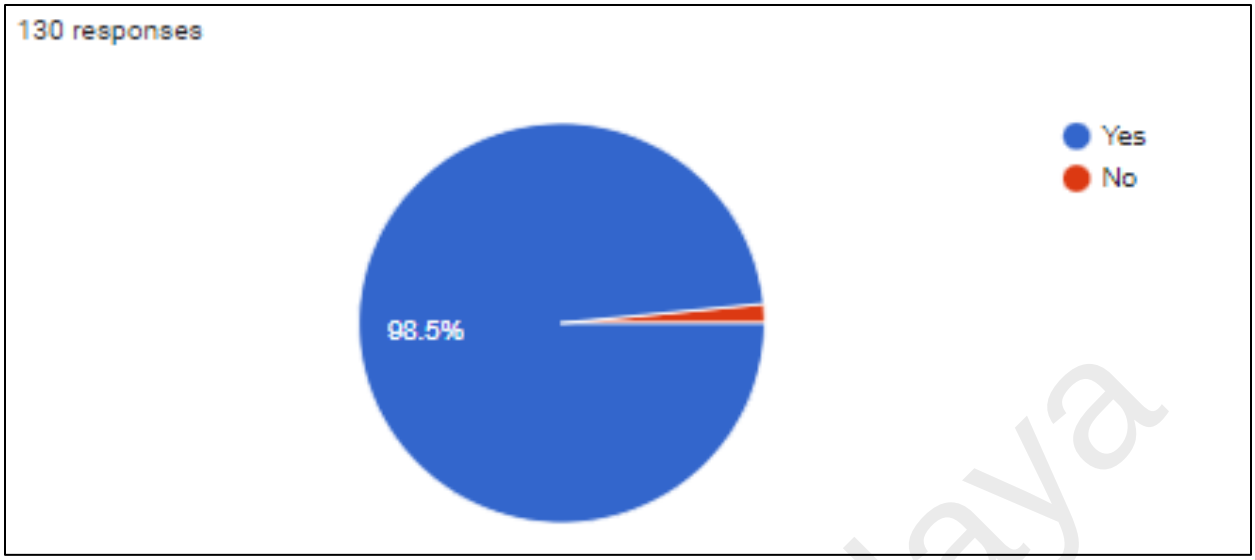

Figure 4.2: Understanding of employees to COVID-19 pandemic

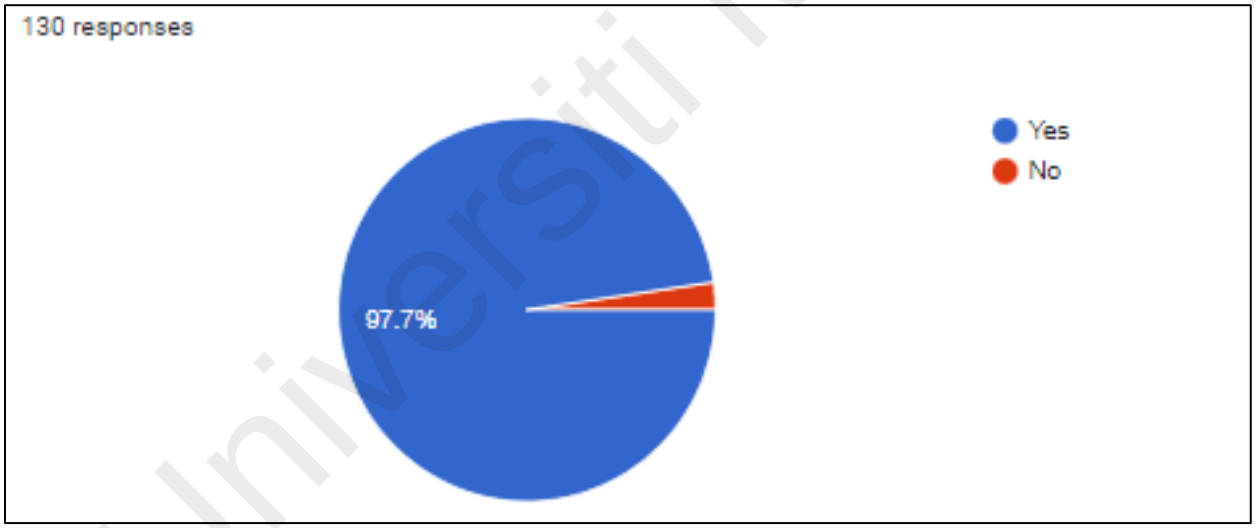

Figure 4.3: Difficulties working during a COVID-19 pandemic

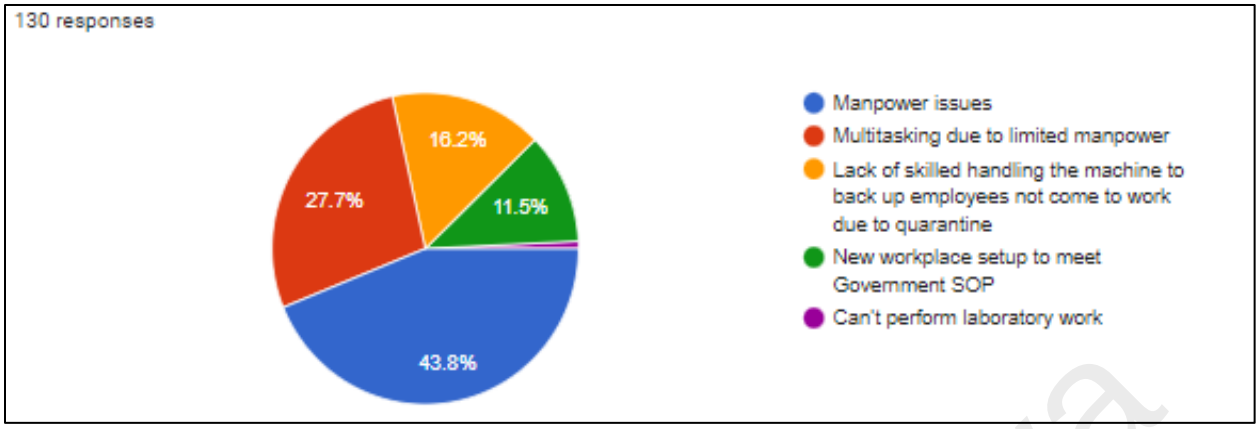

