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Integrating ISO 31000 with POAC: A Novel Framework for Risk Management in Quality Improvement Projects

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ABSTRACT

IntroductionThe urgency to implement quality improvement projects is driven by the need to quickly respond to product quality issues, market demands, regulatory requirements, and consumer dissatisfaction. Delays in addressing product or service quality problems can result in financial losses, reputational damage, and missed business growth opportunities. Despite the need to integrate risk management into quality improvement projects, there is currently no comprehensive guidance on how to apply risk management principles to these projects. The absence of a structured approach to managing risk creates uncertainty and limits the potential success of quality improvement initiatives. To address this issue, this study proposes the development of a risk management framework specifically for quality improvement projects.

Objectives: The purpose of this study is to develop a comprehensive risk management framework for quality improvement projects. The proposed framework integrates ISO 31000 with the POAC (Planning, Organizing, Actuating, and Controlling) approach, aiming to reduce product failures, minimize quality costs, and enhance customer satisfaction.

Methods: The methodology is developed through empirical studies based on literature reviews, utilizing the ISO 31000 framework in combination with the POAC (Planning, Organizing, Actuating, and Control) method. The study follows four key stages: a literature review, framework development, implementation of the framework in case studies, and validation.

Results: The findings demonstrate that applying the risk management framework to quality improvement projects significantly increases project success, mitigates the impact of risks, and strengthens compliance with relevant quality standards. The novelty of this Research lies in the integration of ISO 31000 with the POAC approach for quality improvement projects, a topic that has been underexplored in previous studies. This study addresses a gap in the literature by emphasizing the critical role of structured risk management in quality improvement initiatives. Additionally, the framework provides practical guidance for companies to manage risks more effectively and enhance the success of their quality improvement projects.

Conclusions: The study follows three phases and eight stages for the proposed framework: 1) Establish the context; 2) Risk Measurement (Actuating Cycles); and 3) Risk Treatment (Controlling). The findings demonstrate that applying the risk management framework to quality improvement projects significantly increases project success, mitigates the impact of risks, and strengthens compliance with relevant quality standards. The novelty of this Research lies in the integration of ISO 31000 with the POAC approach for quality improvement projects, a topic that has been underexplored in previous studies. This study addresses a gap in the literature by emphasizing the critical role of structured risk management in quality improvement initiatives. Additionally, the framework provides practical guidance for companies to manage risks more effectively and enhance the success of their quality improvement projects. The developed risk management framework for quality improvement projects enables companies to manage risks more effectively, reduce quality costs, and enhance customer satisfaction. By implementing this framework, companies can identify and mitigate unidentified risks, thereby enhancing the consistency and success of project execution.

Keywords: Framework, ISO 31000, POAC, Quality Improvement Project, Risk Management.

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INTRODUCTION

The urgency to implement quality improvement projects is driven by the need to quickly respond to product quality issues, market demands, regulatory requirements, and consumer dissatisfaction. Delays in addressing product or service quality problems can result in financial losses, reputational damage, and missed business growth opportunities. Companies often implement a series of gradual improvements to enhance quality (Pan, Zhang, and Chen 2018). The most critical aspect of the improvement process is identifying issues at each stage comprehensively (Florent, Zhen, and Romaric 2009). Quality improvement projects are crucial for a company's growth and sustainability, especially in industries where quality, efficiency, effectiveness, cost reduction, and consumer satisfaction are top priorities.

Risk management is a central part of an organization's strategic management (Ekwere 2016a), and its primary goal is to create value for the company (Khameneh, Taheri, and Ershadi 2016). Effective risk management ensures that quality improvement projects are completed on time, within budget, and in alignment with project objectives while maintaining customer satisfaction, company reputation, and compliance with quality standards. Without considering potential risks—such as unexpected product failures, resource shortages, or technology implementation failures—quality improvement projects are vulnerable to failure, resulting in increased quality costs, delayed production, and suboptimal outcomes. Although risk management is widely applied at the enterprise level, its application in quality improvement projects is often overlooked. Some companies use risk management to address broad operational risks but fail to apply it to specific project-based activities. This gap increases the likelihood of risks in quality improvement initiatives, which could be mitigated through a structured approach. Therefore, integrating risk management into quality improvement projects is crucial for reducing product failures, minimizing quality costs, enhancing product quality, and shortening lead times.

The implementation of quality improvement projects in both manufacturing and service sectors has been shown to increase customer satisfaction and company profits (Ganz et al. 2015; Koval et al. 2018; Al Kurdi et al. 2023; Suef, Suparno, and Singgih 2017). Another positive impact is increased investment (Chan, Ahmad, and Kong 2017). However, the failure of such projects results in direct financial losses, particularly related to quality costs (Duarte, Oliveira, and Santos 2016; Murumkar et al. 2017; Soundararajan and Janardhan Reddy 2019).

Despite the need to integrate risk management into quality improvement projects, there is currently no comprehensive guidance on how to apply risk management principles to these projects. The absence of a structured approach to managing risk creates uncertainty and limits the potential success of quality improvement initiatives. To address this issue, this study proposes the development of a risk management framework specifically for quality improvement projects. This framework aims to provide clear and structured guidance for businesses on systematically implementing risk management in quality improvement projects. By following this framework, organizations can anticipate risks, apply effective mitigation strategies, and achieve more consistent and successful outcomes in their efforts to enhance product and service quality, as well as improve their reputation. The purpose of this study is to develop and propose a comprehensive risk management framework for quality improvement projects. This article is structured into six sections: 1) Introduction; 2) Literature Review; 3) Methodology; 4) Result; 5) Discussion; and 6) Conclusions.

