Risk Management on Quality Improvement Project: A Conceptual Framework

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Abstract. Quality is a priority to achieve the business goal of increasing consumer satisfaction. The aim of this study is understanding the framework for risk management on quality improvement project. quality management and risk management are only partially implemented as part of quality improvement projects, many of them are carried out and fail. Although risk management is implemented, it is still at the level of business processes and has yet to produce particular programs for quality improvement. Research on risk management in quality improvement programs is still needed. This research integrates the stages of the PDCA cycle and the framework in ISO 31000. The ISO 31000 risk management framework has four stages of risk management: risk identification, risk analysis, risk evaluation, and treatment of potential risks that impact losses and the emergence of quality costs on quality improvement projects. The PDCA cycle should accomplish quality improvement (Plan, Do, Action and Act). The result this research is the framework model for risk management on quality improvement project can be developed with management commitment. Consumer demand and established product standards serve as the project's initial inputs. When quality improvement is implemented, the risks have already been planned for or created when the quality improvement team was developing the concept of quality improvement. Each 1 cycle is followed by designing the risks contained in each process. Customer satisfaction is the outcome a result. Reducing product quality failures and quality costs are two benefits of using this quality improvement risk concept model. The limitation of this study is the proposed framework can be used to identify, assess, mitigate, and manage or control risks on quality improvement projects for manufacturing companies. Further research that framework be tested on service companies.

Keywords: Framework, PDCA, Quality, Quality Improvement Project, Risk Management.

38. INTRODUCTION

Quality is a priority to achieve the business goal of increasing consumer satisfaction. For a business to survive in a globally competitive market, quality is a crucial component. The secret to remaining competitive is quality [1]. The most critical factor is quality, which must also meet customer expectations [2]. Both consumers and producers value quality [3]. Customer loyalty, more significant profit, customer satisfaction, and an improvement in the company's brand image are the results of meeting consumer expectations. Businesses develop their products by taking consumer needs into account to maximize consumer happiness and loyalty to the items produced [4]. Some companies have

implemented standards as guidelines for running a quality management system. The International Standard for quality management system requirements is ISO 9001. ISO 9001 is a quality management system requirement that focuses on increasing customer satisfaction and conformity of products produced with the standards. Implementing ISO is to realize a company with an optimal process. In addition, several companies have implemented risk management. The standard used in implementing risk management is ISO 31000. It aims to get an excellent business process, producing products that follow standards and preventing the risks contained throughout the business process.

Integration between ISO 9001:2015 and ISO 31000: 2018, namely: ISO 9001:2015 uses the principle of Risk Based Thinking, and ISO 31000 as a guide in identifying risks and implementing risk management. The purpose of ISO 31000 is to evaluate the effectiveness of a company in carrying out risk management. So that by integrating ISO 9001 and ISO 31000 can complement each other to produce quality products and increase customer satisfaction. Integration of Risk Management into the Quality Management System process by applying the PDCA cycle (Plan, Do, Control, and Action). One clause in ISO 9001 is mandatory for risk management measures in every quality management system process. Clause 4.4.1.f, which is supported by Clause 6.1, which is a clause that discusses in detail how to carry out risk management. Implementing ISO 31000 can help companies to achieve goals, help identify risks that have the potential to become threats in the production process, and how to handle these risks. For the sustainability of a company's business, some companies implement quality improvement projects. Quality improvement is a continuous process, that is, its implementation through all stages of the production process of a product. The Risk Based Quality Management System (RBQMS) Model was created by adhering to ISO 31000 and ISO 9001 criteria for management systems. Risk management implemented in the quality management system is regarded as an organization's fundamental or mainstream process. To implement RBQM, metrics, key performance indicators, and quality indicators developed together with a reliable method for analysing and responding to signals. Strong information management, cross-functional training, and communication techniques are required to support both components [5], [6].