Figure 4.4: Main Issue of employee facing working during pandemic

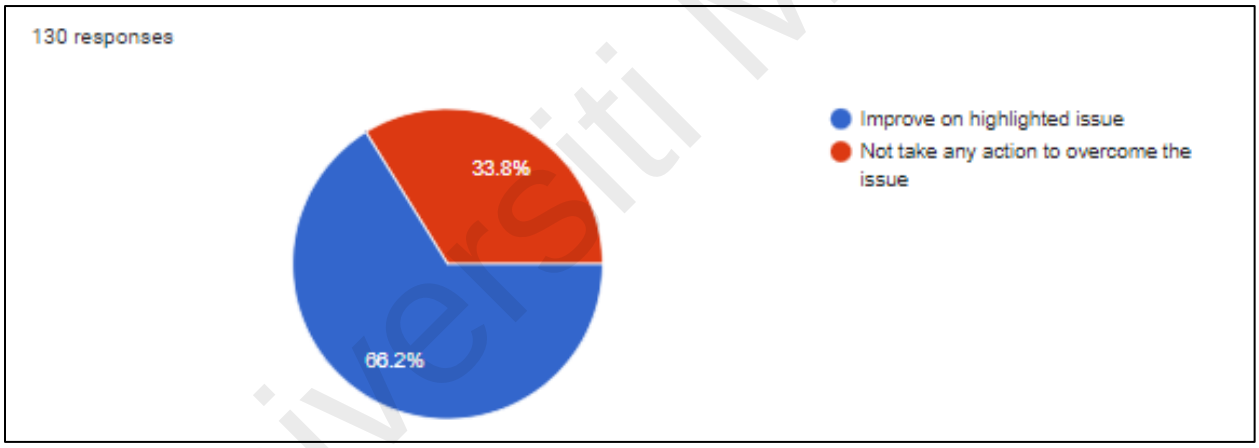

Figure 4.5: Action taken by management on the highlighted issue during working in COVID-19 pandemic