LITERATURE STUDY

The literature review aims to provide a comprehensive understanding of the development of a risk management framework for quality improvement projects. This study utilizes data from Scopus to conduct a literature review on theories and previous Research related to risk management and quality improvement projects. Scopus is one of the most comprehensive citation and abstract databases for peer-reviewed literature (Zahra et al. 2021). The bibliometric Research process consists of three stages: identifying criteria for source selection, extracting software and data, and analyzing and interpreting the data. The first stage involves identifying sources using bibliometric analysis. This results in the collection of relevant publications. The search terms used include "Risk Management" AND "Quality Improvement" or "Risk Management" or "Quality Improvement," yielding results from international journals published between 2000 and 2023. The second stage involves utilizing software and extracting data. The Scopus database was converted into Microsoft Excel in a comma-separated value (CSV) format, containing metadata such as authors, affiliations, titles, year of publication, cited works, keywords, and references. The third stage involves data

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analysis using two approaches: performance analysis and science mapping (Herrera-franco 2021). The analysis includes bibliometric indicators such as country contributions, frequently cited documents, and journal performance. The software used, VOS Viewer, enables analysis of features such as bibliometric coupling, co-citations, and keyword co-occurrence.

Data analysis results from Scopus indicate that between 2000 and 2023, 2,380 scientific documents met the inclusion and exclusion criteria. These documents are divided into four categories: articles (80.6%), conference papers (18.1%), book chapters (1.0%), and books (0.3%). The three fields of study with the most publications between 2000 and 2023 are medicine (1,286 documents, or 54%), engineering (714 documents, or 30%), and computer science (380 documents, or 16%). Six clusters were identified**:** Cluster 1: Risk management and/or quality improvement methods; Cluster 2: Field of study; Cluster 3: Object area with concept; Cluster 4: Connection-related object**;** Cluster 5: Risk mitigation; and Cluster 6: Technology-related studies.

Quality Improvement Project

A Quality Improvement Project (QIP) is a company's primary goal to meet consumer needs while incorporating new technologies and equipment (Ji 2011). In practice, different methods are employed for QIP implementation, depending on the specific conditions and objectives of the project. The development of a framework for QIP implementation typically involves four stages: problem identification, QIP design, implementation, and evaluation (McLean and Antony 2017). Additionally, there are several stages in selecting quality improvement projects based on their contribution to increasing customer satisfaction. These stages include identifying gaps in key performance indicators, determining the potential causes of these gaps, providing alternative quality improvement solutions, selecting projects that have the highest impact on customer satisfaction, and finalizing the chosen project (Tuomala, Danivska, and Gustafsson 2022). The QIP framework typically includes the following stages: defining the problem, analyzing the situation, testing and trialling interventions, locking in improvements, and finally, evaluating and disseminating the outcomes (Hamilton, Jennings, and Forster 2020). To ensure sustainability, frameworks that incorporate new dimensions into the quality improvement model—such as efficiency, timeliness, safety, patient experience, equity, effectiveness, and sustainability—have been developed (Mortimer et al. 2018). The importance of quality improvement projects for companies lies in several key factors: 1) Increasing Competitiveness: In an increasingly competitive market, companies must improve product quality and adhere to standards to enhance consumer satisfaction, reduce waste, and boost the superiority of their products (Antunes et al. 2021; Surya and Senthilselvi 2022); 2). Enhancing Consumer Satisfaction: Consistently improving quality helps companies stay competitive. Implementing quality improvement projects that respond to evolving consumer needs significantly enhances satisfaction (Srivastva, Saxena, and Kumar 2022); 3). Operational Efficiency: QIPs can increase productivity and reduce operational costs by identifying and eliminating inefficiencies, optimizing the use of resources (Alves 2022; Hohmeier et al. 2022); 4) System Compliance: As consumer needs evolve and demands for product quality increase, companies must meet regulatory and certification standards, such as ISO 9001. Continuous improvement as part of a quality management system ensures compliance with consumer and regulatory requirements (Al-rub and Shibhab 2020; Sanchez-Lizarraga et al. 2020); 5) Sustainability and Long-Term Growth: As businesses grow, QIPs help maintain product consistency and high standards, contributing to long-term success and business growth (Duckworth and Hoffmeier 2016; Medina-Rodriguez et al. 2022); 6) Risk Mitigation: Quality improvement projects significantly reduce risks associated with product defects, recalls, and consumer dissatisfaction. At the risk identification stage, companies can proactively address potential risks during project implementation (Gandjour 2022; Helmold et al. 2022).

Risk Management

Risk refers to the uncertainty associated with events or decisions that have the potential to result in gains or losses. The stages of risk management include risk identification and classification, risk analysis, risk management (which involves developing measures to prevent or mitigate consequences), and risk control and monitoring (Marchenko and Cherepovitsyn 2017). Risks differ from obstacles, challenges, and other related concepts in that they involve the combination of the probability of loss and its significance (Popova, Marinova, and Popov 2023). The risk management process involves several phases: defining goals, assessing risks, evaluating their impact, analyzing potential actions, selecting actions, and ongoing monitoring (Olivieri 2023). Risk management serves to identify,

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assess, and mitigate risks while minimizing their effects with the least possible use of resources. It is central to an organization's strategic management (Ekwere 2016a) and is a crucial function in project-based organizations with the primary goal of creating value (Khameneh, Taheri, and Ershadi 2016). Effective risk management ensures that safety is maintained by focusing on loss prevention and mitigation (Ostrowska and Mazur 2015). Studies indicate that risk management plays a crucial role in identifying risks, assessing their potential impacts, and developing effective mitigation strategies to enhance organizational performance. Key components of quality and risk management include (1) risky tasks, (2) risk control, (3) risk review, and (4) communication. Two fundamental principles underpin quality and risk management: (1) quality risk assessments should be based on facts and data, and (2) the level of formality and effort required for risk management should be proportional to the level of risk involved. Common risk categories within organizations include introducing new products into the production line, improving departmental communication, ensuring adherence to vendor agreements, enhancing customer communication, and addressing unexpected production costs (Bhattacharya 2015).

