Publisher homepage: www.universepg.com, ISSN: 2663-7529 (Online) & 2663-7510 (Print)

https://doi.org/10.34104/ejmhs.023.02040217

European Journal of Medical and Health Sciences

Journal homepage: www.universepg.com/journal/ejmhs

Risk Management in Medical Device Maintenance Workshops

Abdulsalam Hamoud A Almoghames[1]*, Turki Lafi Mutlaq Almutairi[1], and Abdullah Saleh S Alqarzaee[2]

[1]Prince Sultan Military College for Health Sciences in Dhahran, Saudi Arabia; and [2]Instructor Prince Sultan Military College for Health Sciences in Dhahran, Saudi Arabia.

*Correspondence: aalmoghames@psmchs.edu.sa (Abdulsalam Hamoud A Almoghames, Instructor, Prince Sultan Military College for Health Sciences in Dhahran, Saudi Arabia).

ABSTRACT

Risk management is a critical aspect of medical device maintenance workshops, as it plays a crucial role in ensuring the safe and reliable operation of medical equipment. This paper examines the significance of incorporating effective risk management strategies in medical device maintenance workshops to minimize potential risks and harm to patients and healthcare workers. The study highlights the importance of understanding regulations, adopting best practices, and providing continuous training to effectively manage risks. By incorporating risk management into the business strategy and involving all members of the organization, potential hazards can be identified and mitigated through appropriate controls. The research objectives include identifying potential risks, developing effective risk management strategies, evaluating current practices, assessing the impact on patient outcomes and healthcare costs, and contributing to the existing body of knowledge on medical device safety and maintenance. The research methodology employed a descriptive-analytical approach, utilizing questionnaires as a data collection tool from specialists and technicians working in medical device maintenance workshops. The findings emphasize the need for comprehensive risk management practices to ensure patient safety, improve equipment functionality, and comply with regulatory requirements. By implementing these strategies, medical device maintenance workshops can protect patients from harm, reduce downtime, and enhance overall healthcare outcomes.

Keywords: Risk management, Medical device maintenance, Patient safety, and Regulatory compliance.

INTRODUCTION:

The risk is understood as the possibility of occurrence of an undesired situation, effect of uncertainty that exists about the fulfillment of the objectives (Arias Perez, 2014), which can produce favorable or negative effects (Perez Barnett, 2014), which are detrimental to organizational performance (Bolano Rodriguez, 2014). Therefore, good management is required to minimize its impacts. Risk management is one of the most innovative elements to consider within internal control, through which companies create their control mechanisms to prevent, mitigate, avoid, transfer, accept or share the different risk events that occur or are likely to occur, and where man, as the most important asset, plays a fundamental role in their identification, treatment, review, and permanent monitoring. Risk management must be incorporated into the business strategy and is an issue that involves all members of the entity, since risk can appear anywhere and under any circumstances. Managing risks with a process orientation contributes to a better identification of these, thus having a greater vision of the activities that

are carried out within each process while involving all personnel in the task and promoting the achievement of objectives. Risk management is a critical aspect of maintenance workshops for medical devices. Medical devices play a crucial role in patient care, and any malfunction or the failure of these devices can have serious consequences. The maintenance of medical devices is therefore essential to ensure their safe and reliable operation (Thompson *et al.,* 2018). The studies conducted by (Thompson *et al.,* 2018; Garcia *et al.,* 2019) underscore the significance of implementing comprehensive risk management strategies in medical device maintenance the workshops. These strategies encompass aspects such as gaining an understanding of regulations, adopting best practices, and the offering continuous training.

Through the application of these strategies, the workshops can effectively ensure the safe and dependable functioning of medical equipment, thereby minimizing the potential risks and harm to patients and healthcare workers. Maintenance workshops for medical devices are responsible for ensuring that medical equipment is maintained and repaired to the highest standards possible. Risk management is a process that helps identify potential hazards and the mitigate them by implementing appropriate controls. Therefore, incurporating risk management into the business strategy & involving all members of the entity becomes the imperative, as risk can appear anywhere and under any circumstances. Managing risks with a process orientation, as suggested by Smith *et al.* (2016), contributes to better hazard identification and a greater vision of activities within each process, involving all personnel & promoting the achievement of objectives. Effective risk management in medical device maintenance workshops requires the thorough understanding of the regulations and guidelines governing medical device maintenance and repair. It also involves the use of best practices in maintenance and repair, as well as ongoing training and education for the maintenance staff. By implementing effective risk management the practices, medical device maintenance workshops can ensure that medical equipment is maintained and repaired to the highest possible standards, reducing the risk of harm to patients and healthcare workers. Therefore, the present study aims to identify the potential risks associated with the medical device maintenance workshops, including risks to patient safety, equipment functionality, and regulatory compliance.

Statement of the Problem

The problem of risk management in medical device maintenance workshops is a critical issue that must be addressed to ensure the safety and effectiveness of the medical equipment. Medical devices are complex machines that require proper maintenance and repair to function correctly (Thompson *et al.,* 2018). Failure to adequately maintain or repair medical devices can result in serious consequences, including patient harm, equipment failure, and increased costs. To address the problem of risk management in medical device maintenance workshops, it is essential to develop & implement effective risk management strategies, including regular assessments of the risks associated with the medical equipment maintenance and repair, training programs that provide comprehensive and up-to-date information on medical device maintenance, & procedures for promptly addressing and reporting equipment failures or malfunctions. By implementing these measures, healthcare organizations can ensure that medical equipment is properly maintained & repaired, thereby protecting patients from harm (Smith *et al.,* 2016).