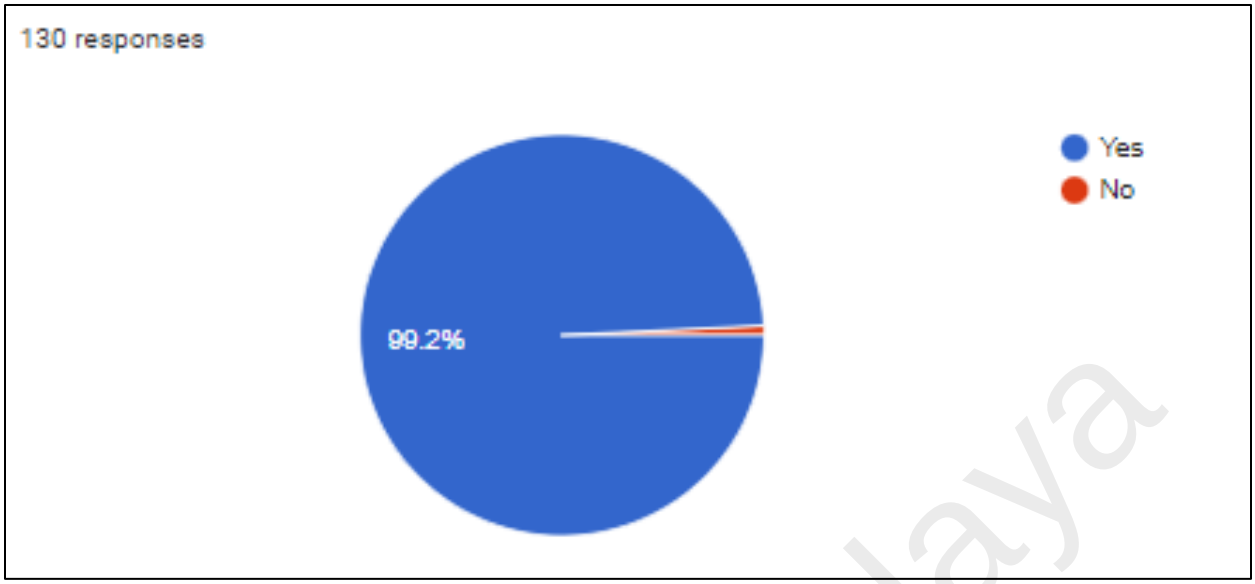

Figure 4.6: Work stress working during COVID-19 pandemic outbreak

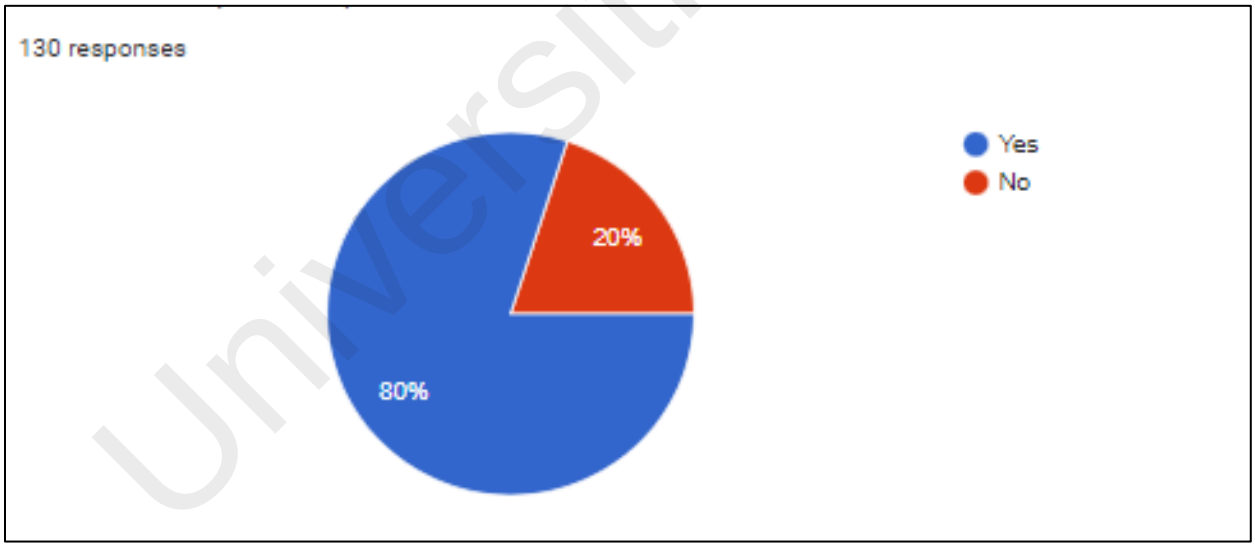

Figure 4.7: Employee understanding on the Hazard