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Original Research Article

Strategy for Addressing Risks in the New Product Development Process at a Stamping Company

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Abstract

This paper describes a strategy for the evaluation and management of risks to mitigate the inherent risks associated with new developments within a stamping company. It highlights the importance of identifying and assessing risks through a semiquantitative for risk management in the company's new development process, enabling adaptation to the organizational context and processes, while facilitating replication in similar manufacturing environments. The goal of the proposed analysis is to define actions to address the risks, thus reducing the likelihood of their occurrence or, in the event they materialize, minimizing their impact. As a result of the applied case in the process of new developments, low, moderate and high risks were identified, which, according to the proposed criteria, led to the establishment of improvement actions to reduce the probability of occurrence.

Keywords: Risks, probability, impact, process, manufacturing, new developments.

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1. INTRODUCTION

In the current business environment, risks are a constant factor in process and operations management. From external uncertainties, such as regulatory changes and economic fluctuations, to internal factors such as system failures or communication deficiencies, risks have the potential to significantly affect the efficiency, profitability, and reputation of organizations. Therefore, within the development of processes in a management system, proactively addressing risks becomes a strategic necessity to ensure long-term continuity and success.

Risk definition and risk management

The concept of risk has been addressed by various international standards and guidelines as a key element in organizational and project management. ISO 31000:2018 defines risk as the effect of uncertainty on the objectives of an organization [International Organization for Standardization ISO, 2018].

In the context of project management, the Project Management Institute (PMI) defines project risk as an uncertain event or condition that, if it occurs, may have a positive or negative effect on project objectives [Project Management Institute, 2017].

Likewise, ISO 31000:2018 states that the risk management process involves the systematic application of organizational policies, procedures, and practices integrated into communication and consultation activities, context establishment, risk assessment, risk treatment, monitoring, review, as well as risk recording and reporting [International Organization for Standardization ISO, 2018].

Within this process, risk assessment constitutes a fundamental stage, as it provides a structured approach to identifying how organizational objectives may be affected and to analyzing risks based on their consequences and likelihood of occurrence, prior to determining the need to implement risk treatment actions, in accordance with the guidelines established in UNE-EN 31010 [Asociación Española de Normalización, 2010]. Figure 1 presents an adaptation of the risk management process in accordance with ISO 31000:2018 and its linkage to the supporting tools established in UNE-EN 31010.

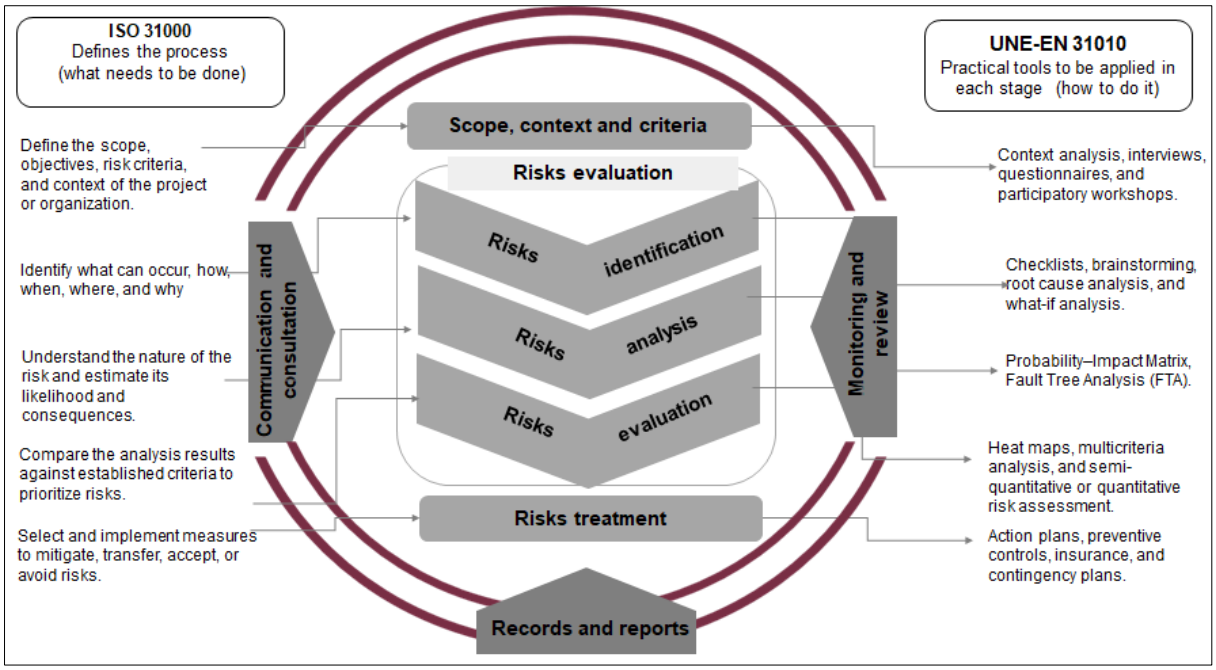


Figure 1. Key stages of risk management.
Source: Adapted from ISO 31000:2018 and UNE-EN31010:2010