Risk is the unpredictability of an event's occurrence that could result in loss or damage. Risk can provide implementation at various levels, including finances, health and safety, reputation, the environment, and the law [7]. The implementation of quality improvement projects is still partial in implementing quality and risk management. Risk management is carried out at the level of business processes in general, yet it leads to specific quality improvement projects. Understanding that hazards can emerge from many sources is crucial in risk management. These include internal and external factors, such as shifts in the market or the regulatory environment and team members' errors or oversights. Understanding possible sources of risk and figuring out the best ways to mitigate them are crucial for effective risk management. Consumer complaints and statistics on product defects, whether in finished items or products still in production, demonstrate that businesses perform quality improvement projects most frequently (finishing goods). The probability of threats affecting the organization is related to the risk component [8]. The two stages of the Quality and Reliability Improvement Models are the problem identification and outcome verification stages. At the result verification stage, the failure improvement measure's the most crucial factor in examining the outcomes of the applied quality improvement [9]. A quality management system can be successfully implemented, maintained, and improved over time with the help of quality and risk management [10]. A systematic and methodical approach to analysing the variability of a process or procedure, including all related hazards and failure modes, and adopting measures to control or eliminate risks in a specific function or system is the combination of quality and risk management [11]. The application of quality and risk management involves four essential components: risk assessment, risk control, risk review, and risk communication [10], [12].

A quality improvement project might gain several advantages from risk management. For instance, proactively identifying and reducing potential risks can lessen the possibility of expensive errors and guarantee that the project is finished on time and under budget.The project team can communicate more effectively with one another and with other stakeholders by using risk management.

Additionally, risk management might aid in raising the project's general quality. We can ensure that the finished project meets the highest standards and achieves the desired goals by detecting and addressing potential risks. Finally, risk management can increase the project's overall success by lowering the likelihood of expensive delays or rework.

The aim of this study is understanding the framework for risk management on quality improvement project. The quality improvement framework collects procedures and methods for locating, evaluating, and reducing potential hazards. Using this framework, the project team can ensure reasonable efforts to identify and mitigate any risks before they have a chance to cause any harm.

39. METHODS

This research integrates the stages of the PDCA cycle and the framework in ISO 31000. The ISO 31000 risk management framework has four stages of risk management: risk identification, risk analysis, risk evaluation, and treatment of potential risks that impact losses and the emergence of quality costs on quality improvement projects. By knowing the risk priority number value and severity value. The PDCA cycle should accomplish quality improvement (Plan, Do, Action and Act).

This research has four stages; namely, the first stage is identifying quality improvement project risks. At this stage, will be: 1) Identifying quality improvement variables which include; 2) Identifying risk variables in quality improvement projects and risk events from achieving quality improvement projects; 3) Calculation of the level of risk contained in the quality improvement project by calculating the RPN value to get the severity rate using the FMEA method; 4. Mapping factors that affect risk management in quality improvement projects. The second stage is the risk analysis of the quality improvement project. At this stage, will be: 1) Modelling risk management in quality improvement projects with PLS-SEM; 2) Calculating quality costs based on FMEA, obtained from calculating the severity value multiplied by the costs incurred according to the failure mode from the RPN calculation; 3) Analysis of influential factors in quality implementation projects; 4) Analysis of the cause of the highest RPN value using root cause analysis and cause-effect diagram (CED). The third stage is risk evaluation on quality improvement projects. At this stage, will be: 1) Preparation of a framework or framework for risk management models in quality improvement projects based on occurrence and severity values using the results of identifying the level of quality improvement and risks contained in quality improvement projects; 2) Focus group discussion (FGD) with related parties according to the measurement results of the level of quality improvement and risks contained in the quality improvement project; 3) Validation of the risk management model framework in the quality improvement project.
Next is the fourth stage, namely risk treatment in quality improvement projects. At this stage, will be carried out: 1) Implementation of risk mitigation; 2) The existence of a risk management policy on quality improvement projects. **Figure 1** shows the research framework.

40. RESULT AND DISCUSSION

The risk management on quality improvement project to enhance quality diverges from Ji's (2011) paradigm for applying the PDCA cycle (Plan, Do, Check, and Action) to ongoing quality improvement. Problem knowledge is transformed into systematic quality knowledge by using the PDCA cycle. As a result, the effects of quality improvement cannot be sustained, and quality management and quality improvement efforts just become formalities that cause ongoing issues. The difficulty in knowledge is changed into systematic quality knowledge using the PDCA cycle. As a result, the effects of quality improvement cannot be sustained, and quality management and quality improvement efforts just become formalities that cause ongoing issues [13]. They used Deming's PDCA cycle in a continuous improvement strategy to promote customer satisfaction. The Quality Management System Model uses a process-based methodology. Next, there is a cycle at the process stage that illustrates management's role in the planning cycle. Next, the management's resources are used at the do stage, and at the control

