

Assessing Risk Management Implementation in Quality Management System

Fathurohman^{1*}, Muhamad Ekhsan², Nur Laela³

Universitas Pelita Bangsa

Corresponding Author: Fathurohman fathur.eng@pelitabangsa.ac.id

ARTICLE INFO

Keywords: Risk Management, Quality Management System

Received : 05, February

Revised : 10, March

Accepted: 15, Month

©2023 Fathurohman, Ekhsan, Laela:
This is an open-access article
distributed under the terms of the
[Creative Commons Atribusi 4.0
Internasional](https://creativecommons.org/licenses/by/4.0/).



ABSTRACT

The implementation of quality management system requires to consider risks and opportunities in planning the system, refers to clause 6.1 ISO 9001:2015. The management of PT. Dharma Poliplast implemented a risk mitigation system to fulfill the needs, expectations and Key Performance Indicators of stakeholders but quality problems still recur. This research aimed to analyze the implementation of risk management according to ISO 9001: 2015 and ISO 31000 requirements and by comparing the implementation of risk management to a best practice company. The approach used in this research was descriptive qualitative using secondary data from the internal company. The results of this research proved that PT. Dharma Poliplast has implemented risk management in accordance with requirements of ISO 9001:2015 and ISO 31000 and best practices effectively.

INTRODUCTION

The development of industry in the current era of globalization is inevitable, this is due to the intense competition in the industrial world. In order to survive in the competition, of course, the company must have strategies such as price differentiation, product or service, the accuracy of delivery time and which is not less important is the quality standard (Kotler et al., 2019). The implementation of a quality management system in a manufacturing industry company is essential for the company to remain able to compete and have superior products. To anticipate the ever-increasing demands of customers and markets, the company needs to have a quality recognition that can be used as proof that the company's products have been internationally recognized.

The implementation of risk management in quality management systems based on the ISO 9001:2015 method has become an important topic in today's business and industry contexts. Risk management aims to identify, evaluate, and manage risks that may occur in the organization's operations. Meanwhile, quality management systems focus on ensuring that the products or services produced meet the established quality standards and satisfy customers. ISO 9001:2015 is an international standard that provides guidelines for quality management systems. This standard emphasizes the importance of risk management in ensuring the effectiveness of quality management systems and provides a clear framework for integrating risk management into quality management system.

In practice, the implementation of risk management in quality management systems can help organizations to identify the risks that may occur in their operations, and take preventive or mitigating measures to reduce or eliminate those risks. Thus, organizations can improve the efficiency and efficiency of their operations, as well as ensure customer satisfaction and other relevant parties.

In the analysis of the implementation of risk management in a quality management system based on the ISO 9001:2015 method, it is necessary to study the best practices that have been applied by organizations in integrating risk management into their quality management systems. In addition, it is also necessary to evaluate the successful implementation of risk management in improving the effectiveness and efficiency of the organization's operations, as well as ensuring customer satisfaction and other relevant parties.

Thus, the analysis of the implementation of risk management in a quality management system based on the ISO 9001:2015 method can provide guidance and recommendations for organizations in developing and improving their quality management systems, as well as ensuring business sustainability and long-term continuity of their operations.

Proof of quality recognition is by obtaining certification and implementing the Quality Management System (SMM) ISO 9001. ISO 9001 quality management system is about quality assurance in organizations concerning the processes of design, development, production, installation and service. The implementation of ISO 9001 SMM plays an important role in

supporting the achievement of a company's quality standards. With the implementation of SMM ISO 9001, it is expected to improve quality so that it can provide customer satisfaction (Arli et al., 2015), meet the needs of the market, and indirectly improve the quality of Human Resources (HR) in the company, which then human resources management can produce quality products (Hariandja, 2021)

ISO 9001:2015 clause 6.1 requires companies to consider risks and opportunities when planning quality management systems. With the goal of continuously monitoring changes, evaluating risks and opportunities and taking action before problems occur or preparing the company to survive in an era of faster change.