According to Nawaz et al. (2019), risk management techniques, their application, and their implications play a significant role in the success of construction projects, particularly in encouraging key project participants to adopt risk management practices (Nawaz et al. 2019). Risk management frameworks align with the continuous improvement cycle of Plan-Do-Check-Act (Galvin 2017). The ISO 31000 standard outlines the fundamental steps in the risk management process, including defining the context, assessing risks, monitoring and evaluating, sharing information, and providing guidance. Risk can have both positive and negative impacts on an organization, depending on its goals and the associated factors. Effective implementation requires continuous monitoring and reviewing of the risk management process.

Risk Management and Quality Improvement Project Framework

A study on the risk model in the quality management process conducted by Malikova (2017) identifies four key steps in reviewing and initiating risks based on quality management: (1) Risk identification and assessment; (2) Risk control; (3) Risk communication, during which the company initiates and implements risk management, reviews the results, and communicates them. This process ensures the smooth implementation of risk management within the company (Krafcik and Malikova 2016). Malikova's RBQM model was later developed by Samani et al. (2017) by integrating the Risk Management System into the Quality Management System, known as the Risk-Based Quality Management System (RBQMS). This model incorporates the Quality Management System process into the Risk Management System process. The stages of this model include (1) Establishing the context of risk management in the organization and (2) Risk assessment, which involves risk identification, risk analysis, and risk evaluation applied to every quality management system process. The RBQMS model is aligned with the requirements of ISO 31000 and ISO 9001 (M. A. Samani et al. 2017). A more detailed approach to designing each stage of the framework can help guide businesses in applying the risk management framework to quality improvement projects. By applying the four principles of the measurement process to risk management at each stage of the quality improvement project, organizations can ensure effective risk management.

Previous researchers have employed specific methods and approaches to implement quality improvement projects; however, they have often overlooked risk factors. Approaches such as Lean Six Sigma, the PDCA Cycle, and Statistical Process Control (SPC) have been applied in manufacturing companies (Pan and Zhang 2018). Companies apply international standards, such as ISO 9001:2008, as guidelines for running quality management systems and improving product quality. ISO 9001:2008 focuses on increasing customer satisfaction and ensuring product conformity with established standards. The process approach in ISO 9001 encourages organizations to improve customer satisfaction by meeting consumer requirements (Mahmoud Asad Samani et al. 2014).

Risk management and quality are essential components of a management system. The ISO 9000 standard's clauses 1, 4, 5, 6, 7, and 8 aim to mitigate risks within management processes, legal compliance, and operational processes (Morska and Ścierski 2012). During the implementation of a quality improvement project, various risks may arise. In this context, a risk is an uncertain event or situation with potentially positive or negative consequences that could affect the achievement of organizational goals (Mahmoud Asad Samani et al. 2014). To minimize potential risks, it is essential to identify their sources, assess their frequency, and evaluate their impact. ISO 31000 provides a framework for implementing risk management to improve business processes and prevent risks throughout the process.

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Despite some organizations establishing quality and risk management systems, they often do so partially. The ISO 31000 standard outlines the essential elements of a comprehensive risk management system. The integration of risk management and quality management is crucial, as quality management focuses on meeting customer satisfaction requirements, while risk management addresses deviations and unfavourable conditions. The Risk Model for an Integrated Management System (RIMS) requires a strong commitment from management. Setting RIMS objectives based on stakeholder requirements and expectations is a priority during the planning phase (Algheriani et al. 2019)— Several approaches, such as Failure Mode and Effects Analysis (FMEA), Hazard Operability (HAZOP), Failure Mode and Effects Criticality Analysis (FMECA), and risk-based SWOT analysis, can be used to identify, analyze, and evaluate risks. The results of risk evaluation guide the selection of preventive and corrective actions based on the risk level. Organizations that obtain ISO 9001 certification benefit by ensuring that their business processes and products meet standard requirements. The Risk Development Model, based on ISO 31000, demonstrates three processes in risk management: risk identification, risk analysis, and risk evaluation. While ISO 9001:2015 does not have a dedicated clause for risk management, it emphasizes the need for risk documentation in the introduction and appendix (Ezrahovich et al. 2017). Based on the previous discussion, the following conclusions can be drawn: 1) Some methods for implementing quality improvement have yet to fully consider risk factors.; 2) Some frameworks that integrate ISO 9001 and ISO 31000 are still conceptual; 3) The integration of ISO 9001 and ISO 31000 frameworks at the operational level needs further application in quality management.

METHODOLOGY

This framework was developed through an empirical approach that combines a literature review with the ISO 31000 framework and the POAC (Planning, Organizing, Actuating, and Controlling) method to develop a risk management process for quality improvement projects. ISO 31000 is an international standard for risk management aimed at identifying activities related to risk management (Akkiyat and Souissi 2019; Barafort, Mesquida, and Mas 2017, 2019; Henrique et al. 2019; Rampini and Berssaneti 2024). The POAC method is an organizational approach that ensures effective and efficient planning, organizing, leading, and managing resources (Derana 2021; Maduretno and Fajri 2019; Narindro et al. 2020; Sudaryono, Rahardja, and Lutfiani 2020). This Research consists of three phases and eight steps for the Proposed risk management framework for quality improvement projects.