Significant of the Study

The study of the risk management in medical device maintenance workshops is crucial for several reasons. Firstly, proper maintenance of medical devices is vital to ensure patient safety and well-being. Neglecting maintenance can have serious consequences, including patient harm, equipment failure, and increased costs. Therefore, the understanding and managing the risks associated with these workshops are essential for the safe and effective use of medical equipment. Secondly, medical device maintenance workshops play a key role in training healthcare professionals on proper maintenance and repair. However, these workshops themselves carry potential risks, such as the insufficient training, lack of the equipment or tools, & outdated information. Consequently, comprehending & addressing the risks associated with these workshops is vital to ensure their effectiveness and the safety. Lastly, studying risk management in medical device maintenance workshops can assist healthcare organizations in reducing equipment failure, minimizing downtime,

and improving patient outcomes. By identifying and managing risks, organizations can ensure that medical equipment is the adequately maintained and repaired, protecting patients from harm. This can lead to the improved patient outcomes, increased efficiency, and reduced costs.

Objectives of the Study

1) To identify the potential risks associated with the medical device maintenance workshops, including risks to the patient safety, equipment functionality, and regulatory compliance.
2) To develop effective risk management strategies for medical device maintenance the workshops, including identifying best practices for training, equipment maintenance, and documentation.
3) To evaluate the effectiveness of the current risk management practices in medical device maintenance the workshops, including assessing the adequacy of training and documentation, and identifying areas for improvement.
4) To assess the impact of risk management on patient outcomes and healthcare costs, including evaluating the benefits of the effective risk management in terms of improved patient safety and reduced costs associated with equipment failure or downtime.
5) To contribute to the existing body of knowledge on medical device safety and maintenance, by the identifying new best practices for risk management in medical device maintenance workshops and the publishing the results in a peer-reviewed journal or other publication.

METHODOLOGY:

This research adopted the descriptive-analytical methodology as it is the most commonly used methodology in the study of Risk management in medical device maintenance workshops, according to previous studies reviewed in this research. The descriptive methodology involves collecting both quantitative and qualitative data about the phenomenon under study in order to the analyze and interpret it. The descriptive-analytical methodology allows for the collection of accurate & comprehensive data about the phenomenon under study, which can then be systematically and logically analyzed. This methodology enables the identification of factors that affect the phenomenon under study and the analysis of changes that occur over time. The descriptive-analytical methodology allows for a multi-faceted analysis of the phenomenon under study & provides an opportunity to analyze relationships between different variables and identify factors that directly or indirectly affect the phenomenon. Therefore, using the descriptive - analytical methodology in this research helps to achieve the research objectives & answer the research questions accurately, systematically, & comprehensively.

Research Sample

The research sample consists of specialists and technicians working in the medical device maintenance workshops.

Research Tool

In order to achieve the research objectives and answer its research questions, a questionnaire was used as a tool to collect the data and information related to the research. The questionnaire was developed based on previous research and studies and was prepared using Google Forms and sent to the study sample as a link through social media channels to answer the questionnaire questions.

Review of Literature

The term risk is often characterized as a possibility of having negative consequences in relation to a set of activities or potential events. That is to say, the risk is in itself the effect of the uncertainty of an event which may imply in non-completion of the objectives of an activity, a function or an organization (Araújo Da *et al.,* 2018). According to this, the risks must be the eliminated. If necessary, risk management methods are put in place to minimize them to an acceptance scale where the risk-benefit ratio justifies its presence. Thus, predicting, controlling, and managing risks has become a fundamental need. According to the guidelines provided by the International Organization for Standardization (ISO, 2018), the effective risk management practices are essential for ensuring safety in various industries. The NF ISO 31000 standard provides guide lines for risk management and defines it as a set of coordinated activities which aim to guide an organization with respect to risk. This standard can be used and adapted for any organization aiming to develop a strategy to confront the risks present in their activities

Effective risk management is always improving and must aim creation or preservation of an organization's mission. That is why the integration of risk management in the fundamental activities and in the different levels of hierarchy of an organization is essential. In the context of medical devices, risk management is very important, since if we are not able to foresee the risks before they occur, the consequences go until the death of a patient or a user. Therefore, risk monitoring must begin before these devices are used by patients in order to ensure their quality & performance. Risk management for medical device manufacturers in this way, manufacturers of medical devices to ensure the safety of equipment in the marketing phase, they must, in the production phase, establish a risk management system that meets all the requirements of standard NF EN ISO 14971. The difference between risk management and the management of these is that the first focuses more on the risks during the tasks and the second on the risks which can affect the results. Thus, this standard was developed specifically for manufacturers of the medical devices and is based on the principles of risk management. The requirements that are presented to manufacturers can apply throughout the life cycle of the devices. Thus, NF EN ISO 14971 requires that a documented risk management process be established, & often updated, so as to allow the analysis, evaluation and control of risks (Mokhtari *et al.,* 2021). Risk management, according to standard, requires that the manufacturer must also analyze the presence of residual risks and their impacts. Therefore, it is necessary to verify if the benefit for use is greater than the residual risk in order to consider possible changes. Since failure to identify a risk or a dangerous situation can have major consequences. In any case, even if overall residual risk is acceptable, manufacturer is obliged in the documentation accompanying the device to inform users of the presence of these risks and of possible dangerous situations (ISO, 2019; Faisal *et al*., 2023).