This article aims to describe the strategy used to address the management of risks associated with the new product development process within a Management System in a company dedicated to the stamping of electrical steel components, under the framework of ISO 31000:2018.

The proposal is presented as an application case of the risk-based approach to the new product development process, with the objective of ensuring the achievement of intended results, preventing or reducing undesired effects, and contributing to continuous improvement.

Furthermore, the methodology employed is intended to be replicable and applicable to the remaining processes that comprise the Management System, as well as to other organizations.

2. METHOD

The ISO/TR 31004 standard establishes that, although organizations differ in terms of their context and starting point, a generic approach to risk management can be applied in all cases, provided that such an approach is adapted to the specific characteristics of each organization (International Organization for Standardization ISO, 2016).

Complementarily, the UNE-EN 31010 standard states that the depth of risk analysis should reflect the initial perception of the potential consequences, the level of available technical knowledge, and the resources available to the organization. It also emphasizes that the proper application of a simple method can produce better results than the use of more complex procedures applied inadequately (Asociación Española de Normalización UNE, 2010).

In this context, for risk management focused on the new product development process within a Quality Management System, a risk assessment framework based on a semi-quantitative tool was designed.

The risk management methodology employed in this study was developed following the structure and guidelines established by ISO 31000:2018. In particular, its systematic approach was adopted for risk assessment and treatment, as well as for communication, monitoring, and review activities, ensuring consistency of the risk management process with internationally recognized best practices and its appropriate integration into the organization's Management System.

1) Scope, context, and criteria

At this stage, it is important that the person responsible for leading the risk management process has already defined the scope of the risks to be assessed, as well as the internal and external context. The criteria established during the risk management design stage constitute the tool to be used during the risk analysis.

2) Risk assessment

Risk assessment comprises three main elements, as described below:

Risk identification: Correctly identifying risks is an essential part of conducting an effective analysis and treatment process. Communication and consultation with all stakeholders involved are particularly important at this stage, as is having a clear understanding of the scope

and context from which the assessment will be conducted.

Different techniques and tools can be used to support risk identification. Some of these include brainstorming, root cause analysis, interviews and questionnaires, Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis, Ishikawa diagrams, checklists, and reviews.

Risk analysis: Risk analysis was conducted using a semi-quantitative approach based on the tool proposed by Alfonso *et al.,* (2019). This tool includes an initial qualitative assessment of the probability of occurrence and impact of risks, classifying them into five levels: very low, low, medium, high, and very high, to which numerical scores are assigned on a scale from 1 to 9.

Subsequently, a quantitative analysis is performed, in which the risk rating is obtained by applying Equation (1), thereby determining a relative risk level for each identified event.

Table 1: Criteria for estimating the probability of occurance

Classification	Value	Probability Criteria	Estimated Occurance Range
Very low	1	Unlikely to occur. It may occur under exceptional circumstances. To date, there are no previous records of its occurrence.	<5%
Low	3	Low likelihood of occurrence. Although not entirely impossible, the conditions required for its occurrence are uncommon and cannot be completely ruled out.	5-20%
Moderate	5	Moderate likelihood of occurrence. The contributing factors are relatively common, although their presence does not guarantee that the event will occur.	20-40%
High	7	High likelihood of occurrence. This type of risk is relatively frequent or almost always present in similar situations.	50-70%
Very high	9	Extremely high likelihood of occurrence. The risk event is almost certain to occur, either because it is associated with inherent process conditions or due to other recurring factors.	>70%

Source: *Prepared by the author*

The probability and impact criteria were defined according to the organization's specific context, considering its operational experience and historical data from new product development projects, as presented in Table 1.

Subsequently, the impact of each risk is defined based on the established criteria. In this case, Cost, Time, and Quality were used as the criteria to be considered, as shown in Table 2.