Proposed Risk Management Framework for Quality Improvement Projects

After reviewing several journals on the Research topic, the next stage was to propose the development of a conceptual risk management framework for quality improvement projects. The framework was developed using the POAC (Planning, Organizing, Actuating, Controlling) approach. The objective of this framework is to integrate the ISO 31000 framework and the POAC cycle into quality improvement projects. The framework development process consists of three steps: data collection, data processing, and data analysis.

a) Data Collection Stage

Data collection was conducted through interviews, observations, and documentation. Three key methods were employed: (1) a literature review, (2) purposive sampling interviews with expert informants, and (3) observations based on the literature review and interview results. The interviews were conducted with experts from both academia and industry, while field Research helped verify the validity of the findings. The informants included academics with a minimum of a head lecturer position who had implemented risk management in their Research. Practitioners included permanent employees with at least three years of experience in quality improvement project teams.

The researcher interviewed academics, directors, managers, supervisors, and members of quality improvement project teams from various departments, including integrated production systems (IPS), quality assurance, innovation and improvement, quality control, maintenance, and Research and development. The results of the interviews and literature review were verified through an online focus group discussion (FGD). The FGD allowed for the confirmation of findings regarding quality improvement projects, risk management practices, and the challenges encountered during implementation.

b) Data Processing Stage

After data collection, the data were classified into primary and secondary sources. Triangulation was used to ensure data accuracy, with triangulation methods applied to sources (informants) and data collection techniques

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(interviews, observations, and documents). The results of the data processing provided insights into quality improvement project procedures, classifications of risk categories and factors, and the impact of risks. Data analysis was then conducted using the ISO 31000 framework and the POAC method.

c) Data Analysis Stage

The data analysis stage resulted in the development of a risk management framework for quality improvement projects. The framework development process comprises three phases and eight stages. The selection of the ISO 31000 framework and the POAC method was based on the comprehensive nature of ISO 31000 and the precise process delineation in the POAC cycle, which includes input, process, and output stages (Maduretno and Fajri 2019; Sudaryono, Rahardja, and Lutfiani 2020). The integration of the ISO 31000 framework and the POAC method produced a comprehensive and systematic risk management framework for quality improvement projects. The framework includes three stages: 1) Stage 1: Establish the concept (ISO 31000) and the planning and organizing cycle (POAC); 2) Stage 2: Risk measurement, including risk identification, risk analysis, risk evaluation (ISO 31000) and the actuating cycle (POAC); and 3) Stage 3: Risk treatment (ISO 31000) and the controlling cycle (POAC). The proposed risk management framework is illustrated in **Figure 1,** which presents a new model for applying risk management in quality improvement projects.

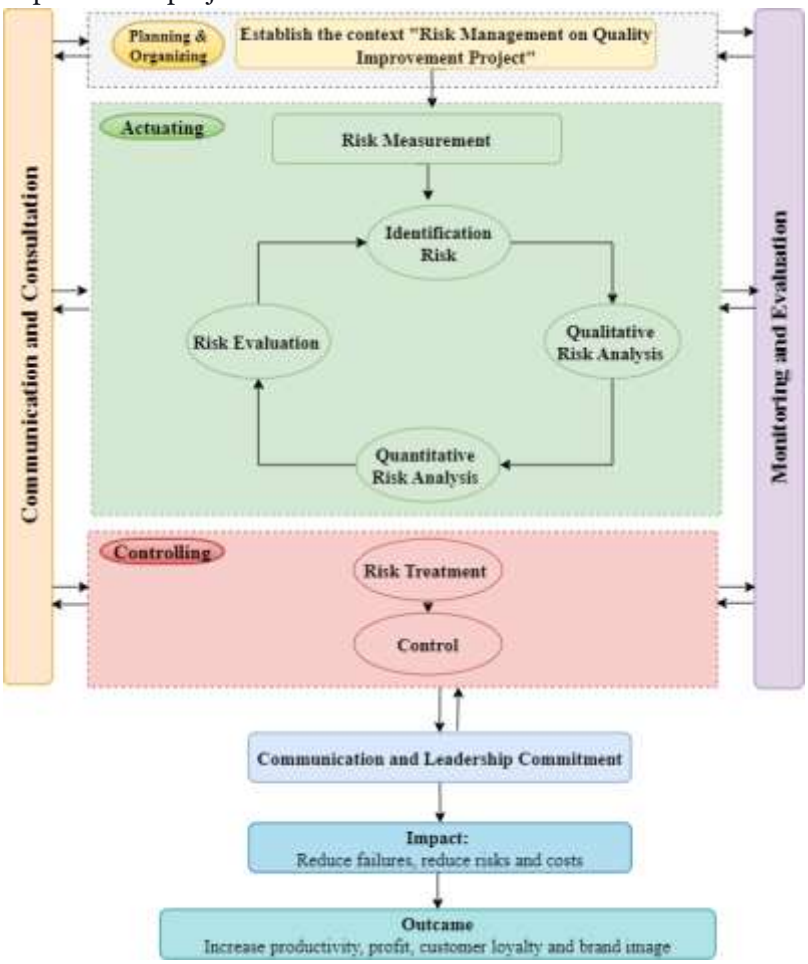

Figure 1. Risk Management Framework on Quality Improvement Projects

RESULTS

The proposed risk management framework is illustrated in Figure 1, which presents a new model for applying risk management in quality improvement projects. The detailed preparation for the framework development includes three phases and eight stages. Below are the phases for developing a risk management framework for quality improvement projects:

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Phase 1- Establish The Context

The first phase, Establish the Context, as outlined in the ISO 31000 framework, defines the organization's goals and the external and internal factors that may influence their achievement (Rodiyah et al. 2021). This phase includes the planning and organizing cycles of the POAC method.