Compliance with all requirements during production, post-production and marketing procedures ensures that a medical device of good quality and good performance is made available to the healthcare market. Following procurement procedures, this equipment arrives at the health services. And to health establishments, quality care presents itself within biomedical services as the need to ensure good control of the risks associated with the operation of medical devices, with the intention of guaranteeing the safety of patients, users, & nursing staff. Risk management for operators of medical devices at the level of biomedical services, the importance of setting up a risk management system is directly linked to the safety of users through the proper use of medical devices. According to this, risk management also allows the service to comply with normative and regulatory requirements in addition to planning the actions necessary to prevent or correct breakdowns. This is why in biomedical services in France, the use of and compliance with the NF S99-172 standard is of great importance. There are different methods for analyzing the criticality of a risk.

The operator can use the method referenced of the Standard NF S99-172. This method is proposed by SNITEM and CETIM. This is based on the FMECA method, which means analysis of failure modes, their effects, and their criticality. It makes it possible to identify all the dangers that may occur on a medical device, to assess the risks and to minimize or even eliminate them, through actions. This method requires a review and therefore the continuous improvement because the risks can occur at several times in the life of the device and are not always foreseen. Each event causes a danger and therefore a risk, which must be considered and traced in a document with the actions undertaken and to be taken to minimize it.

A Medical Device

A Medical Device (MD) is defined according to the Public Health Code (CSP) in article L5211-1 as "any instrument, device, equipment, material, product, with the exception of products of human origin, or other article used alone or in combination, including accessories & software necessary for its proper functioning, intended by the manufacturer for use in humans for medical purposes and from which the principal intended action is not obtained by pharmacological or immunological means or by metabolism, but whose function can be assisted by such means. Also constitutes a medical device the software intended by the manufacturer to be used specifically for diagnostic or therapeutic purposes"

Development

In this sense, a specific procedure for risk management is proposed that consists of five stages, framed in the Deming cycle (plan, do, verify and act), expressed as: establishment of the context; risk assessment; risk treatment; monitoring and supervision; and making timely decisions, in the Annex No. 3 you can see the design of the procedure elaborated with the help of Microsoft Visio. Communication and consultation is an aspect to take into account during all stages of the risk management process, in accordance with the observance of international and national standards and the research carried out (AIRMIC, ALARM, & IRM, 2002), (Association Australian and the New Zealand Standards, 1999), (Fornet Batista, 2007), the (Office National Standardization, 2015).

Risk Assessment

Stage that includes the identification, analysis, and evaluation of the risks. Risk Identification: Allows an initial inventory of risks to be drawn up, classified as internal or the external. Risk identification is the initial step in the evaluating potential vulnerabilities. The reduction or elimination of risks, mainly those with a high probability of occurrence and a greater impact, guarantees reasonable security in the organization (Medina León *et al.,* 2014). Each entity has its mechanisms or scenarios to identify risks, which can be meetings of the Prevention and Control Committee, affiliate assemblies, quality committee, meetings with the change team, among others, where brainstorming is frequently used to promote the generation of proposals.

Risk Analysis

At this stage, the risks are classified by the type (operational, financial, occupational health and safety, information technology security, reputational and the environmental), the control objectives are determined, the causes that cause the risks, the consequences that they bring with them, probabilities of manifestation and negative manifestations of presentation. Here the qualitative and the quantitative evaluation scales are generated. The qualitative scale proposes four ranges to select the one that best suits the workshop and is shown in **Table 1**.

Table 1: Range levels for the qualitative scale.

Ranks	Probability (P)	Worth	Consequence (C)	Worth
3	Certainty	10	Elderly	10
	Likely	6	moderate	6
	Unlikely	2	Minor	1
4	Certainty	10	Catastrophic	10
	Likely	7	Elderly	7
	moderate	5	Minor	5
	Strange	2	Insignificant	2
5	Certainty	10	Catastrophic	10
	Likely	8	Elderly	9
	moderate	6	moderate	6
	Unlikely	3	Minor	3
	Strange	2	Insignificant	1
7	very high	10	Catastrophic	10
	Very high	8	Elderly	8
	high	6	high	6
	Half	4	moderate	4
	Low	3	Minor	3
	Very low	2	minimum	2
	remote	1	Insignificant	1

Source: Adapted from Fraga, 2016.

Table 2: Range levels for the quantitative scale.

Probability	Value	Consequence	Scale type
Daily 365 times a year	365		Quantities
Monthly 12 times a year	12		
Quarterly 4 times a year	4	Add for each bias	
Semester twice a year	2		
Annual I time a year	1		

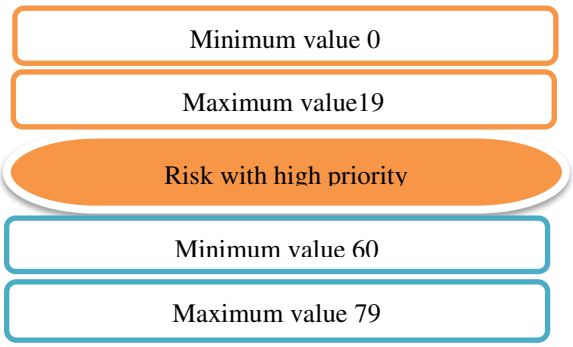
Source: XGER software tool v. 1.

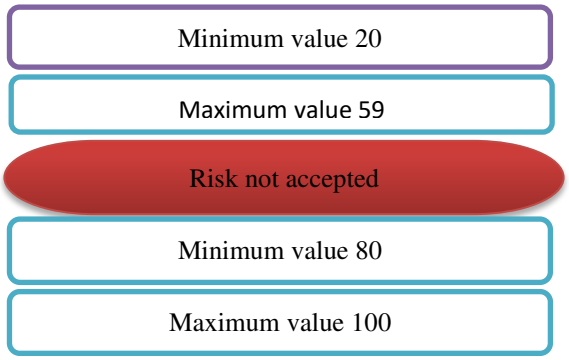
Risk assessment

In this stage, the risk levels obtained are compared with the predetermined tolerance levels to give priority to risk treatment. The risk tolerance levels of the qualitative scale are shown in **Table 3**, values that can be changed according to the entity's criteria.