stage, it is ensured that the product or service's condition is in line with consumer demand. Finally, action is taken by measuring and analysing the current conditions. As a result, the output will take the form of satisfied customers [14]. Then The development of the quality management model was a consideration of risk. Risk encompasses all corporate endeavours, human behaviour, and managerial responsibilities [15]. Risk comprises two (two) components: a) the event that takes place; b) the expense that results from it; c) the problem that will eventually arise. By resolving or lowering the likelihood of the occurrence, the consequence can reduce the risk of each event [16]. Risk is the likelihood that a circumstance will harm quality control, either directly or indirectly, which would result in increased expenses [17]. Risk is calculated by multiplying likelihood by consequence, where the result is the amount of potential loss and probability is the possibility of the risk [18]. Risk management aims to detect risks, assess the likelihood and potential consequences of events, and deal with risks by minimizing the use of resources while eliminating or reducing their effects. Risk management is a vital component of any organization's strategic management [15]. A project-based organization's critical role in risk management is to add value to the business [19]. Risk management is the process of making decisions in such a way as to minimize the adverse effects of potential causes on a functioning economic organization and to prioritize loss mitigation and prevention [20].

The plan-do-check-act cycle of continuous improvement is analogous to the risk management framework [21]. To calculate the risk caused, the first stage involves identifying hazards and evaluating the likelihood and related effects. After that, controls are created to eliminate each risk or significantly lower its associated risk thoroughly. These controls need to be risk assessed to ensure they work, to ensure they won't increase risk, and to figure out how much risk there is. The effectiveness of the risk assessment process should then be confirmed by keeping track of performance once the controls have been put in place.

The Risk Development Model refers to ISO 31000. The risk measurement process has 3 (three) steps, namely: (1) risk identification; (2) risk analysis; and (3) risk evaluation, while in ISO 9001:2015, there is no clause, but the risk document is mandatory in the general introduction [22]. The main advantages and values based on risk are (1) Rejection Risk, a decision where the process accepts the desired outcome, regardless of the risk to the organization. In this case, the organization overrides the implementation of the process; (2) Reducing risk, which is an organization or technical team that aims to eliminate future risks; (3) Limiting risk, which is setting limits in risk management operations; (4) Risk diversification, which is the distribution of risks aimed at minimizing absolute risk; (5) Risk allocation, which seeks to distribute the overall risk value and its components (probability or consequences) with other stakeholders; (6) Reducing likelihood, which aims to reduce the possibility of risk occurrence; and (7) Reducing effects, which seeks to minimize the consequences of risk [22], [23].

The ISO 31000 standard contains an essential risk management process scheme that reflects context definition (situation), processing risk assessment (risk impact), monitoring and review, information exchange, and advice. The effect of risk on an organization can be positive and negative, according to the organization's objectives and different aspects. Developing an awareness of process or procedure variability, including all associated hazards and failure modes, and applying measures to limit or eliminate risks in a specific process or procedure are the goals of quality and risk management integration [11].

Regular risk monitoring is the penultimate phase in the risk management process. Risk management practice is dynamic since the danger likelihood might change over time. It is critical to comprehend the cost of quality when working on programs to increase the rate. The cost of quality is the sum of the expenses for preventing, identifying, and fixing any mistakes in the project. The cost of quality can facilitate better communication between the project team and other stakeholders. The team will have a better knowledge of the budget and be able to communicate any changes on time by knowing

the costs involved with each project phase. Finally, being aware of the price of quality can assist in guaranteeing that the project is finished on schedule and within the allocated budget.

Making a risk register is the first step. In this document, all potential risks connected to the project are listed together with their possible effects. The moment has come to create and put into practice risk mitigation measures after the risks have been identified and evaluated. The solutions must be developed to lessen each risk's possible effects and applied correctly. The most often utilized tools and techniques include risk analysis, mapping, and risk assessment. Identification of potential risks and evaluation of their possible effects comprise risk assessment. Numerous methods may be used, including brainstorming, interviews, and surveys. Risk analysis entails evaluating the potential impact of each risk and selecting the most effective mitigation solutions. Last but not least, risk mapping entails visualizing potential hazards and their potential effects. It's time to start identifying potential risks in quality improvement projects after better understanding the tools and procedures utilized to identify and assess risks. It's crucial to consider both internal and external sources when assessing potential dangers. While team members' errors or oversights are considered internal sources, market or regulatory environment changes are considered external sources. The time has come to begin creating and putting into practice risk mitigation measures after possible risks have been identified and evaluated. It is crucial to include all stakeholders in the process of designing risk-reduction methods.