Identification, Risk Assessment and Risk Control (HIRARC)

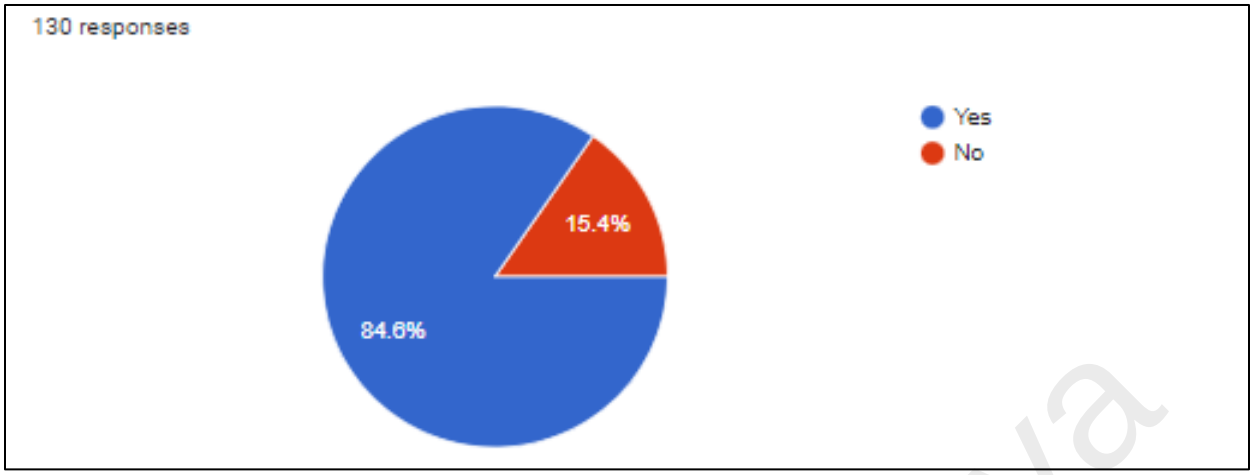

Figure 4.8: Manager and Supervisor highlighted on the Hazard when they setup new workstation to meet government SOP