Step 1 - Quality Improvement Project Planning

At the planning stage, the areas for applying risk management in the quality improvement project are identified (Dudin et al. 2017). In the POAC method, there are two cycles: the planning and organizing cycles. To identify the area, several factors are considered (Jevgeni, Eduard, and Roman 2015; B. Jones, Kwong, and Warburton 2021; Mcnab et al. 2020; Silver et al. 2017). One such factor is setting the goal of the quality improvement project. Determining the project's implementation goals is crucial and must consider the following: the company's strategy, the results of performance measurements, and prior improvement efforts (Gelders, Mannaerts, and Maes 1994). The company's strategy can be categorized into four dimensions: high product quality, consistent product quality, customization, and reliable product delivery (Gelders, Mannaerts, and Maes 1994). Brainstorming is one technique used for goal setting. This process, often conducted as a focus group discussion, helps generate ideas or solutions to problems. Participants in this process typically include directors, quality department managers, production managers, and planning department managers, also known as planners. During the goal-setting process, mapping the achievement of key performance indicators (KPIs) becomes a standard set by the company based on its vision and mission.

An empirical study using brainstorming highlights several considerations for proposing a quality improvement project in a department:

1. KPI Achievement: Each department is responsible for meeting its KPI targets, which may necessitate improvement projects.
2. Process Optimization: Even if a department meets KPI standards, further improvement may be warranted to enhance performance.
3. Underperforming Departments: Departments that fail to meet KPIs may propose quality improvement projects to address their shortcomings and align with company goals.

The process of identifying areas or departments for quality improvement project risk management involves cross-departmental brainstorming and discussions with company leaders to assess the urgency and feasibility of each proposed project.

a) Governance *(Organizing)* of Risk Management in Quality Improvement Projects

The steps in the organizing stage include:

1. Forming a Quality Improvement Project (QIP) Team: The QIP team consists of individuals from various departments related to the business processes in need of improvement, accompanied by a coach.
2. Identifying the Problem: The team reviews the problem identified in the planning stage.
3. Proposal Preparation: The QIP team, with the guidance of the coach, prepares a proposal for the quality improvement project, which is submitted to leadership under the coordination of the change management division.

b) Setting Objectives or Targets

Once the Risk Management for Quality Improvement Project (RMQIP) team is formed, the team will determine several key elements (Brennan et al. 2013; Levin 2016; Vos et al. 2010). The Goal Setting: Verifying data for the quality improvement project and ensuring it aligns with departmental standards. This involves:

1. Verifying data through departmental systems.
2. Consulting with personnel responsible for data management.
3. Comparing verified data with company standards.

c) **Data Verification**

The QIP team conducts data verification through checklists and interviews with responsible personnel, such as production managers. For example, when examining rejection data from the production process, an interview may be conducted with the production manager to gain a comprehensive understanding of the process and its results.

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d) Assign activities to achieve *output*.

The QIP team must identify necessary activities, develop a risk management plan, allocate time and resources, and assign tasks to team members. Costs associated with the project may already be included in the departmental budget, such as raw materials for trial runs or training costs for new work standards. If alternative solutions yield unsatisfactory results, the procedure for modifying solutions involves reporting to the coach and the change management division, which is crucial due to potential impacts on time and costs. Periodic monitoring and evaluation are conducted throughout the process to ensure the achievement of quality improvement project objectives

Step 2- *Risk Management Plan*

At the risk management planning stage, the work breakdown structure (WBS) of the quality improvement project is established, and risks at each stage are identified and categorized into level 1 risks (Khameneh, Taheri, and Ershadi 2016). In manufacturing, particularly during final optics assembly, combining Work Breakdown Structure (WBS) and Risk Breakdown Structure (RBS) with the Analytical Hierarchy Process (AHP) streamlines the risk identification process. The integration of the planning and organizing stages in the POAC cycle is captured in the Phase 1 framework, which establishes the Context.

Phase 2- Risk Measurement (Actuating Cycles)

The second phase involves risk measurement, which corresponds to the actuating cycle in the POAC method. Risk measurement is based on the goals established in the "Establish the Context" phase and involves consultation with management, department leaders, and the RMQIP team. By ISO 31000, risk measurement involves three stages: risk identification, risk analysis, and risk evaluation. These stages are integrated into the actuating cycle and are continuously communicated and consulted with the QIP team and coach (Banawi and Bilec 2014; Kozień 2020; Tuno et al. 2022).

Step 3 - Risk Identification

The goal of risk identification is to compile a comprehensive list of risks, encompassing risk events, their causes, potential outcomes, and the affected areas. Risk identification in quality improvement projects is crucial for systematically recognizing potential threats that could impact project objectives (Endris Yadeta 2019). Identifying factors that affect costs, schedules, quality, and project teams helps mitigate potential negative impacts.

In product innovation projects, using RBS during the risk identification stage can enhance the efficiency of all project phases, especially during planning (Ekwere 2016b). In manufacturing, particularly in final optics assembly, WBS and RBS combined with AHP are used to expedite risk identification (Khameneh, Taheri, and Ershadi 2016). RBS involves grouping risks in a hierarchical structure, organizing them in a logical, systematic manner (Rifai, and, and 2018 2018). WBS defines key project milestones and serves as both a planning tool and a project status-reporting mechanism (Su 2012). Risk identification focuses on identifying risk sources, events, their causes, and potential consequences (Luko 2013; Rodiyah et al. 2021). Key activities include measuring QIP performance and establishing risk categories (RBS) for each stage of the quality management project (WBS).

1) Measurement of Quality Improvement Project Results

The actuating stage employs the DMAIC cycle concept and the ISO 31000 framework for risk measurement (Needham et al., 2009; Weiner et al., 2006). Each DMAIC cycle is implemented according to the set objectives, encompassing risk identification, analysis, evaluation, and mitigation. Any changes in improvement solutions are communicated and discussed with the QIP team and coaches, with reports submitted to the change management division to account for time and cost considerations.