The quantitative scale, shown in **Table 2**, displays the number of times that the risk may occur in the year, in order to calculate the possible loss.

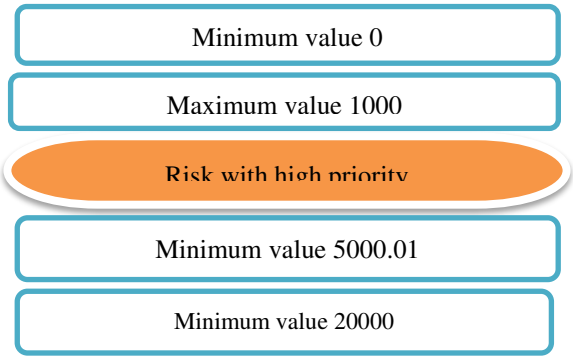
Table 3: Range levels for risk tolerance for qualitative scale.





Likewise, **Table 4** shows the risk tolerance levels of the quantitative scale, the values can be modified at the discretion of the entity. The tolerance levels obtained serve as support to senior management for informed decision-making, gives the measure of the how to treat the risks and induces timely action to be taken. The most significant risks require treatment and, if possible.

Table 4: Risk tolerance levels for quantitative scale.



Risk Treatment

At this stage, the measures are taken to reduce the probability of risk manifestation. In the same way, an action plan is created to minimize the occurrence of risk and its consequences, measures that contribute to making the right decision to avoid, accept, increase, eliminate, share or the maintain the risk (Maxitana & Naranjo, 2009), the (Perez Barnett, 2014). It is also

possible to act on the causes, negative manifestations, measures, dates of the compliance, responsible parties, executors, in order to reduce the residual risk existing after having treated the risk. “The date of compliance should not be identified with the daily, permanent, bimonthly or quarterly deadlines, according to what is established for its execution. In all cases, the date on which compliance with the measures is controlled or their results evaluated is specified” (Fraga Dominguez, 2016). On the other hand, "all the measures are the assigned a person in charge and a performer, it is taken into account that the performers are not the people who, due to the content of the position, carry out the activity, in this case the performer is a third party and the person in charge can being maximum representative of both, the performer has to know in detail the activity that he is going to the review” (Guerrero *et al.,* 2014). In this stage, the Risk Prevention Plan is designed, which must be communicated among the members of the organization and interested parties. In this regard, it is stated that "the Risk Prevention Plan constitutes a working instrument for management to systematically monitor the control objectives determined, it is periodically updated and analyzed with the active participation of workers and in the presence of events that so the require" (Comptroller General of the Republic, 2011, p. 42).

Monitoring and Supervision

In this stage, compliance with the measures contemplated in the plan is reviewed and evidence of the check carried out is left, through a report detailing the incidents detected, which must be communicated to internal and the external interested parties, promoting feedback to the system to improve risk management. In medical device maintenance workshops, monitoring and supervision are critical components of effective risk management. This stage involves the reviewing compliance with the measures outlined in the risk management plan and documenting evidence of the checks carried out. Regular monitoring and supervision can help identify potential problems and address them before they become more significant issues. This may involve conducting regular audits of equipment and procedures to ensure that they are functioning correctly & are in compliance with relevant regulations & standards. In addition to monitoring & supervision, it is essential to document any incidents or issues that are detected during the monitoring process. This documentation should include details of the incident, the measures taken to the address it, and any feedback received from internal and external interested parties. By documenting incidents and promoting feedback from interested parties, medical device maintenance workshops can continually improve their risk management systems. This may involve making changes to the procedures or equipment to reduce the likelihood of similar incidents occurring in the future.

Timely Decision Making

All information related to risks is stored in the XGER computer tool, an instrument that supports the systematic control and supervision of the Prevention Plan measures, which issues reports with useful and the relevant information, which serve the highest management to the make decisions successful, anticipate deviations and meet the objectives set. Timely decision making is crucial in risk management for medical device maintenance workshops. It is essential to have access to the up-to-date information on risks and the effectiveness of risk management measures to make informed decisions. The XGER computer tool is an effective instrument that the supports the systematic control & supervision of the Prevention Plan measures. This tool can store all information related to risks and can issue reports with useful and relevant information. These reports can provide senior management with the data they need to make decisions that are successful, anticipate deviations, and meet the objectives set. By using the XGER computer tool, senior management can monitor the status of risk management measures and identify any potential deviations from the plan. This can help them make timely decisions to address any issues that arise, prevent potential problems, and ensure that the objectives of the risk management plan are met.

RESULTS AND DISCUSSION:

This section covers a deep analysis of the collected data from the sample of 50 respondents in order to achieve the objectives of the research, the researcher used the descriptive analytical method using SPSS, and used the questionnaire to collect data from the research vocabulary, where questionnaires were distributed to the specialists and technicians working in the medical

devices maintenance workshops. Hypotheses for the following variables are tested and are concluded to be accepted or the rejected based on the correlation co-efficient: Training Equipment Maintenance Documentation: the Regulatory Compliance Risk Assessment Performance Testing Predictive Maintenance Technologies Quality Control As well as Likert-scale items that were used to measure the eight variables of the study in order to determine the degree of approval of each statement of the questionnaire as in **Table 5**.

Table 6 shows that the sample members are all males, at a rate of 100%, and this indicates that most of the workers in the medical equipment maintenance workshops are males.