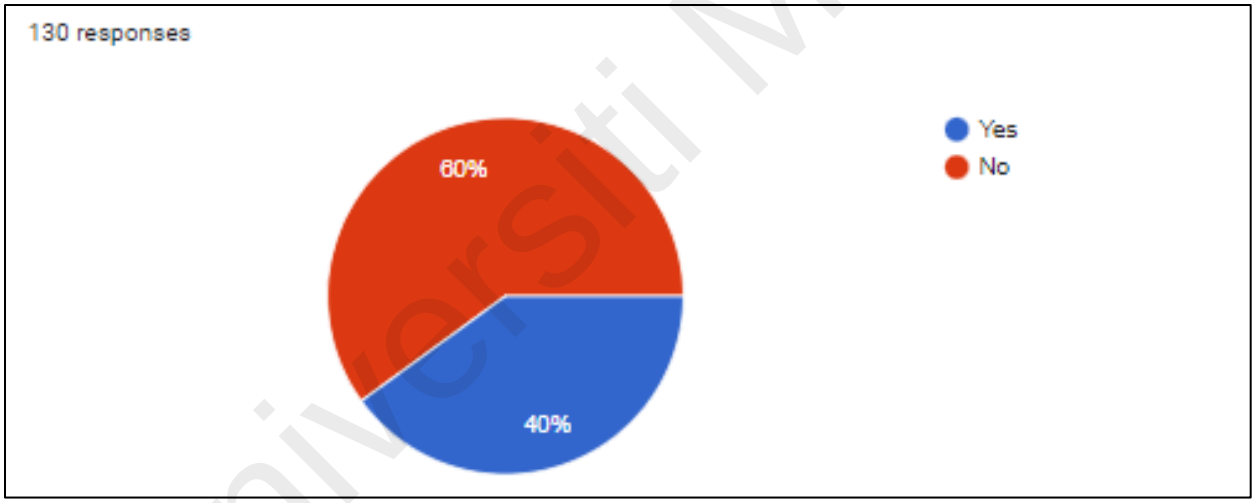

Figure 4.9: Current Practice and Personal Protection Equipment (PPE) is enough to ensure employee can perform work safely

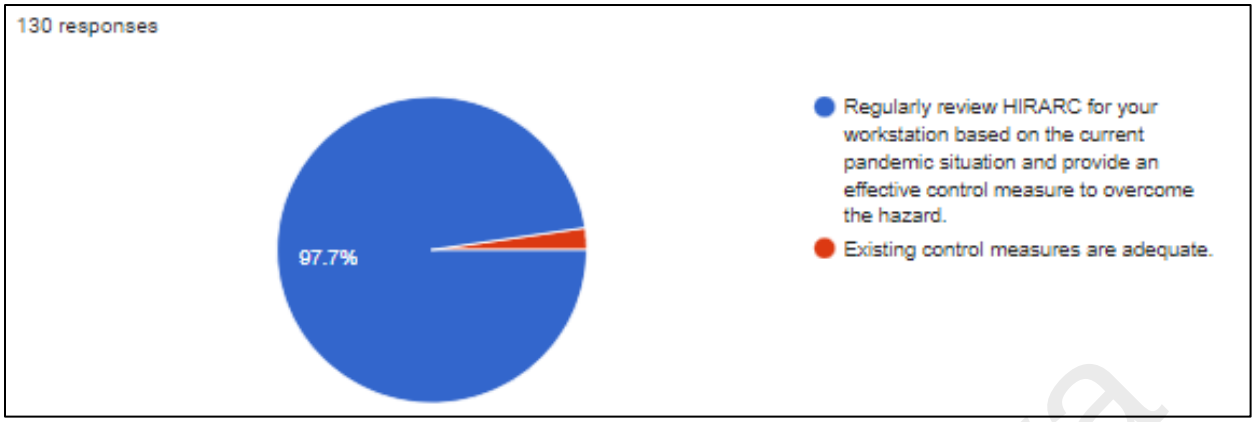

Figure 4.10: Employee Expectation from management to improve safety and health

Based on the survey that have been conducted in Medical Device Manufacturing company from 130 respondents, all received feedback tabulated in pie chart form as per stated from Figure 4.0 to Figure 4.10. The summary of higher percentage score for each question in survey conducted as per shown in Table 4.7. The highest percentage of respondent working from production which is 40% from 130 respondents. During COVID-19 pandemic outbreak, the main value stream that required to ensure business can be operate is from production stream compared to other stream that some of them can working remotely or work from home (WFH). The range of respondent age is 60% which age from 18 to 29 years old. Normally production value stream will hire this range of age due to their capability working inside production compared to other range of age. From 130 respondents' feedback, 98.5% are understand with definition of COVID-19 pandemic. From this data, it can show that most of employees are aware with what currently happen in their working environment. Then 97.7% agreed that working during COVID-19 outbreak is very difficult and challenging compared to normal situation. Due to COVID-19 pandemic outbreak, even medical device manufacturing company can operate as normal, but have challenging and difficulties to employees. From the survey, 43.8% stated that the main