Table 2: Criteria for impact estimation

Classification	Value	Impact Criteria	Impact On Objectives
Very low	1	The occurrence of the risk would have minimal or no consequences for product development. It would not significantly affect project progress or alter the development objectives.	**Cost**: Additional costs would be negligible or nonexistent. **Time**: Development time would remain unaffected. **Quality**: Product quality would not be affected in any way.
Low	3	The risk would have limited and relatively insignificant consequences for the project. Although its occurrence could cause certain inconveniences, these could be easily managed without jeopardizing the project schedule or budget	**Cost**: Minor cost increases with no significant impact on the budget. **Time**: Minor delays (e.g., a few days or weeks) that would not jeopardize the delivery deadline. **Quality**: Minor design changes that would not affect the final product quality.
Moderate	5	The occurrence of this risk would have a noticeable impact on the project, potentially causing issues related to time, cost, or quality. However, the project could continue with modifications to the plans or adjustments to the available resources.	**Cost**: A moderate budget increase that could require adjustments but would remain within manageable limits. **Time**: Delays that could require schedule replanning but would not jeopardize the final delivery objective. **Quality**: The risk could affect product quality or require adjustments, but would not seriously compromise its functionality.

Classification	Value	Impact Criteria	Impact On Objectives
High	7	This risk would have a considerable impact on product development. Its consequences would be severe and could compromise project progress, affecting costs, delivery timelines, or product quality.	**Cost**: A considerable budget increase that could require financial replanning or additional resources to cover unforeseen expenses. **Time**: Significant delays that could jeopardize the original delivery date and require substantial schedule replanning. **Quality**: The risk could seriously affect product quality, requiring modifications that would increase development costs or time.
Very high	9	The occurrence of this risk would have devastating consequences for the project. Its repercussions could jeopardize the success of product development and even its overall feasibility. This type of risk could lead to project suspension or significant deviations from expected outcomes, affecting profitability, corporate reputation, and the product's commercial future.	**Cost**: A dramatic increase in costs that could render the project unfeasible or require substantial additional funding. **Time**: Delays so significant that the project might not be completed within the original timeframe, affecting its ability to reach the market on schedule. **Quality**: The product might fail to meet the expected quality standards, potentially resulting in product failures or consumer rejection.

Source: *Prepared by the author*

It is important to note that the criteria used to estimate probability and impact, as well as their respective weightings, are not established as generic values; rather, they are adapted to the specific context of the organization. Their definition considers both the experience of the project management team and the analysis of the historical performance of new product development projects, allowing for a risk characterization consistent with the company's operational reality.

Risk Evaluation: Once the values from the Probability table and the Impact table have been identified, the following mathematical formula (1), which defines the assessment method used in this tool, is applied.

$$Risk = Probability\ x\ Impact$$

Based on the result obtained from the formula and following the Probability–Impact Matrix presented in Table 3, the final score is determined to establish the corresponding risk rating.

3) Risk Treatment

At this stage, the aim is to establish the appropriate treatment based on the criteria defined for each type of risk, as indicated in Table 4.

Table 3: Probability–Impact Matrix

		PROBABILITY				
		Very low	Low	Moderate	High	Very high
		1	3	5	7	9
IMPACT						
Very low	1	1	3	5	7	9
Low	3	3	9	15	21	27
Moderate	5	5	15	25	35	45
High	7	7	21	35	49	63
Very high	9	9	27	45	63	81

Source: *Prepared by the author*

Table 4: Risk Prioritization for Action

Score	Evaluation	Actions to be taken
>45	High risk	They must be addressed urgently, prioritizing mitigation measures, contingency planning, and response planning. Management and senior leadership must be informed.
21-35	Moderate risk	Implement minor modifications or improvements to procedures or strategies to prevent the risk. Inform supervisors.
>20	Low risk	Controls may or may not be established. Extensive monitoring is not required; however, the risk must be documented and reviewed periodically. Action should only be taken if unexpected changes in conditions arise.

Source: *prepared by the author*

For risk treatment, safeguards or controls can be defined to mitigate or reduce risks.

The types of safeguards are as follows:

- Preventive safeguards: controls designed to prevent or reduce the occurrence of a risk.
- Containment safeguards: controls designed to contain potential effects and reduce the impact that could occur if the risk materializes.

Within the method used, supporting elements are considered and integrated into each of the three main steps: (1) Scope, context, and criteria; (2) Risk assessment; and (3) Risk analysis.