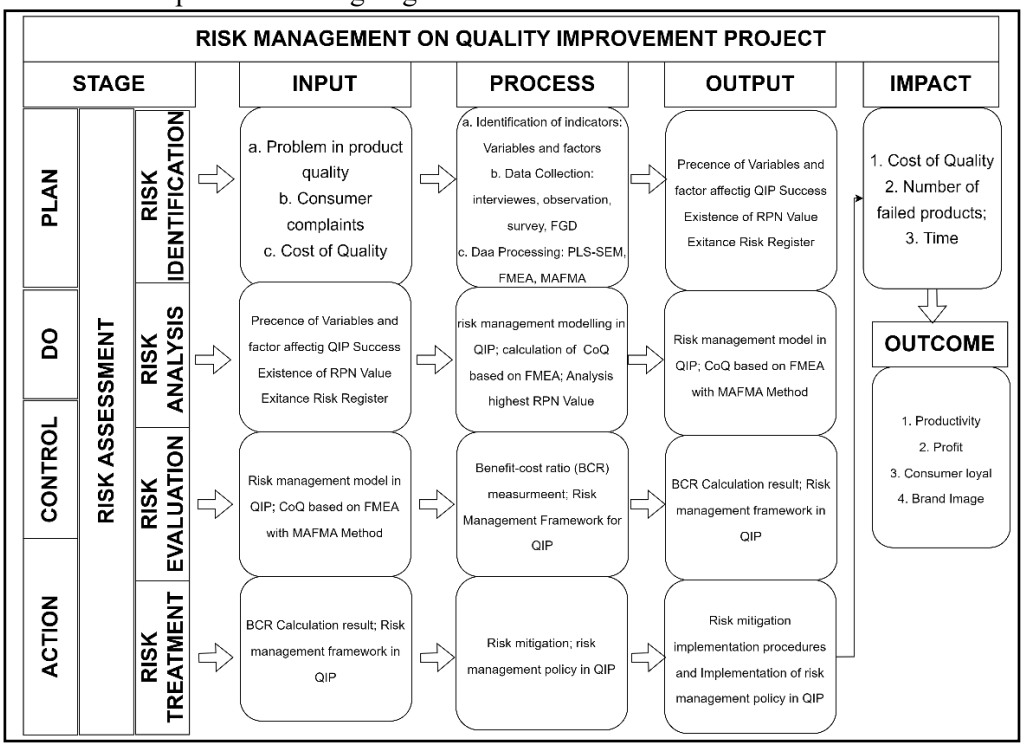

Figure 1. Research Framework

This can make it easier to ensure everyone working on the project is on the same page and pursuing the same objective. Ensure that the final product satisfies the highest standards and consider the costs associated with each technique. The risk management process's evaluation is vital after implementing risk mitigation methods. Figure 2 (see. Appendix 1) shows the conceptual development of a risk management framework for a quality improvement project.

Finally, it's critical to get input from all parties involved. This can make it easier to ensure everyone working on the project is on the same page and pursuing the same objective. Feedback from stakeholders can also be used to find any potential dangers that the risk management process may have missed. Any successful quality improvement project must include risk management, which can make achieving the objectives safer and more effective. The Framework synthesizes risk-based quality management (RBQM) models and the PDCA cycle. Figure 3 shows the creation of a conceptual model to boost customer satisfaction by lowering quality expenses and failure rates. The framework model for risk management on quality improvement project can be developed with management commitment. Consumer demand and established product standards serve as the project's initial inputs. The PDCA cycle should accomplish quality improvement (Plan, Do, Check and Act). When quality improvement is implemented, the risks have already been planned for or created when the quality improvement team was developing the concept of quality improvement. Each 1 cycle is followed by designing the risks contained in each process. Customer satisfaction is the outcome a result. Reducing product quality failures and quality costs are two benefits of using this quality improvement risk concept model. The development of this Framework or conceptual model incorporates the ISO 9001 framework on quality management. Under ISO 9001, clause 6.1 mandates that organizations manage risks, and ISO 31000 is a manual for measuring and putting risk management into practice. One must connect the two frameworks to effectively implement quality standards and measure risks using the PDCA cycle.