challenging working during COVID-19 pandemic is manpower issues. As COVID-19 spreading too fast, it causes many of employees got infected. When infected, as per stated in COVID-19 Malaysia Standard Operating Procedure (SOP), they need to undergo home surveillance order (HSO) or known as quarantine. This will give impact to business since lack of manpower on-site to run the production. Even company can run operation with this limitation, 66.2% of respondent feedback stated management still focus to improve any issue highlighted by them. From this feedback, show that management not only thinking on the profit or production target, but also to safety and health for their employees. From the survey conducted 99.2% of respondent stated that they are working in stress. Employee stress mostly due to manpower issues. They need to cover their friend work which not able to come due to need to undergo home surveillance order (HSO) or quarantine. Working during COVID-19 pandemic is totally different compared to normal situation. To meet Malaysia Standard Operating Procedure (SOP), some requirements need to follow such as workplace arrangement must have physical distancing, need to wearing proper Personal Protective Equipment (PPE) while working especially face mask or face shield. From the survey, most of employees understand on the hazard identification, risk assessment and risk control (HIRARC) definition and application in their daily routine job. 80% from respondent feedback stated their understand on the hazard identification, risk assessment and risk control for their daily routine job during COVID-19 pandemic outbreak. 84.6% respondent feedback that their manager and supervisor keep highlighted hazards when they do some change on the workplace arrangement. This is important, employees need to remind always to ensure they aware on the hazard surrounding them. Since most of them aware on the hazard identification, risk assessment and risk control (HIRARC) and management take action on highlighted issue for improvement, 60% of respondent stated that current practice still not sufficient to make them

confident working during COVID-19 pandemic outbreak. 97.7% of respondent expected management to have regularly review on hazard identification, risk assessment and risk control (HIRARC). When management frequently review, they will provide effective control measure based on current situation. COVID-19 pandemic risk level is different from time to time. The variant from this virus keeps changing and give different impact.to human.

Table 4.7: Summary of higher percentage score for each question in survey conducted

No.	Survey Description	Percentage (%)	Remark
1.	Employee role in medical device manufacturing company	40.0%	Production stream
2.	Employee range of age	60.0%	18-29 years old
3.	Employee understanding on COVID-19 pandemic outbreak	98.5%	Most of employee understand on COVID-19 outbreak
4.	Difficulties working during COVID-19 pandemic outbreak	97.7%	Most of employee agree work during COVID-19 is very difficult
5.	Main issue working during COVID-19 pandemic	43.8%	Manpower issue is most critical during working in COVID-19 pandemic outbreak
6.	Action taken by management on the highlighted issue by employee	66.2%	Most of employee agreed management take action on the highlighted issue by them

7.	Working stress during COVID-19 pandemic outbreak	99.2%	Most of them facing work stress working during COVID-19 pandemic
8.	Employee understanding on the hazard identification, risk assessment and risk control (HIRARC)	80.0%	Most of employee understand on the hazard identification, risk assessment and risk control (HIRARC)
9.	Manager and supervisor highlighted on the hazards when do new arrangement at workstation to meet COVID-19 Malaysia Standard Operating Procedure (SOP)	84.6%	Employee stated manager and supervisor keep highlighting on the hazard of new workplace arrangement.
10.	Current Practice and Personal Protection Equipment (PPE) is enough to ensure employee can perform work safely	60.0%	Most of employee stated current practice and PPE is still not enough for them to work during COVID-19 pandemic outbreak.
11.	Employee Expectation from management to improve safety and health	97.7%	Most of employee agreed management should perform regularly review on the HIRARC based on the current situation of COVID-19 pandemic.

4.3 Discussion

According to this cross-sectional study, hazards with a high-risk rating or higher could be reduced to an ALARP level by implementing control measures. According to the research, routine Hazard Identification, Risk Assessment and Risk Control (HIRARC) studies can be used to lower the incidence of illness or injury in the medical device manufacturing sector.

Any manufacturing industry's foundation is the department of Environment, Health and Safety (EHS). The EHS Department is closely related to many departments such as Engineering, Production, Admin, and Human Resources.

The EHS Department carries out a number of common tasks, and through regular Safety Committee Meetings, they contribute significantly to the process of identifying hazards, performing risk assessment studies, and implementing control measures.

It is imperative to keep in mind that lack of proactive management in workplace safety and health during pandemic outbreaks cost money. Additionally, case studies demonstrate that a company's performance and profitability are positively correlated with its management of occupational safety and health.

Risk Assessment can be performed by 3 ways:

1. Qualitative
2. Quantitative
3. Semi-Quantitative

Semi-quantitative risk assessments are now widely used in order to address some of the drawbacks of qualitative approaches. By putting multiplier values on likelihood and consequence, the semi-quantitative approach to risk assessment builds on the qualitative approach. Additionally, frequency level multiplication might be included.