The supporting elements are as follows:

a) Communication and Consultation

All interested parties must be informed and consulted to ensure their involvement and sense of ownership. This ensures that risk perceptions are shared and that informed decisions are made. This element should be present in order to:

- Clearly communicate the context and objectives. stakeholders regarding their understanding of the context and expectations.
- Share information on the identified risks.
- Consult stakeholders to obtain their input regarding risk identification.
- Communicate decisions regarding risk treatment.
- Explain the rationale behind decisions and their benefits.
- Obtain feedback on the proposed strategies.
- Involve stakeholders in the implementation of risk treatment actions.

b) Recording and Reporting

This is a key element because it enables the proper documentation and communication of identified risks, their assessment, and the treatment applied, as follows:

- Record the criteria and parameters for risk management.
- Document stakeholder expectations and requirements.
- Record policies and procedures.
- Record all identified risks.
- Record risk assessments.
- Report the most critical risks.
- Record risk treatment actions and the action plan.

c) Monitoring and Review

This approach ensures that the organization can adapt its actions to changing circumstances and respond effectively to risks. This element should be present in order to:

- Monitor changes in the environment.
- Review objectives.
- Continuously review risk identification.
- Monitor the assessment of probability and impact.
- Review risk assessments against the established criteria.
- Monitor the effectiveness of control measures.
- Review the feasibility of risk treatment actions.
- Assess available resources and capabilities.

3. RESULTS

To carry out this study, the New Product Development process within the Quality Management System of a company dedicated to the stamping of electrical steel components was selected.

The process was carried out as follows:

1. Define the process to be analyzed.
2. Risk assessment.
3. Risk treatment.
4. Risk monitoring and review.

The development of each step is presented below:

1) Define the Process to Be Analyzed

The New Product Development process at the stamping company is structured as shown in Figure 2. The scope, as well as its inputs, activities, and outputs, are defined to provide a better understanding of the context.

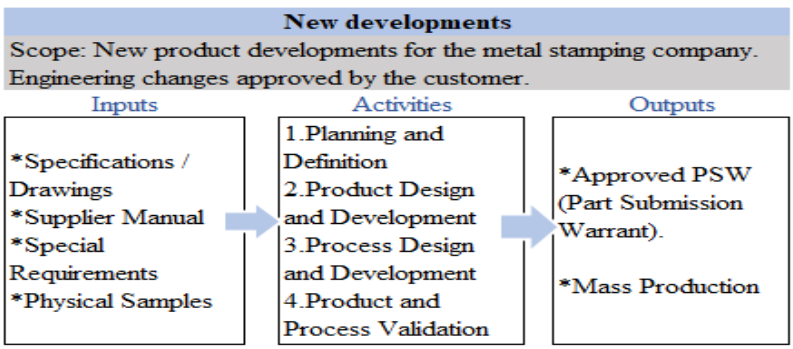


Figure 2: Structure of the New Product Development Process
Source: prepared by the author

2) Risk Assessment

To assess the risks, the three elements were integrated into Table 5 to provide a clearer overview. The following aspects were considered:

- **Risk Identification:** The risk descriptions, as well as their potential causes and consequences, were included. The activities defined in the New Product Development process, as indicated in Table 4, were used as the basis for identifying these risks, and the risks were subsequently broken down from each activity.
- **Risk Analysis:** A column was included to indicate the classification and value assigned to Probability (P value) and Impact (I value). The criteria were based on those established in Tables 1 and 2.
- **Risk Evaluation:** The last column of Table 5 presents the risk level, calculated by multiplying the probability and impact values. The criteria for the risk evaluation were established based on Tables 3 and 4.

Table 5: Risk Assessment of the New Product Development Process

Risk assessment									
Process:		**New developments**							
#	Risk description	Possible causes	Probability		Consequencce	Impacto		Risk level	
			Classification	Value P		Classification	Value I	PxI	Classification
1	Incomplete or inaccurate process input information.	Ambiguous or incomplete specifications; outdated drawings; inadequate communication with the customer.	High	7	Design errors; rework; development delays.	High	7	49	High risk
2	Errors in product design and development.	Incorrect interpretation of requirements; lack of cross-functional review; limited experience.	Moderate	5	Nonconforming product; validation rejection; failure to meet requirements.	Moderate	5	25	Moderate risk
3	Deficiencies in process design and development.	Inappropriate process selection; lack of capability analysis; insufficient pilot testing.	Low	3	Process variability; quality issues; failures during mass production.	Moderate	5	15	Low risk
4	Insufficient product and process validation.	Incomplete testing; unclear acceptance criteria.	Moderate	5	Release of nonconforming products; PSW rejection; rework.	Moderate	5	25	Moderate risk
5	Delays in the release for mass production.	Late engineering changes; dependence on external approvals; failures detected during the final stages.	Moderate	7	Missed deadlines; negative impact on customer satisfaction.	Moderate	7	49	Moderate risk

Source: prepared by the author

3) Risk Treatment

Once the evaluation of each risk had been completed, its treatment was defined in accordance with the criteria established in Table 4. The analysis resulted in risk levels classified as high, medium, and low. Based on these criteria, preventive and control actions were assigned to risks classified as high and medium.