Table 5: Likert-scale items.

Option	Rank
Strongly Disagree	1
Disagree	2
Neutral	3
Agree	4
Strongly Agree	5

Table 6: Distribution of the study sample according to gender.

Gender	Frequency	Percent %
Male	50	100.0
Female	0	0
Total	50	100.0

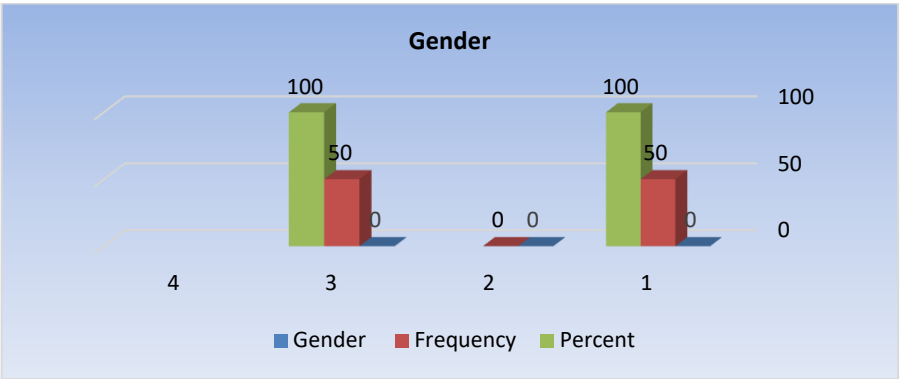


Fig. 1: Distribution of the study sample according to gender.

The **Table 7** show that most of the member sample are from the age group 35 and above with a rate of 42%, followed by the age group from 30-25 with a rate of 24%, then the age group from 20-25 with a rate of 22%, and in the last place are those with the age group from 30-35 with a rate of 12%

Table 7: Distribution of the study sample according to age.

Age	Frequency	Percent %
20-25	11	22.0
25-30	12	24.0
30-35	6	12.0
35 and above	21	42.0
Total	50	100.0

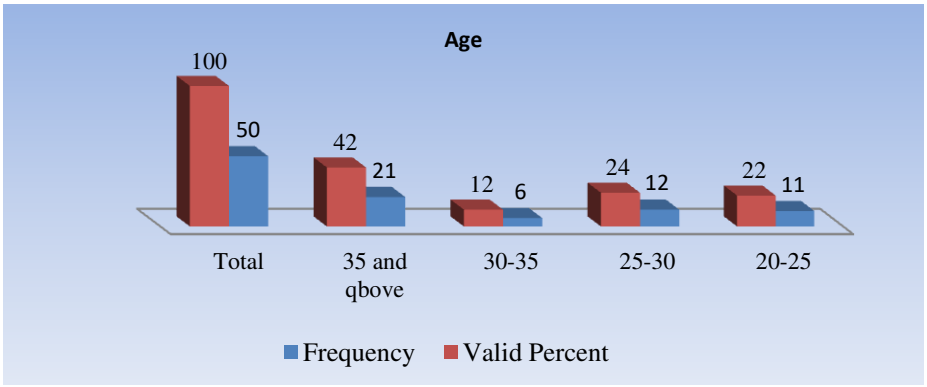


Fig. 2: Distribution of the study sample according to age.

The **Table 8** shows the research observed that largest percentage of the research sample are those who holding a bachelor degree with rate 60.0% followed by those who holding master degree with rate 22.0% followed by those who holding diploma with rate of 18.0% means that the most of the people who work in medical workshops has logical and knowledgeable.

Table 8: Distribution of the study sample according to academic qualification.

Education leave	Frequency	Valid Percent
Diploma	9	18.0
Bachelor's degree	30	60.0
Master's degree	11	22.0
Total	50	100.0

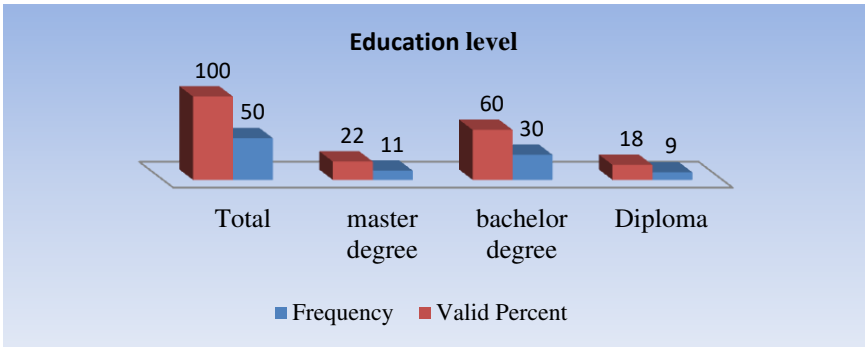


Fig. 3: Distribution of the study sample according to academic qualification.

It is clear that most of the samples are the biomedical engineers and health practitioners, with a rate of 30% for each. followed by the others at 24%, followed by biomedical technician at 16%.

Table 9: Distribution of the study sample according to job position.