PT. Dharma Poliplast is a company that operates in the plastic injection industry. The company has always strived to always produce quality products as the primary policy on both design, production and finished products according to customer needs. Evidence that the company has strived to do all that can be seen from the commitment of the company that has obtained ISO 9001:2015 certification. ISO 9001:2015 certified by PT. Dharma Poliplast is something that is obtained with the hard work done by all parties in the company. ISO 9001:2015 requires companies to implement risk management in every process. However, from the audit results of 2019, there are audit findings in PT. Dharma Poliplast means that there is no risk mitigation in an effort to meet the needs and expectations of the interested parties and focus on the KPI (Key Performance Indicator) not just of the history problem.

THEORETICAL REVIEW

ISO 9001:2015 is the latest version of the standard on quality management systems. ISO 9001:2015 uses the concept of risk based thinking (RBT), which is to identify risks within an organization so that it can avoid various risks in carrying out the process. Considering risk in the process is important, because processes must have several risks that will interfere with the continuity or the purpose of the process. RBT incorporates its process approach into the entire organizational environment in order to urge organizations to be more cautious and adopt long-term thinking. As a result, prevention becomes a habit, and RBT becomes ingrained in their culture and the company can reduce the impact of the risks that will arise (Chiarini, 2017)

The ISO 31000 standard, which is based on the PDCA (plan-do-check-act) cycle, is a commonly utilized risk technique. The standard gives businesses instructions for handling risks in a flexible manner (ISO/TC, 2018). Because ISO 31000 focuses on how to execute risk management, a component not included in ISO 9001 criteria, it is a viable option (Muzaimi et al., 2017). The success of risk management will depend on the effectiveness of the management framework that provides the basis and governance that will adhere to the entire organization at all levels. The framework assists in managing risk effectively through the application of the risk management process at various levels and in the specific context of the organization. The framework ensures that information on risks arising from the risk management process is adequately

reported and used as a basis for decision making and accountability at all relevant levels of the organization (Hiles, 2012). The risk management framework based on ISO 31000 begins with mandate and commitment, this is important because it determines the accountability, authority and capability of risk management actors, implementation of "Plan, Do, Check, Act", which includes understanding the organization and its context, establishing risk management policies, establishing risk management accountability, integrating risk management into the organization's business processes, allocating risk management resources, and establishing communication mechanisms internal and external and implementation of risk management processes, namely monitoring and reviewing followed by continuous improvement to facilitate changes that occur in the internal and external context of the organization. This process is carried out repeatedly to produce a reliable risk management application (Vorst et al., 2018)

One of the ISO 31000 series standards proposes strategies to help with risk management. According to de Aguiar (2015), the Failure Mode and Effects Analysis (FMEA), a widely used method for analyzing potential failures from any organizational perspective, follows a structured approach that starts with recognized failure modes and progresses through levels of investigation until the entire mode and effect relationship is defined and prioritized. Its major goal is to solve the problems that have been recognized, as well as to develop preventative action plans to prevent them from happening again.

METHODOLOGY

Stage in conducting this research to analyze the implementation of risk management in the quality management system ISO 9001:2015. In the initial phase is to carry out secondary data observations and literature and best practice studies. To observe secondary data in this study is to look at actual conditions. Actual conditions are already existing conditions related to planning and procedures, then actual conditions compared with the requirements of ISO 9001:2015 and ISO 31000 as well as perform observations of best practices related to the application of risk management by the company so as to obtain the result gap with actual conditions. Each department makes a Risk profile based on the KPI and performs Cascading against the Risk that is made subsequently submitting recommendations for improvement of planning and research procedures carried out in PT. Dharma Poliplast uses secondary data, which is the collection of data from the internal PT company. Dharma Poliplast by itself.