A Quality Improvement Project (QIP) is a primary objective for companies to meet consumer needs while leveraging new technologies and equipment (Mahmoud, Solyman, and Elhag 2019). The framework for QIP implementation includes four stages: problem identification, QIP design, implementation, and evaluation (Algheriani et al. 2019). The process for selecting quality improvement projects involves identifying gaps in key performance indicators (KPIs), determining potential causes of these gaps, offering alternative quality improvement projects, selecting projects based on their highest contribution to increasing customer satisfaction and finalising the projects (Robayo-Avendaño and Prato-Garcia 2022).

2) Integration of WBS and RBS in Quality Improvement Projects

During the risk register preparation stage, the risk management team for the quality improvement project identifies risk categories and factors that may be encountered during project implementation. Risks are categorized

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and described using a Risk Breakdown Structure (RBS). The integration of WBS and RBS involves aligning risk categories and factors with each stage of quality improvement project implementation. Identifying stages of the project and their associated risk factors is achieved through focus group discussions (FGDs) with academic experts (lecturers) and practitioners (directors, managers, and supervisors) from the production (IPS), Quality Assurance, Maintenance, and Research and Development departments.

Step 4 - Risk Analysis

The purpose of the risk analysis stage is to assess the impact and probability of risks associated with quality improvement projects. This stage helps prioritize risks and determine the most effective mitigation strategies. The risk analysis process consists of the following steps:

1. Input

The input for the risk analysis stage comes from the output of the risk identification stage, which includes the risk categories that arise during the implementation of quality improvement projects, as well as the risk register developed during the risk identification process.

2. Process

The risk analysis process involves determining the probability (P) and impact (I) categories using the severity index, which is calculated based on responses from all respondents. The process includes:

- Determining the level of risk impact and probability.
- Calculating the impact and probability levels using the risk matrix.

The following steps are involved in risk analysis:

1. Severity Index

Severity Index: The severity index categorizes the risk based on the calculated probability and impact. The higher the percentage of a risk variable, the greater its influence. The severity index is calculated using the formula presented in Chapter 2. According to Hilson (2002), the following formula can be used to calculate the risk level:

$$SI = \frac{\sum_{i=0}^{4} ai \; x \; Xi}{4 \sum_{i=0}^{4} Xi} \; x \; (100) \qquad (1)$$

Where: SI = Severity Index
ai = Rating Constant
Xi = frequency of respondents
i = 0,1,2,3,4, ...n

2. Risk Impact

The severity rating is used to assess the impact level of risk events on project outputs, adjusted according to the risk categories identified during the implementation of the quality improvement project. Table 1 provides the levels of risk impact, noting that risks inherently carry negative consequences and impact (M[onika, Lavin, and Riives 2011).

Table 1 The level of risk impact.

Level	Impact
1	Very low
2	Low
3	Moderate
4	High
5	Very High

3. Risk Probability

A risk event is characterized by its likelihood of occurrence, ranging from just above 0 per cent to just below 100 per cent (M[onika, Lavin, and Riives 2011). Table 2 outlines the levels of risk probability.

Table 2 The level of risk probability

Probability	Level	Description	
Very High	5	Usually occurs in a frequency of weeks per month	More than 10 times in a year
High	4	Likely to occur in months per year	6 – 9 times a year
Moderate	3	Likely to occur in four months per year	3-5 times a year

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Low	2	Very rare occurrence	1-2 times a year
Very low	1	Never happened	Zero

4. Probability Impact Matrix (Risk Matrix)

The risk matrix is a tool to classify risk zones and determine the criticality of each risk factor. A 5x5 matrix is used, with impact levels on the horizontal axis and probability levels on the vertical axis (A. Kassem, Khoiry, and Hamzah 2019; Kassem, Khoiry, and Hamzah 2020). The matrix consists of five zones:

1. Dark Red Zone: Critical risks that must be avoided or transferred; they require top priority and close attention.
2. Light Red Zone: Critical risks that should be reduced, transferred, or shared with stakeholders; they require careful attention.
3. Yellow Zone: Moderate risks that require control.
4. Dark Green Zone: Low-risk areas that require monitoring or control.
5. Light Green Zone: Very low-risk areas that can be monitored, controlled, or ignored.

The probability-impact matrix (PIM) method is used to evaluate the level of risk for each factor (A. Kassem, Khoiry, and Hamzah 2019). The Probability Impact Matrix (PIM) method is used to evaluate risk factors (A. Kassem, Khoiry, and Hamzah 2020). Once the probability and impact are assessed, the values are multiplied using the formula to determine the overall risk level. Table 3 illustrates the risk levels in the probability-impact matrix. To calculate the level of risk, the following formula 2 can be used:

$$R = P \times I \quad (2)$$

Where: R = Risk Level
P = Probability of the risk
I = Impact level of the risk

Table 3 illustrates the risk levels in the probability impact matrix

Risk Level	Value	Severity Index (%)	Control
Critical	20-25	87,5 < SI < 100	Risks cannot be tolerated. Follow-up details must be established, and senior management must implement priorities.
High	15-19	62,5 < SI < 87,49	Risks are tolerable if preventive measures are implemented, such as routine procedures and inspections. Monitoring and inspection should occur at least every six months.
Medium	10-14	37,5 < SI < 62,49	Risks are tolerable if preventive measures are implemented, such as routine procedures and inspections. Monitoring and inspection should occur at least every six months
Low	5-9	12,5 < SI < 37,49	Risks are tolerable, and precautions have been taken. Review annually.
Very Low	0-4	0,00 < SI < 12,49	Risks are tolerable, and precautions have been taken. Review annually, as risks have a minor effect.

5. Risk Management Priorities

Following the probability-impact matrix assessment, risk management priorities are established. Table 4 categorizes risk levels and outlines the corresponding actions to be taken.