Table 6: Presents the actions defined for these risks

Risk treatment			
# Risk	Actions	Date	Responsible
1	Formal review of requirements; development of input checklists; validation of information with the customer.	ene-25	Eng. APQP
2	Establish design reviews involving a multidisciplinary team and require formal approval from all team members.	feb-25	Eng. APQP
4	Clearly define validation criteria and obtain formal approval prior to release.	mar-25	Eng. APQP
5	Establish a Change Management Procedure and conduct periodic project monitoring.	feb-25	Eng. APQP

Source: *prepared by the author*

3) Risk Monitoring and review

Once the treatment actions had been implemented, the risks were subjected to a monitoring and review process in order to verify the effectiveness of the defined actions and promptly detect deviations or the emergence of new risks. This monitoring was carried out through specific indicators, periodic reviews, and analysis of the risk status, ensuring the continuous improvement of the New Product Development process within the Management System, as shown in Table 7.

Table 7: Risk monitoring and review

Risk	**Implemented action**	**Monitoring indicator**	**Review frequency**	**Risk status**	**Responsible**	**Evidence**
1	Formal review of requirements and validation with the customer.	Percentage of requirements validated without rework.	Monthly	Controlled	Eng. APQP	Requirements checklists, validation emails.
2	Multidisciplinary design reviews.	Number of findings identified during design reviews.	At each Project phase	Under monitoring	Eng. APQP	Design review meeting minutes.
4	Definition of validation criteria and formal approval.	Compliance with established criteria prior to release	Per project	Controlled	Eng. APQP	Approval records, validation reports.
5	Change Management Procedure and project monitoring.	Number of uncontrolled changes.	Monthly	Under monitoring	Eng. APQP	Change requests, progress reports.

Source: *prepared by the author*

Once the stages of risk identification, assessment, treatment, monitoring, and review had been completed, the application of the proposed methodology was concluded, following the structure established by ISO 31000. This process made it possible to systematically assess the risks associated with the New Product Development process, ensuring consistency in the analysis and the integration of a risk-based approach into the Management System.

4. DISCUSSION

The results obtained demonstrate that the application of a risk management methodology based on ISO 31000:2018 and UNE-EN 31010 contributes to a more structured management of the New Product Development process within the Management System. The use of a probability–impact matrix, defined according to the context of the stamping company, made it possible to prioritize management risks and support preventive decision-making.

From a methodological perspective, the integration of a semiquantitative approach is consistent with the findings reported in the literature, which highlight the effectiveness of simple tools when properly applied [UNE-EN 31010, 2010; Doria *et al.,*2020]. Likewise, the incorporation of monitoring and review stages made it possible to verify the effectiveness of the defined treatment actions and strengthened the continuous improvement of the New Product

Development process, in accordance with the good practices established by ISO 31000:2018 and the approach proposed by the Project Management Institute (2017) in the field of project management.

Finally, the results show that the methodology is adaptable and replicable in other processes within the Management System or in manufacturing organizations with similar characteristics. This reinforces its practical validity and its contribution as a supporting tool for risk-ares management in industrial environments.

5. CONCLUSIONS

The study made it possible to establish a structured methodology for addressing risks in the New Product Development process, aligned with ISO 31000:2018 and supported by the risk assessment techniques described in UNE-EN 31010. The application of this approach facilitated the incorporation of risk-based thinking into the Management System, strengthening process planning and control.

The main contribution of the study is the practical adaptation of the regulatory framework to a specific manufacturing context through the use of a semiquantitative tool that enables the prioritization of management risks and the systematic definition of preventive actions. The methodology can be applied to other processes within the Management System, promoting continuous improvement and proactive risk management.

As future work, it is suggested that the analysis be expanded through the incorporation of performance indicators to evaluate the impact of risk management on long-term organizational outcomes. This version retains the focus and terms used in your article, including New Product Development process, Management System, risk-based approach, semiquantitative approach, risk treatment, monitoring and review, and continuous improvement.

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