Current Position	Frequency	Valid Percent
Biomedical Technician	8	16.0
Biomedical Engineer	15	30.0
Health practitioner	15	30.0
Other	12	24.0
Total	50	100.0

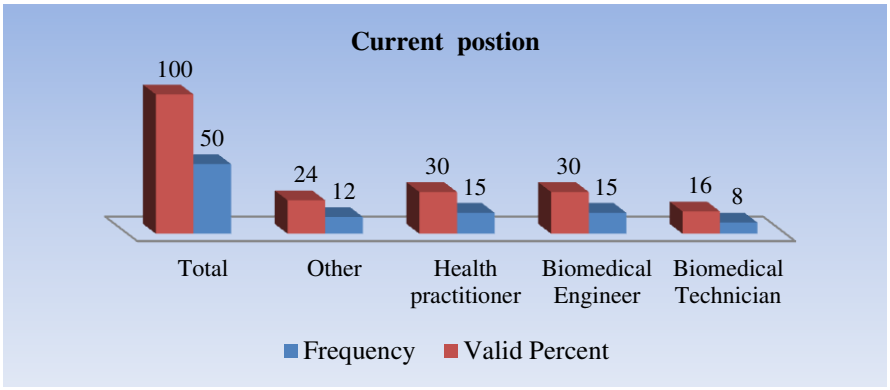


Fig. 4: Distribution of the study sample according to job position.

Table 10: show descriptive statistics for Training.

Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
All maintenance personnel receive sufficient training in maintaining and repairing healthcare equipment	N	9	19	8	6	8	3.30	1.34
	%	18.0	38.0	16.0	12.0	16.0		
Maintenance personnel trained in infection control protocols	N	2	20	14	9	5	3.10	0.984
	%	4.0	40.0	28.0	18.0	10.0		
Ongoing training programs provided for maintenance personnel	N	8	24	12	4	0.984782	3.64	1.07
	%	16.0	48.0	24.0	8.0	4.0		

The descriptive statistics for the training on the risk management in the medical device maintenance workshops show that the highest average score was awarded to the question three about ongoing training programs provided for maintenance personnel, with a mean of 3.64 and a standard deviation of the 1.07. This was followed by the question one about whether all maintenance personnel receive sufficient training in maintaining and repairing healthcare equipment, which received a mean score of 3.30 and a standard deviation of 1.34. The third highest average score was given to the question two about maintenance personnel trained in infection control protocols, with a mean score of 3.10 and a standard deviation of 0.984. Based on these results, the researcher observed that the questionnaire responses ranged between "agree" & "strongly agree," indicating that training is considered important by those who work in the medical workshops in order to reduce risk management.

Table 11: Show descriptive statistics for Equipment Maintenance.

Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
There is a preventive maintenance program for all healthcare equipment?	N	12	25	7	4	2	3.82	1.02
	%	24.0	50.0	14.0	8.0	4.0		
Healthcare equipment inspected, cleaned, calibrated, and repaired on a periodical's basis	N	10	22	11	3	4	3.62	1.12
	%	20.0	44.0	22.0	6.0	8.0		
All maintenance activities documented, including inspections, repairs, and calibrations	N	10	25	4	9	2	3.64	1.12
	%	20.0	50.0	8.0	18.0	4.0		

The descriptive statistics for the Equipment Maintenance on risk management in medical device maintenance workshops show that the highest average score was awarded to the question one about There is a preventive maintenance program for all healthcare equipment, with a mean of the 3.82 and a standard deviation of 1.02. This was followed by the question three: All maintenance activities documented, including inspections, repairs, and calibrations, which received a mean score of 3.64 and a standard deviation of 1.12. The third highest average score was given to the question two Healthcare equipment inspected, cleaned, calibrated, & repaired on a periodical's basis, with a mean score of 3.62 & a standard deviation of 0.984. Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree," indicating equipment maintenance is considered important by the respondents. The highest average scores were given to questions related to the presence of a preventive maintenance program for all healthcare equipment, the documentation of all the maintenance activities (including inspections, repairs, and calibrations), and the periodic inspection, cleaning, calibration, & repair of healthcare equipment. These findings suggest that the respondents place a high value on the implementation of preventive maintenance programs and the proper documentation of the maintenance activities.

Table 12: Show descriptive statistics for Documentation.

Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
There is a comprehensive documentation system to track all maintenance activities	N	9	21	11	4	4	3.55	1.13
	%	18.4	42.9	22.4	8.2	8.2		
All maintenance records regularly reviewed to ensure compliance with regulatory requirements	N	7	18	16	6	3	3.4	1.06
	%	14.0	36.0	32.0	12.0	6.0		
There is a system to ensure that all maintenance personnel, equipment, and parts used during maintenance activities are recorded	N	13	16	13	5	3	3.62	1.15
	%	26.0	32.0	26.0	10.0	6.0		

Ensuring that the healthcare equipment is regularly inspected, cleaned, calibrated, and repaired can help reduce the risk of equipment malfunction and improve patient safety in the medical device maintenance workshops.

The descriptive statistics for Documentation on risk management in medical device maintenance workshops show that the highest average score was awarded to the question three about There is a system to ensure that all maintenance personnel, equipment, and parts used during maintenance activities are recorded, with a mean of 3.62 and a standard deviation of 1.15. This was followed by the question one There is a comprehensive documentation system to track all maintenance activities, which received a mean score of 3.55 and a standard deviation of 1.13. The third highest average score was given to the question two all maintenance records regularly reviewed to ensure compliance with regulatory requirements with a mean score of 3.4 and a standard deviation of 1.15. Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree,". This indicates that the respondents recognize the importance of maintaining accurate and up-to-date records of the maintenance activities in order to ensure accountability and traceability.

Table 13: Show descriptive statistics for Regulatory Compliance.

Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
Regulatory Compliance: The work-shop complies with CIBAHI and JCI standards and regulations	N	6	22	13	7	2	3.46	1.01
	%	12.0	44.0	26.0	14.0	4.0		
All maintenance activities carried out in compliance with regulatory requirements	N	7	28	7	4	4	3.6	1.08
	%	14.0	56.0	14.0	8.0	8.0		
There is a system to monitor changes in regulatory requirements & update policies and procedures accordingly	N	8	24	12	2	4	3.6	1.08
	%	16.0	48.0	24.0	4.0	8.0		

The descriptive statistics for Regulatory Compliance on risk management in medical device maintenance workshops show that the highest average score was awarded to the question three and two. There is a system to monitor changes in regulatory requirements and the update policies and procedures accordingly, activities carried out in compliance with regulatory requirements with a mean of the 3.6 and a standard deviation of 1.08. This was followed by the question one Regulatory Compliance: - The workshop complies with CIBAHI and JCI standards and regulations, which received a mean score of 3.46 and a standard deviation of 1.01. Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree," This indicates that the respondents recognize the importance of staying up to date with the regulatory requirements and adapting policies and procedures to ensure ongoing compliance.

Table 14: show descriptive statistics for Risk Assessment.

Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
A risk assessment conducted to identify potential risks associated with maintenance activities	N	11	19	8	6	6	3.46	1.29
	%	22.0	38.0	16.0	12.0	12.0		
There are strategies to mitigate identified risks	N	7	24	8	5	6	3.42	1.21
	%	14.0	48.0	16.0	10.0	12.0		

The descriptive statistics for Risk Assessment on risk management in the medical device maintenance workshops show that the highest average score was awarded to the question one a risk assessment conducted to the identify potential risks associated with maintenance activities with a mean of 3.46 and a standard deviation

of 1.29. This was followed by the question two There are strategies to mitigate the identified risks, which received a mean score of 3.42 and a standard deviation of 1.21Based on these results, the researcher observed that the questionnaire responses ranged between the "agree" and "strongly agree," This indicates that the respondents recognize the importance of proactively identifying and the assessing potential risks associated with maintenance activities in order to prevent adverse events and ensure patient safety.

Table 15: show descriptive statistics for Performance Testing.

Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
All equipment performance tests conducted regularly	N	8	23	11	4	4	3.54	1.11
	%	16.0	46.0	22.0	8.0	8.0		
Equipment performance tested every three months	N	4	25	11	5	5	3.36	1.10
	%	8.0	50.0	22.0	10.0	10.0		
There is a system to address identified issues during equipment performance testing	N	8	19	9	8	6	3.3	1.26
	%	16.0	38.0	18.0	16.0	12.0		

The descriptive statistics for Performance Testing on risk management in the medical device maintenance workshops show that the highest average score was awarded to the question one about - All equipment performance tests conducted regularly, with a mean of 3.54 and a standard deviation of the 1.11. This was followed by the question two Equipment performance tested every three months, which received a mean score of 3.36and a standard deviation of 1.10 The third highest average score was given to the question two There is a system to address identified issues during equipment performance testing with a mean score of 3.3 and a standard deviation of 1.26 Based on these results, the researcher observed that the questionnaire responses ranged between the "agree" and "strongly agree," This indicates that the respondents recognize the importance of the addressing any issues identified during performance testing in a timely and effective manner to prevent adverse events and ensure patient safety.

Table 16: Show descriptive statistics for Predictive Maintenance Technologies.

Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
Are predictive maintenance technologies, such as machine learning algorithms and predictive analytics, used in the facility	N	6	15	15	3	11	3.04	1.32
	%	12.0	30.0	30.0	6.0	22.0		
There are technologies used to identify potential equipment issues before they occurred	N	6	25	9	5	5	3.44	1.14
	%	12.0	50.0	18.0	10.0	10.0		
Are all of these technologies effective in reducing the likelihood of technical equipment failures	N	7	24	13	2	4	3.56	1.05
	%	14.0	48.0	26.0	4.0	8.0		

The descriptive statistics for Predictive Maintenance Technologies on risk management in medical device maintenance workshops show that the highest average score was awarded to the question three about - Are all of these technologies effective in the reducing the likelihood of technical equipment failures, with a mean of 3.56 and a standard deviation of the 1.05. This was followed by the question two There are technologies used to identify potential equipment issues before they occurred, which received a mean score of 3.44 and a standard deviation of 1.14 The third highest average score was given to the question one Are predictive maintenance technologies, such as machine learning algorithms and predictive analytics, used in the facility with a mean score of 3.04 and a standard deviation of 1.32 Based on these results, the researcher observed

that the questionnaire responses ranged between the "agree" and "strongly agree This indicates that while the respondents recognize potential benefits of these technologies, their utilization in the medical device maintenance workshops may not be as widespread as the other technologies assessed.

Table 17: Show descriptive statistics Quality Control.

Questions		Strong Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Sat Deviation
There Is a quality control program in place to ensure that all maintenance activities are carried out to high standards	N	11	13	14	6	6	3.34	3.34
	%	22.0	26.0	28.0	12.0	12.0		
Maintenance activities audited to ensure compliance with policies & procedures	N	5	24	15	2	4	3.48	1.01
	%	10.0	48.0	30.0	4.0	8.0		
There is a system to address non-compliance or specific areas that require improvement during audits	N	6	17	16	6	5	3.26	1.13
	%	12.0	34.0	32.0	12.0	10.0		

The descriptive statistics for the Quality Control on risk management in medical device maintenance workshops show that the highest average score was awarded to the question two about - the Maintenance activities audited to ensure compliance with policies & procedures, with a mean of 3.48 & a standard deviation of 1.01. This was followed by the question one. There Is a quality control program in place to ensure that all maintenance activities are carried out to high standards, which received a mean score of the 3.34 and a standard deviation of 3.34. The third highest average score was given to the question three. There is a system to address non-compliance or specific areas that require improvement during audits with a mean score of 3.26 and a standard deviation of 1.13. Based on these results, the researcher observed that the questionnaire responses ranged between "agree" and "strongly agree. This indicates that the respondents recognize the importance of addressing any non-compliance issues or areas for improvement identified during audits in a timely and effective manner to prevent adverse events and ensure patient safety.