All risks cannot be completely eliminated. When a risk is deemed critical or high, immediate action is required. This may entail isolating the hazard or issuing instructions for an immediate halt to work until long-term solutions can be implemented. For moderate risks, written control plans with roles and due dates are required.

Risk that is deemed acceptable by regulatory bodies and the general public is known as an acceptable risk. There are no officially acknowledged regulatory standards for worker risk in the manufacturing of medical devices. Employee risk criteria have been developed by various organizations. Due to the uncertainties involved in the probabilistic risk analysis that was used to quantify the risk levels, the general guiding principle is that the risk be reduced to a level considered As Low As Reasonably Practicable (ALARP).

Preventive Actions

Implementing prevention strategies aims to lower the probability of a workplace accident or the occurrence of an occupational disease. The following actions were taken:

a) Engineering Control

- Remove – When designing a workplace, machinery or equipment that does not meet the standards for occupational health and safety should not be used.
- Reduce – Proper ventilation system like exhaust fan can reduce level of hazardous substance in the workplace.
- Replace – If there are any high-risk tools, materials, or chemicals in the workplace, they should be substituted out for low-risk types.

b) Administrative of Control

- Employee Education – Each employee must understand the risks, to which they are subjected while performing their daily duties, as well as the potential harm they may cause and the safety precautions that may be taken to reduce this risk.

Measures of Protection

a) Enclose the hazards

• By using guarding or protecting machinery components, you can contain or isolate the risk.

b) Remove from employees

CHAPTER 5: CONCLUSION AND RECOMMENDATION

5.1 Conclusion

As a conclusion, each of the objectives for this study can be achieved. The COVID-19 pandemic impacted a medical device manufacturing company because it created new hazards in the workplace. It can be evaluated by using the HIRARC method to measure a risk rating level. The risk rating level from this study is considered high compared to the risk rating for a company operating during a normal season. Employees' perception of COVID-19 can also be evaluated through this study. The majority of respondents stated that the COVID-19 pandemic had an impact on their daily routine job in a medical device manufacturing company. Despite being recognized as essential industries during the COVID-19 pandemic outbreak, medical device manufacturing company continues to face obstacles and restrictions. A business must have a solid plan in place to address the COVID-19 pandemic outbreak problem. One approach to reducing the problem is through the processes of hazard identification, risk assessment, and risk control (HIRARC). The first step in preventing occupational disease in employees and to maintain a safe and healthy workplace is identifying and analyzing hazards. Hazard Identification, Risk Assessment, and Risk Control (HIRARC) studies ought to be carried out frequently in all manufacturing sectors. This contributes to two objectives: First, it can pinpoint urgent and high-risk hazard that need to be dealt with first; and second, by putting control measures into place as quickly as possible, it lowers the risk to an As Low as Reasonably Practical Level (ALARP). Instead of reducing manpower at the company for work from home (WFH), the company must have an ideal plan on how to operate with 100% of its employees onsite. To optimize employees' contributions to achieve the company target, recommended

control measures must be in place. For example, a regular swab test programme and providing suitable personal protective equipment (PPE) for employees can assist to minimize or prevent the spread of COVID-19 and make employees feel safe at work. Regular swab tests can help companies screen and quickly isolate employees infected with COVID-19. No work stress, no difficulties performing daily tasks, no lack of skilled and trained employees on-site if ideal control measures have been considered from a continuous review of hazard identification, risk assessment, and risk control of the medical device manufacturing company.

5.2 Recommendation

- Continuously performing Hazard Identification, Risk Assessment, and Risk Control (HIRARC) is needed to assist medical device manufacturing companies to control the risk level for their work activities.

- Management of medical device manufacturing companies must be alerted to the change in risk based on the current situation of COVID-19 impact.

- Response to the risk must be at the risk level that defines the action level that needs to be taken either immediately or not.

5.3. Future Recommendation

- Other risk assessment methods or techniques can be used to measure the risk level of work activities in a medical device manufacturing company operating during the COVID-19 pandemic outbreak.

- Applying the hazard identification, risk assessment, and risk control (HIRARC) method to other types of industrial operations that operate during the COVID-19 pandemic outbreak

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