Table 4 Categories of risk levels and actions taken

Risk Level Category	Score (X)	Actions Taken
1 (low)	$X \leq 4$	No action required (*Acceptable*)
2 (Moderate)	$4 < X \leq 8$	Action is recommended if resources are available (Supplementary Issue).
3 (High)	$8 < X \leq 12$	Action required to manage risk (Issue)
4 (Extreme)	$12 < X \leq 25$	Immediate action is needed to manage risk (Unacceptable).

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3) Output

The output of the risk analysis is a risk matrix for quality improvement projects.

Step 5 - Risk Evaluation

The purpose of the risk evaluation stage is to determine whether the identified risks are acceptable or require further mitigation. This step ensures that risks that may threaten quality improvement projects are identified and addressed appropriately. The risk evaluation process includes the following:

1. Input

The input for the risk evaluation stage comes from the output of the risk analysis stage, primarily the risk matrix.

2. Process

The risk evaluation process involves determining the level of risk that can be accepted. The following steps are included:

a. Compare the results of the risk analysis with the company's established risk criteria.

b. Classify risks into the following categories:

1) Acceptable Risks: Risks that are deemed manageable and do not necessitate further action.

2) Risks Needing Mitigation: Risks that require a mitigation plan due to their unacceptable probability or impact.

3) Risks Requiring Monitoring: Risks that require continuous monitoring despite being acceptable.

3. Output

The output of the risk evaluation is the risk register, which details whether each risk is accepted, avoided, transferred, or requires mitigation measures. The results of the risk evaluation guide decision-making for risk handling during the control stage.

Phase 3 – Controlling (Risk Treatment and Control Cycles)

The control phase focuses on managing critical factors to maintain the results of the product quality improvement project and the processes implemented (Banawi and Bilec 2014; E. C. Jones, Parast, and Adams 2010; Soundararajan and Reddy 2020). The goal of the control stage is to optimize critical factors, develop solutions, and enhance quality. It aims to minimize the negative impact of risks on achieving project objectives. Risk control is a key element in quality improvement project management and includes the following strategies: a. Avoiding Risks: Deciding not to start or continue activities that pose risks by altering the project plan to eliminate risks; b. Mitigating Risks: Reducing the likelihood or impact of risks through proactive measures; c. Transferring Risks: Shifting risks to third parties; and d) Accepting Risks: Accepting certain risks while preparing contingency plans in case they materialize. After completing all activities in the actuating stage, the next step is to implement risk control. The risk control process in this stage includes:

Step 6 - Risk Treatment

Risk treatment involves actions aimed at reducing, avoiding, transferring, or accepting evaluated risks. The chosen strategy depends on the potential impact of the risk on the quality improvement project. Risk treatment influences the level of residual risk remaining after mitigation. Effective risk treatment ensures that significant risks do not interfere with the project's objectives. The risk treatment process includes:

1. Input

The input for risk treatment comes from the risk evaluation stage, specifically the decisions made regarding whether to accept, avoid, mitigate, or manage the risks. This information is recorded in the risk evaluation register.

2. Process

The process involves:

- Implementing strategies to manage risks based on evaluation decisions.
- Monitoring and adjusting mitigation measures as necessary.

3. Output

The output of the risk treatment process is a risk mitigation action plan, an updated risk status, and steps to be taken, all of which are documented in the risk register.

Step 7 – Standardization

The results of risk treatment should be formalized into a risk response plan and updated in the risk register. To implement the results of risk management in quality improvement projects, legal documents such as Standard Operating Procedures (SOPs) or Work Instructions (WIs) must be created. The steps for standardization include:

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1. Input
   The input comes from the risk register following the risk treatment phase.
2. Process
   The process of standardizing the results of risk management includes:
   a. Establishing leadership policies in the form of changes to SOPs, WIs, or work standards
   b. Demonstrating management's commitment and support for implementing risk management in quality improvement projects (RMQIP).
3. Output
   The output includes the creation of legal documents, such as SOPs, WIs, and company policies. These documents mandate the implementation of risk management in all business lines and processes within the organization.

The Change Management Division coordinates management policies related to SOP changes, while the Human Resources Development Department handles training and education for employees. Any changes in equipment or processes are coordinated by the production department in collaboration with the RMQIP team.

Step 8 - Sustainability of RMQIP Implementation

The sustainability of RMQIP results is ensured through continuous monitoring and evaluation of the implementation of risk management projects and periodic quality improvement (Boguslavsky and Gutierrez 2019; Bullington et al. 2002).

The steps for ensuring sustainability include:

1. Input
   Standardization serves as the input, ensuring the legality of the quality improvement project management results.
2. Process
   The standardization process includes:
   a. Preparing a monitoring schedule for the first six months following the dissemination of the RMQIP results.
   b. Conducting periodic evaluations based on the monitoring results.
3. Output

The output is a report detailing the success rate and obstacles encountered during the implementation of RMQIP. This report helps identify potential improvement solutions. Monitoring the implementation of risk management in quality improvement projects helps assess how effectively the company applies risk management practices and implements changes to its business processes. **Figure 2** is a detailed design of the risk management framework for the improvement project, which includes each phase, stage, input, process, output, tools and methods used, the person in charge, and the outputs produced at each stage.

DISCUSSION

This study found that integrating ISO 31000 with the POAC method in developing a risk management framework for quality improvement projects had a positive impact on product quality, customer satisfaction, and quality cost reduction. By systematically identifying and assessing risks using the probability-impact matrix, the framework enabled practical risk evaluation and prioritization. The highest risks were identified and mitigated to reduce their occurrence. After risk response activities, a risk register was developed to document identified risks, their analyses, responses, and any residual risks.