RESULTS

Assess the effectiveness of risk management measures. Dharma Poliplast performs monitoring and review in 2 levels, namely Efficiency of the risk management system and Effectiveness of the management of each risk. The process of monitoring and reviewing the management of each risk is carried out through SDCA and PDCA processes. Risk Treatment that has been agreed must be drawn up by written standards formally, followed by PDCA on the implementation of those standards. The main focus in monitoring and review is

how effective the implementation of risk treatment and how effective risk treatment is carried out in reducing the risk to the agreed. The monitoring and review process can be carried out in routine coordination meetings, such as weekly, monthly and quarterly. Analysis of the effectiveness of the implementation of the risk management system and management of the main risks, preferably included in the company's annual report, and being discussed in the meeting between the Directorate and the Board of Commissioners. The following presentation on the monitoring table achievement:

MONITORING PENCAPAIAN									
NO	Proses	TARGE T	ACTUAL PENCAPAIAN						KETERANGAN
			TAHUN 2019			TAHUN 2020			
			OKT	NOV	DES	JAN	FEB	MAR	
I	MARKETING								
1	Kepuasan Pelanggan	- EPS Good Performance (W2 N+1)	RANK A	RANK A	RANK A	RANK A	RANK A	RANK A	Excellent Supplier
2	Property Customer	- Tidak ada kehilangan property customer/ kerusakan sebelum waktunya	Tidak masuk ke dalam monitoring pencapaian			100%	100%	100%	Data vs Act 100%
II	PRODUKSI								
1	Proses produksi (Injection dan Painting)	- AR 100%	88,80%	90,60%	90,2%	91,3%	89,6%	89,8%	Tidak tercapai karena line stop mesin, material dan MP
		- Reject Rate 2,5% dari sales	3,80%	2,90%	2,90%	2,3%	2,1%	2,1%	Good
		- Claim 40 ppm	40ppm	60ppm	22ppm	18 ppm	35 ppm	17 ppm	Good
		- Line stop MP (0 Menit)	13,892	8,311	7,777	0	970	1500	Tidak tercapai karena Tidak ada MP (MP Sakit)
		- Zero Accident	0	1	1	1	1	2	Rank C (Apparatus) karena MP bekerja tidak sesuai WI
III	MAINTENANCE								
1	Perawatan dan Perbaikan Mesin, Mold dan utility	- Perawatan mesin berjalan/ sesuai schedule (100%)	Tidak masuk ke dalam monitoring pencapaian			100% on schedule	100% on schedule	100% on schedule	on schedule
		- Zero line stop	13,892	8,311	7,777	160 menit	23 menit	29 menit	Tidak tercapai karena perawatan, penanganan, dan manajemen sparepart belum tepat
		- OT MTC (480 jam/ bulan)	Tidak masuk ke dalam monitoring pencapaian			On budget	On budget	On budget	On budget
		- Zero Accident	0	0	0	0	0	0	Zero Accident
IV	QUALITY								
1	Pengendalian Kualitas	- Claim sesuai target (40 ppm)	40ppm	60ppm	22ppm	18 ppm	35 ppm	17 ppm	Good
		- PICA supplier closing 100%	Tidak masuk ke dalam monitoring pencapaian			0	0	0	100% close
		- Zero Accident	0	0	0	0	0	0	Zero Accident
2	PTS	- Claim berulang = 0	Tidak masuk ke dalam monitoring pencapaian			0	0	0	Zero claim berulang
		- Respons time dalam menjawab PICA (based on customer)				On schedule	On schedule	On schedule	On schedule
		- 100% Ontime verifikasi limit sample				100% ontime	100% ontime	100% ontime	100% ontime
3	Kalibrasi dan Alat Ukur	- 100% Ontime kalibrasi (D)	Tidak masuk ke dalam monitoring pencapaian			100% ontime	100% ontime	100% ontime	100% ontime
		- Zero Claim yang disebabkan oleh alat ukur				0	0	0	Zero claim alat ukur
		- Zero Accident				0	0	0	0
V	MDEV								

1	Tinjauan Manajemen (Pengendalian PM danAM)	- AR COE + Tingkat Kehadiran (Q)	Tidak masuk ke dalam monitoring pencapaian	95%	85%	97%	Tidak tercapai karena ada project internal atau agenda customer
		- MOM + PICA Gap Performance Analysis (Q,D)		On schedule	On schedule	On schedule	On schedule
		- Progress PICA Closed (Q,D)		85%	85%	90%	Tidak tercapai karena perbaikan tidak ontime dilaksanakan dan kendala dengan budget

Table 1. Monitoring of Achievement

Certification of ISO 9001:2015

In ISO 9001:2015 requirements, clause 6.1 requires companies to consider risks and opportunities in conducting company quality management system planning to promote risk-based thinking. Here is a comparison of requirements with the actual company:

