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إدارة المخاطر في ورش صيانة الأجهزة الطبية
Risk management in medical device
maintenance workshops

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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 impact.

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 failure of these devices can have serious consequences. The maintenance of medical devices is therefore essential to ensure their safe and reliable operation.

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 mitigate them by implementing appropriate controls.

The goal of risk management in medical device maintenance workshops is to minimize the risk of harm to patients, healthcare workers, and others who may come into contact with medical equipment. This involves identifying potential hazards, assessing the level of risk associated with each hazard, and implementing appropriate measures to control or eliminate the risk.

Effective risk management in medical device maintenance workshops requires a 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 maintenance staff. By implementing effective risk management 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.

Statement of the problem

The problem of risk management in medical device maintenance workshops is a critical issue that must be addressed in order to ensure the safety and effectiveness of medical equipment. Medical devices are complex machines that require proper maintenance and repair in order to function properly. Failure to properly maintain or repair medical devices can lead to serious consequences, including patient harm, equipment failure, and increased costs.

Medical device maintenance workshops are designed to provide healthcare professionals with the knowledge and skills necessary to perform maintenance and repairs on medical equipment. However, these workshops also present potential risks, such as inadequate training, lack of equipment or tools, and incomplete or outdated information. Additionally, there may be risks associated with the use of medical equipment during the training, which may increase the risk of equipment failure or malfunction.

The lack of proper risk management in medical device maintenance workshops can have serious consequences for patients, healthcare providers, and healthcare organizations. For example, inadequate maintenance or repairs can lead to equipment failure during medical procedures, which can result in patient harm or even death. In addition, equipment downtime can lead to delays in patient care and increased costs for healthcare organizations.

To address the problem of risk management in medical device maintenance workshops, it is essential to develop and implement effective risk management strategies, including regular assessments of the risks associated with medical equipment maintenance and repair,

training programs that provide comprehensive and up-to-date information on medical device maintenance, and procedures for addressing and reporting equipment failures or malfunctions. By implementing these measures, healthcare organizations can ensure that medical equipment is properly maintained and repaired, and that patients are protected from harm.

Here are some questions that can be used as part of a study on risk management in medical device maintenance workshops:

1. What are the risks that patients may face due to inadequate maintenance of medical devices?
2. What steps should be taken to identify potential risks in medical device maintenance workshops?
3. How can risk management in medical device maintenance workshops be improved?
4. What are the international standards followed in risk management in medical device maintenance?
5. What steps should be taken to evaluate the effectiveness of risk management procedures in medical device maintenance workshops?
6. What are the procedures to be followed in case of any risks in medical device maintenance workshops?
7. How can we ensure that the participants in medical device maintenance workshops are adequately trained in risk management?
8. What is the recommended timeline for conducting a comprehensive audit to ensure compliance with the approved risk management plan in medical device maintenance workshops?

9. What are the procedures to be followed in case of an incident or problem related to risk management in medical device maintenance workshops?

10. What are the tools and techniques used to document risk management in medical device maintenance workshops?

Significant of the study

The study of risk management in medical device maintenance workshops is significant for several reasons. First, medical devices are critical components of modern healthcare, and their proper maintenance is essential for ensuring the safety and well-being of patients. Failure to properly maintain or repair medical devices can lead to serious consequences, including patient harm, equipment failure, and increased costs. Therefore, understanding and managing the risks associated with medical device maintenance workshops is essential for the effective and safe use of medical equipment.

Second, medical device maintenance workshops are an important tool for training healthcare professionals in the proper maintenance and repair of medical equipment. These workshops are designed to provide participants with the knowledge and skills necessary to ensure that medical devices are functioning properly and safely. However, the workshops themselves present potential risks, such as inadequate training, lack of equipment or tools, and incomplete or outdated information. Therefore, understanding and managing the risks associated with medical device maintenance workshops is essential for ensuring that the workshops are effective and safe.

Third, the study of risk management in medical device maintenance workshops can help healthcare organizations to reduce the risk of equipment failure, minimize downtime, and improve patient outcomes. By identifying and managing the risks associated with medical device maintenance workshops, healthcare organizations can ensure that medical equipment is properly maintained and repaired, and that patients are protected from harm. This can ultimately lead to better patient outcomes, increased efficiency, and reduced costs.

Overall, the study of risk management in medical device maintenance workshops is significant because it can help to ensure the safe and effective use of medical equipment, improve patient outcomes, and reduce costs for healthcare organizations.

The objectives of a study

1. Identify the potential risks associated with medical device maintenance workshops, including risks to patient safety, equipment functionality, and regulatory compliance.
2. Develop effective risk management strategies for medical device maintenance workshops, including identifying best practices for training, equipment maintenance, and documentation.
3. Evaluate the effectiveness of current risk management practices in medical device maintenance workshops, including assessing the adequacy of training and documentation, and identifying areas for improvement.
4. Assess the impact of risk management on patient outcomes and healthcare costs, including evaluating the benefits of effective risk

management in terms of improved patient safety and reduced costs associated with equipment failure or downtime.

5. Contribute to the existing body of knowledge on medical device safety and maintenance, by identifying new best practices for risk management in medical device maintenance workshops and publishing the results in a peer-reviewed journal or other publication.

Theoretical foundations of the study

The theoretical foundations of the study are based on cognitive theories of scientific research, where the theory emphasizes the importance of project management offices in the success of projects and the strength of communication between project management offices and projects. The role of project management offices is crucial to the success of these projects. These theoretical foundations provide a framework for understanding the factors that influence risk management in medical device maintenance workshops and for developing effective risk management strategies to ensure patient safety and minimize potential adverse events.

Research 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 analyze and interpret it. The descriptive-analytical methodology allows for the collection of accurate and 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 and 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 and answer the research questions accurately, systematically, and comprehensively.

Research sample

The research sample consists of engineers and technicians working in 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 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.

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