CONCLUSION:

In conclusion, risk management is a critical component of medical device maintenance workshops to ensure the safety and reliability of equipment used in patient care. Effective risk management involves identifying potential risks, assessing their likelihood and impact, and implementing strategies to mitigate or eliminate them. Establishing tolerance levels for different types of risks is an important aspect of risk management. These levels serve as a guide for decision-making and help senior management determine how to allocate resources to manage risks effectively. Risk treatment involves implementing measures to reduce the probability of risk manifestation & minimize the occurrence of the risk and its consequences. This may involve developing an action plan and using a risk matrix to prioritize risks based on their likelihood and potential impact. Monitoring and supervision are critical components of effective risk management. Regular monitoring and the supervision can help identify potential problems and address them before they become more significant issues. Documentation of the incidents & promoting feedback from the interested parties can continually improve risk management systems.

Timely decision-making is also crucial in risk management for medical device maintenance workshops. The XGER computer tool is an effective instrument that supports the systematic control & supervision of the Prevention Plan measures and the issues reports with useful and relevant information. Overall, effective risk management is critical to the ensuring the safety and reliability of medical devices used in patient care. By implementing appropriate risk management strategies, the medical device maintenance the workshops can minimize the potential for harms and promotes better patient outcomes.

ACKNOWLEDGEMENT:

The authors would like to acknowledge the contributions of the specialists and technicians working in medical device maintenance workshops in the preparation of this article. Thanks are extended with a

profound sense of gratitude and respect to all those who helped them out, in one way or another, to finish the research article.

CONFLICTS OF INTEREST:

The authors declare no conflicts of interest related to this research.

REFERENCES:

1) AIRMIC, ALARM, & MRI, (2002). A Risk Management Standard. Retrieved 05-29-16, retrieved from - www.airmic.com
2) Arias Perez, M. A. (2014). Application of the Integrated Risk Management Procedure to increase the Strategic Prevention capacity of the company Central de equipos Cubiza. Australian and New Zealand Standards Association. (1999). AS/NZS 4360, *Risk Management Australia*.
3) Bolaño Rodríguez, Y. (2014). Strategic management model based on risk management for the integration of the company's management system. *José Antonio Echeverría" Higher Polytechnic Institute, Havana, Cuba*.
4) C. Araújo *et al.* (2018). Managing risks to guarantee the success of your project. *IRBM News*, **39**(6), 102-106. https://doi.org/ 10.1016/j.irbmnw.2018.10.003
5) Collective of Authors. (2011). Procedures Manual for Risk Prevention Management. Santiago de Chile: Chilean Security Association.
6) Collignon, P. C., Conly, J. M., and Woo, G. J. (2016). World Health Organization ranking of antimicrobials according to their importance in human medicine: a critical step for developing risk management strategies to control antimicrobial resistance from food animal production. *Clinical Infectious Diseases*, **63**(8), 1087-1093.
7) Da Silva, C. A., Escande, J., & Farges, G. (2018). Manager les risques pour garantir le succès de votre projet. IRBM News, **39**(6), 102-106.
8) El Younoussi, L., Soulaymani, A., & Mokhtari, A. (2021). Radiodiagnostic Equipment: Regulations & Materiovigilance. In E3S Web of Conferences (Vol. **319**, p. 01090). *EDP Sciences*. https://doi.org/10.1051/e3sconf/202131901090
9) Faisal MA, Islam J, Sakib KN, Tasnim MM, and Yeasmin S. (2023). Estimation of radiological risk on healthcare workers and public in Mymensingh medical college hospital campus, Bangladesh, *Eur. J. Med. Health Sci*., **5**(3), 54-62. https://doi.org/10.34104/ejmhs.023.054062
10) Hashemi-Beni, L., Johnson, C., & Gebrehiwot, A. (2018). Challenges and opportunities for UAV-based digital elevation model generation for flood-risk management: a case of Princeville, *North Carolina*. *Sensors*, **18**(11), 3843.
11) International Organization for Standardization. (2018). Risk Management: Guidelines. *ISO*.
12) International Organization for Standardization. (2019). Medical Devices: Application of Risk Management to Medical Devices. *ISO*.
13) Lehmann, G. M., Verner, M. A., and Simmons, J. E. (2014). Improving the risk assessment of lipophilic persistent environmental chemicals in breast milk. *Critical Reviews in Toxicology*, **44**(7), 600-617. https://doi.org/10.3109/10408444.2014.926306
14) Pérez-Cornejo C., de Quevedo-Puente E., & Delgado-García J.B. (2019). How to manage corporate reputation? The effect of enterprise risk management systems and audit committees on corporate reputation. *Euro. Mana. J.*, **37**(4), 505-515.
15) Thesis in option to the Scientific Title of Master in Direction), Higher Polytechnic Institute "José Antonio Echeverría", Havana, Cuba.
16) World Health Organization ranking of antimicrobials according to their importance in human medicine: a critical step for developing risk management strategies to control anti-microbial resistance from food animal production. *Clin. Infect. Dis.*, **63**(8), 1087-1093.

Citation: Almoghames AHA, Almutairi TLM, and Alqarzaee ASS. (2023). Risk management in medical device maintenance workshops, *Eur. J. Med. Health Sci.*, **5**(6), 204-217.
https://doi.org/10.34104/ejmhs.023.02040217