This study highlights the importance of applying risk management to quality improvement projects, which has often been overlooked in industry practice. By integrating ISO 31000 and POAC, the framework provides a comprehensive solution for managing risks throughout all project phases. The findings align with previous Research, which suggests that failure to manage risks is often a primary cause of quality improvement project failures (Ekwere 2016a; Khameneh, Taheri, and Ershadi 2016). The risk management framework also demonstrated its ability to improve productivity by reducing the number of product defects, thereby increasing yield and decreasing quality costs. This is consistent with previous research showing that implementing the ISO 31000 risk management framework improves performance in terms of cost, safety, quality, and time management (Oduoza 2020). Likewise, Research that integrates ISO 9001:2015 and ISO 31000 can improve performance (Ezrahovich et al. 2017). However, Research conducted by Suprin et al. (2019) in developing a framework through the integration of ISO 9001 and ISO 31000 risk management framework in quality management and improvement processes by considering the strategy

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of improvement solutions as a decision-making strategy, setting consumer and performance expectations, and business aspects of the company's internal processes and process priorities for improvement that have an impact on performance and critical factors in Competitive competition (Suprin et al. 2019). Meanwhile, the Research conducted by Popescu in developing a framework through the integration of ISO 9001 and a risk framework in the purchasing process in a company only considers organizational factors to implement a risk-based quality management system (Popescu and Dascalu 2011).

The results of this study also indicate that the use of the POAC method effectively controls the stages of implementing risk management in quality improvement projects. This results in potential risks that can be managed more effectively and efficiently. By integrating the ISO 31000 framework with the POAC cycle, it can be learned that each phase and stage of implementing risk management in an improvement project is structured and systematic with an overview of inputs, processes, outputs, methods or tools used and the person in charge, this is a guide for companies in managing risk management in each of their business processes. The results of this study are in line with previous Research related to project management improvement strategies using the POAC method can control costs (Sudaryono, Rahardja, and Lutfiani 2020). Meanwhile, Research applied to the field of education by applying the POAC method can help students be more active and optimistic, quickly understand the concept of learning (Maduretno and Fajri 2019).

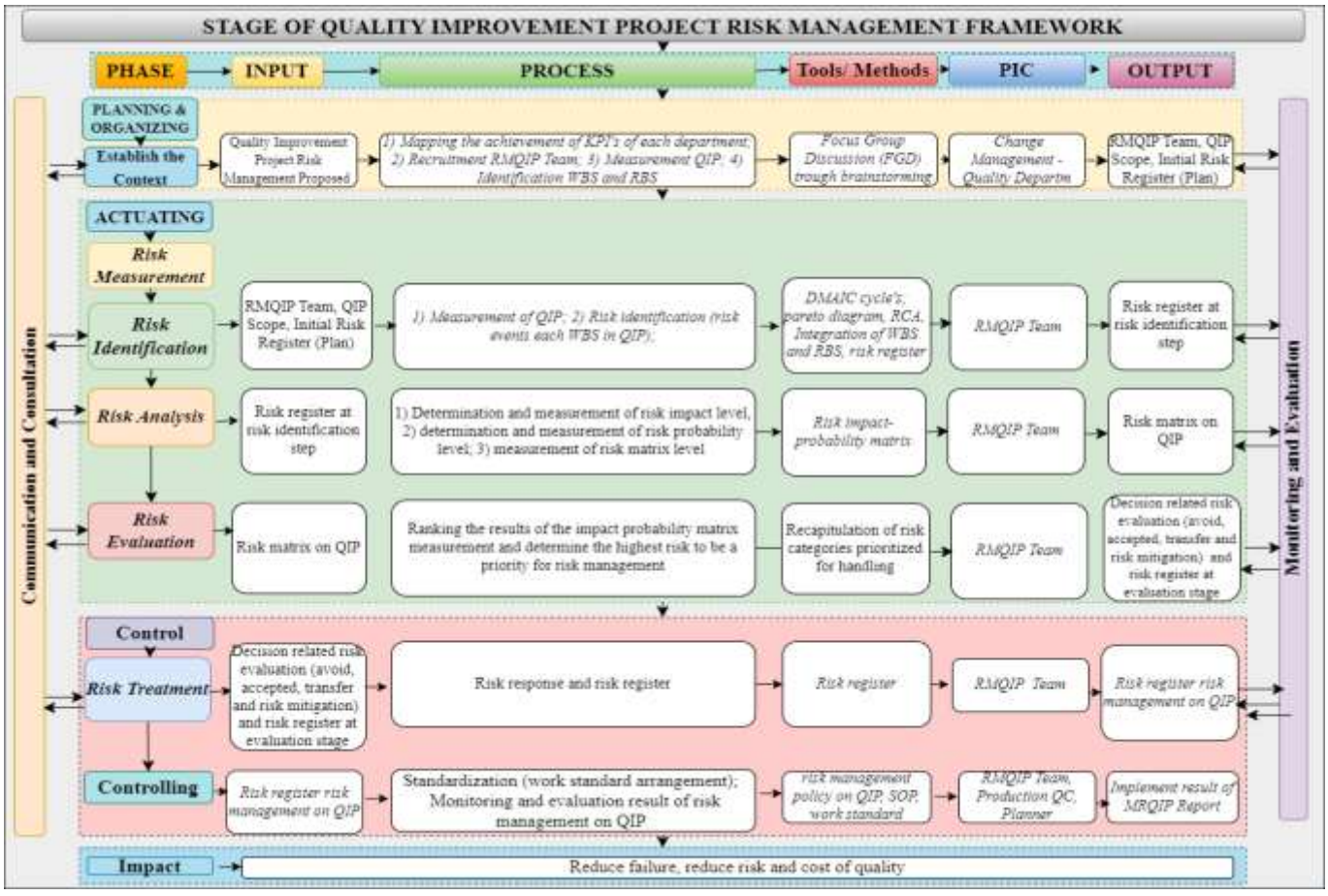

Figure 2 Detailed Design Of The Risk Management Framework For The Improvement Project

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