41. CONCLUSION

Any successful quality improvement project must include risk management, which can make achieving our objectives safer and more effective. We may advance the project and enjoy the advantages of risk management by comprehending its fundamental ideas and how they can be applied to help succeed with a quality improvement project. The framework model for risk management on quality improvement project can be developed with management commitment. Consumer demand and established product standards serve as the project's initial inputs. The PDCA cycle should accomplish quality improvement (Plan, Do, Check and Act). When quality improvement is implemented, the risks have already been planned for or created when the quality improvement team was developing the concept of quality improvement. Each 1 cycle is followed by designing the risks contained in each process. Customer satisfaction is the outcome a result. Reducing product quality failures and quality costs are two benefits of using this quality improvement risk concept model.

The limitation of this study is the proposed framework can be used to identify, assess, mitigate, and manage or control risks on quality improvement projects for manufacturing companies. It is recommended that it be tested in future research on service companies.

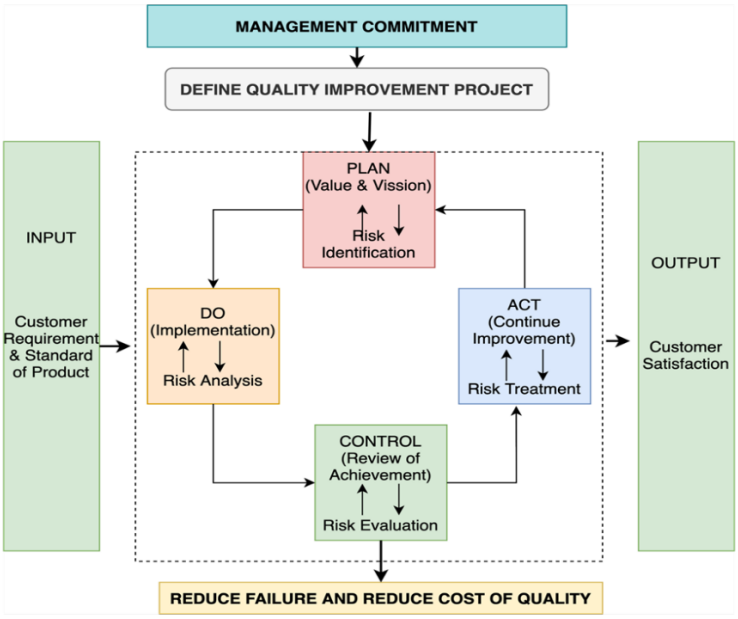

Figure 3. A conceptual framework model for risk management on quality improvement project