Requirement ISO 9001:2015	Implementation PT. Dharma Poliplast
1. Identifying internal and External	1. Identifying problems Internal
2. Monitoring risks and opportunities	2. Create an activity plan for each part.
3. Changes in risk thinking	3. Company policy
4. Implementation of risk	4. Risk Profile Procedure of owner

Tabel 2. Comparison with actual company requirements

The first requirement, the company / organization to always grow in the face of the challenges and opportunities related to the core business.ISO 9001:2015 calls on the company to no longer focus on the control of routine and only carry out evaluation or improvement on the current problems. ISO 9001:2015 encourages companies to think ahead, identify current and upcoming issues, and evaluate risks and opportunities. In accordance with this requirement. Dharma Poliplast identifies risks to internal issues in the company.

The second requirement, ISO 9001:2015, puts the Risk and Opportunity requirements in the planning clause (planning), adds the work program requirements to the quality objectives (clause 6.2), with the aim of the company can continuously monitor changes, carry out risk and opportunity assessments and take action before the problems occur (prevention concept) or prepare the company to be able to seize opportunities, so that the company does not miss the opportunity. According to the requirements above PT.Dharma Poliplast carries out the development of the activity plan at each process and review and monitoring at the coordination meeting each week.

The third requirement, ISO 9001:2015, is also aware that the implementation of risk management would not be possible without a change of mindset. If the Company still uses an old mindset that focuses on routine and only takes action after problems arise, then the implementation of risk management will only be considered a burden. But if the company's mindset has changed, then the requirements related to risk and opportunity will become a necessity. The need to be able to survive in an era of change that is moving faster than ever before. Same with PT. Dharma Poliplast makes the company policy as a joint commitment related to the implementation of risks in each process so that risks arise to be immediately controlled.

The fourth requirement, ISO 9001:2015 has required every organization that implements it to identify risks and opportunities to things that affect its business processes. Steps in Identifying Risks and Opportunities: Establishing Organizational Context, Risk Control, and Risk Assessment. In accordance with the requirements above. Dharma Poliplast makes plans for risk control through risk profile tables created by each department continuously to better meet the company's goals.

DISCUSSION

PT. Dharma Poliplast carries out risk identification by identifying each process activity in each department that is its responsibility based on the activities of its work area and determining the aspects/dangers posed and their impact. Determine the values of severity and probability to estimate the probability of the risk and the severity of the consequences of such risk and control them by creating an action plan to minimize the occurrence of risk (Wicaksono et al., 2016).

Documentation of risk management is carried out throughout the company, Risk Management in PT. Dharma Poliplast has been implemented in every activity and is listed in the standard operational procedures (SOP) of each section. SOPs are created based on business process mapping that already meets QCD (Quality, Cost, Delivery) aspects and contains its calculation formula. risk identification and mitigation for each KPI present in each SOP based on its historical/potential problems, the control that is carried out (minimisation of risk) has been included in SOP/WI as part of preventive action (Kartikasari, 2018). Below is an example of a risk picture in SOP PT. Dharma Poliplast: From the results of ISO 9001:2015 and ISO 31000 standards, companies are required to consider risks and opportunities in conducting Quality Management System planning to promote risk-based thinking as well as support the application of existing risks in the enterprise in order to ensure the achievement of organizational goals.

PT. Dharma Poliplast has identified internal issues, drafted action plans, policies and commitments of the company and identified each process activity in each department to support the implementation of risk in an effort to ensure the achievement of company objectives. Based on Best Practice Analysis. TMMIN carries out processes to control the existing risks in the company by identifying, evaluating and measuring risks, as well as risk management in

accordance with the application of risk management existing in PT. Dharma Poliplast, where the identification is carried out by PT. Dharma Poliplast view from the PESTLE aspect (Politik, Ekonomi, Sosial , Teknologi, Legal, dan Environment). Risk assessment and measurement are also made based on risk tables (Probability and Severity) to see the degree of probability of failure. Risk control is also carried out by PT. Dharma Poliplast by Making an Action Plan. Plans include risk avoidance, risk retention, risk diversification, risk transfer, risk control or risk financing. The current risk profile. Dharma Poliplast still identifies risk related to internal issues only has not included risk related external issues into the risk profile of each related department, where the primary goal is to control or minimize the risk