42. ACKNOWLEDGEMENT

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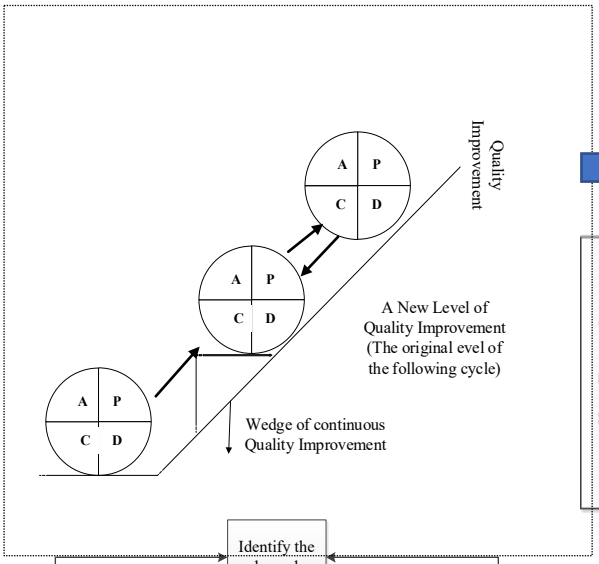
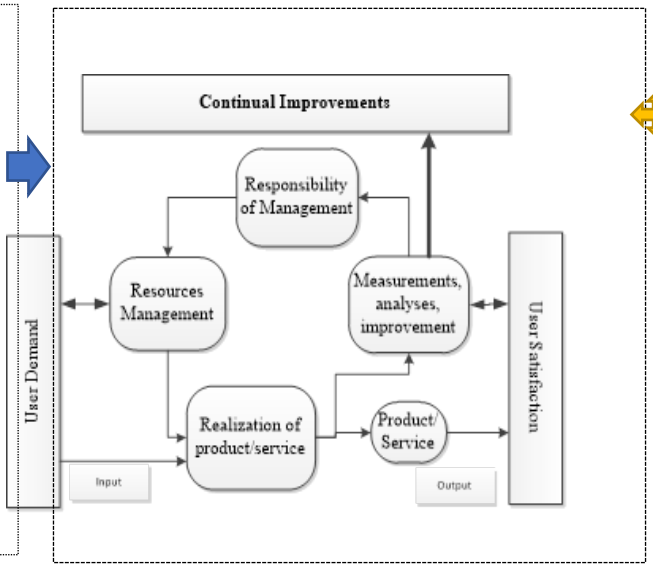
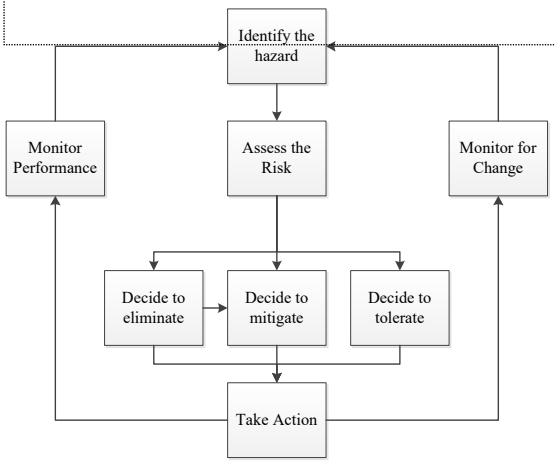
Appendix 1. The conceptual development of a risk management framework for a quality improvement project (figure 2)

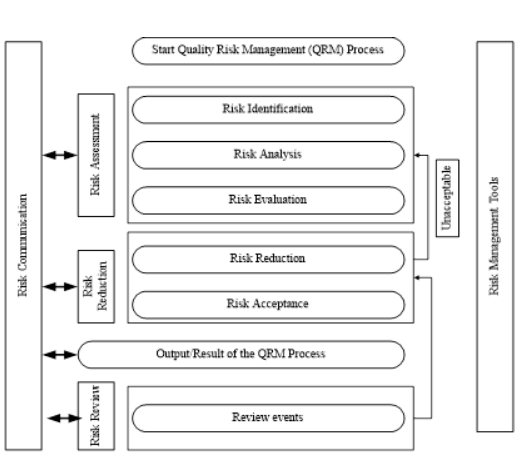






Quality Management System Model based on Process Approach

Basic frameworks for managing risk.
Sources: Galvin, 2017



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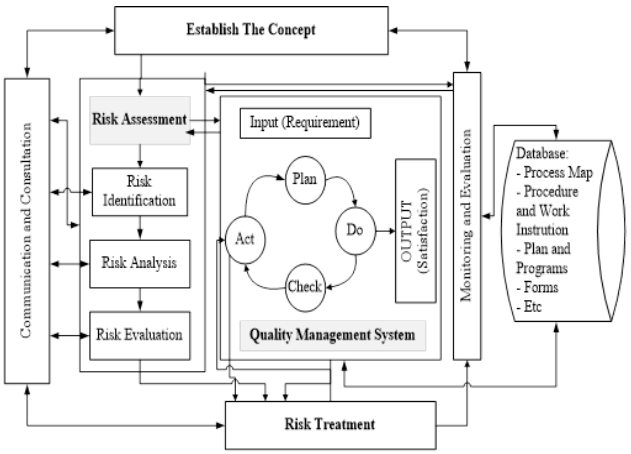

Risk Based Quality Management System Conceptual Model
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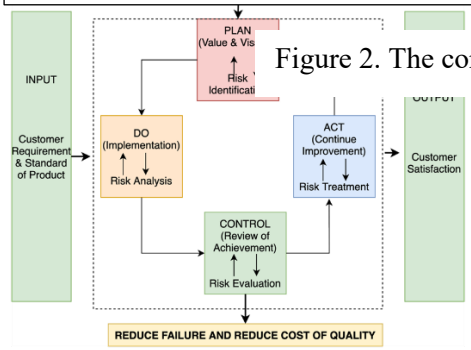

Figure 2. The conceptual development of a risk management framework for a quality improvem

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