CONCLUSIONS

Based on the results of research and analysis carried out by previous authors, it can be concluded that the application of Risk Management in PT. Dharma Poliplast that Application Analysis of Internal and External Contexts in PT. Dharma Poliplast has been established, understood, communicated and evaluated by all existing parts of the company. The company integrates risk management into the process of the quality management system. each process has defined key performance indicators (KPIs) and strategies on the risk management table in order to see the gap so that the problem does not repeat. As well as documentation of risk management is carried out throughout the company department on each activity and operating standard procedures (SOP) of each department. Evaluation of the effectiveness of actions in risk management by monitoring and conducting reviews in the internal coordination meetings of the company, such as weekly, monthly and quarterly, can be concluded that PT. Dharma Poliplast has effectively implemented risk management in accordance with ISO 9001:2015 and ISO 31000 requirements. Risk assessment in PT. Risk identification, evaluation and measurement and risk management can be drawn the conclusion that the application of risk management exists in PT. Dharma Poliplast is in line with PT. Measurement of risk in PT. Dharma Poliplast is not as sharp in determining probability and severity values as well as actual risk profiles. Dharma Poliplast still identifies risk related to internal issues only has not included risk related external issues into the risk profiles of each related department.

FURTHER STUDY

Further research could explore the effectiveness of different risk management strategies, such as risk assessment tools, risk mitigation plans, and risk monitoring protocols. Studies could also investigate the impact of risk management on quality performance metrics, such as defect rates, customer satisfaction, and process efficiency.

REFERENCES

- Arli, D., Rundle-Thiele, S., & Lasmono, H. (2015). Consumers' evaluation toward tobacco companies: implications for social marketing. *Marketing Intelligence & Planning*, 33(3), 276–291.
- Chiarini, A. (2017). Risk-based thinking according to ISO 9001: 2015 standard and the risk sources European manufacturing SMEs intend to manage. *The TQM Journal*, 29(2), 310–323.
- de Aguiar, D. C., Salomon, V. A. P., & Mello, C. H. P. (2015). An ISO 9001 based approach for the implementation of process FMEA in the Brazilian automotive industry. *International Journal of Quality & Reliability Management*, 32(6), 589–602.
- Hariandja, E. S. (2021). Customer perspective on dynamic marketing capability in international hotels of Indonesia during Covid-19: Confirmatory factor analysis. *Innovative Marketing*, 17(3), 74.
- Hiles, A. (2012). Enterprise risk management. *The Definitive Handbook of Business Continuity Management*, 1–21.
- Kartikasari, D. (2018). Perancangan Prosedur Berbasis Manajemen Risiko pada Perguruan Tinggi dalam Rangka Migrasi ke ISO 9001: 2015. *Journal of Applied Accounting and Taxation*, 3(2), 143–149.
- Kotler, P., Kartajaya, H., & Setiawan, I. (2019). *Marketing 3.0: From products to customers to the human spirit*. Springer.
- Muzaimi, H., Chew, B. C., & Hamid, S. R. (2017). Integrated management system: The integration of ISO 9001, ISO 14001, OHSAS 18001 and ISO 31000. *AIP Conference Proceedings*, 1818(1), 20034.
- Vorst, C. R., Priyarsono, D., & Budiman, A. (2018). Manajemen risiko berbasis SNI ISO 31000. *Jakarta Pusat: Badan Standardisasi Nasional*.
- Wicaksono, T. I., Yanuar, A. A., & Lalu, H. (2016). Perancangan Proses Menetapkan Risiko Dan Peluang Berdasarkan ISO 9001: 2015 Klausul 6.1 Dengan Pendekatan ISO 31000: 2009 Menggunakan Metode Business Process Improvement Di CV. XYZ. *JRSI (Jurnal Rekayasa Sistem Dan*

Fathurohman, Ekhsan, Laela

Industri), 3(04), 72–81.