DFMEA-Based Model for SMEs' Risk Management

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Abstract. This study aims to develop a risk management assessment model for Small and Medium-Sized Enterprises (SMEs) in Indonesia based on the ISO 31000 concept and Design Failure Mode and Effect Analysis (DFMEA). The research used a qualitative approach and descriptive analysis to identify, analyze, evaluate, and treat hazards in SMEs. The results show that the model consists of four steps: risk identification, risk analysis, risk evaluation, and risk treatment, using Risk Priority Number to quantify risk in four factors: raw material risk, production process risk, marketing process risk, capital risk, and legality risk. The findings suggest that SMEs could reduce failures and quality expenses by monitoring risk throughout the process and raising the quality of their goods to increase competitiveness. The implication of this study could support SMEs in implementing risk management to enhance their performance and contribute to the Indonesian economy.

Keywords: Indonesian SMEs · Competitiveness · DFMEA · Risk Management · Enhancement

1 Introduction

An online system (cyber-physical system), the internet for everything or IoT (Internet of Things), and networking are all part of the industrial change 4.0. (networks). Sidoarjo Regency's creative economy drives growth. Creativity—a limitless resource—powers the creative economy. The creative economy is a new economic notion that uses Human Resources' creativity for production and management. Improving product and process quality hinders creative economy growth. SMEs and SMIs dominate the creative sector. Indonesian SMEs are vital to the economy [1]. Competitiveness requires quality [2]. [3]. Producers and customers value quality [4]. Product quality is intended suitability received by the consumen [5]. There are several key elements of quality such as quality chain, process management, employee empowerment, teamwork and synergy, creativity and innovation, benchmarking, cleanliness, and continuous quality improvement [6]. This is because there is no standardized measurement of the production process and output, there is no risk measurement contained in the process and the resulting product. During the quality control process, there may be several things that cause quality standards or consumer requirements to not be fulfilled, so that this will cause losses

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and risks during the design, processing, materials, equipment, human and environmental changes which are risks of product quality [7]. Risk includes all human actions, all types of business, and every area of corporate management [8]. Risk is a function of the likelihood of a given threat exploiting a potential vulnerability, resulting in the impact of that event on the organization [9]. The company carries out a series of improvement steps to improve quality gradually [10].

The purpose of this study is to determine the measurement of risk management in Small and Medium Enterprises which is part of the creative economy, so it is necessary to develop a risk management measurement model by integrating the concept of ISO 31000 and Design Failure Mode and Analysis (DFMEA). The ISO 31000 standard contains a basic schema for the risk management process that reflects the main stages, namely context definition (situation), processing risk assessment (risk impact), monitoring and review, exchange of information and advice [11, 12]. Design Failure Mode Effect and Analysis (DFMEA) is a structured method to identify potential failure modes and provide corrective actions before production starts [13]. So it is hoped that the risk management measurement model based on ISO 31000 and DFEMA in Small and Medium Enterprises can be used as a reference in measuring the risks contained in businesses run by creative economy actors in the form of Small and Medium Enterprises in Sidoarjo Regency. With the mitigation of risks that exist along the value stream in the production/business process, it will improve product quality and customer satisfaction.

2 Literature Review

The Risk Development Model refers to ISO 31000 that in fact, the risk measurement process consists of 3 (three) steps, namely: (1) Risk identification; (2) risk analysis; and (3) risk evaluation [12]. There are main elements in the implementation of quality and risk management, namely: 1. Risk Assessment; 2. Risk Control; 3. Risk Review and 4. Communication Risk [14, 15]. Taking into account the risk, the consequence is reducing the inefficiency caused by the lack of synergy between risk management departments, this will minimize the costs incurred [16].

Risk management has a strong inspirational effect on major shareholders to invest more in the organization and this investment is a stimulus for companies to provide better business opportunities which ultimately leads to long-term competitive advantage [17]. Risk has 2 (two) components, namely involving events that occur, the consequences are costs, and the second component is problems that will occur. Consequently, it can reduce the risk of each event by taking mitigation steps, resolving complications that occur, or reducing the probability of events [18].

Meanwhile, the Failure Mode Effect and Analysis (FMEA) methodology strongly supports decisions from the design phase and the design process, by identifying poor performance [19]. The FMEA methodology was developed to identify and analyze potential failure modes during product design and process design activities [19]. The FMEA methodology was developed to identify and analyze potential failure modes during product design and process design activities [19]. The main purpose of FMEA is to identify potential failures and their effects and then prioritize failure modes according to their risks. The conventional FMEA classification of each failure model is according to Severity (S), Occurrence (O), and Detection (D) using a rating scale. The failure mode with the

highest Risk Priority Number (RPN) rating, in the critical failure mode, then indicates areas that need to be redesigned, so that it will provide recommendations for correction and mitigation [19]. The Failure Mode Effect and Critically Analysis (FMECA) methodology consist of two separate analyzes, namely FMEA which identifies failures that have an impact on system function, and CA (Critically Analysis) which ranks significant potential failures based on the level of failure [20]. FMECA consists of two different analyzes namely FMEA, which was later expanded to analyze critical failure modes, called criticality analysis [21]. DFMEA is used to analyze designs before the design is given to start production [22]. DFMEA is used to analyze product design before it is released to manufacturing and Process FMEA is used to analyze manufacturing and/or assembly processes [23].

3 Methodology

This research method is to use a qualitative approach and descriptive analysis with the approach to the concept of ISO 31000 and DFMEA. This study has four stages as shown in Fig. 1, showing that the ISO 31000 framework has four stages, namely: 1) Risk identification; 2) Risk Analysis; 3) Risk Evaluation and 4) Risk Treatment. Each of these stages is: 1) Risk Identification Stage, at this stage will be carried out: (a) Identification of risk variables and indicators contained in Small and Medium Enterprises; (b) Identify risk factors using the DFMEA method so that the Risk Priority Number (RPN) value will be generated. In the second stage, namely risk analysis, this stage will be carried out: (a) preparation of risk management models for small and medium enterprises; (b) Analysis of the root causes of the highest risk level by using a cause-effect diagram. Then in the third stage is evaluation, at this stage, the cost calculation will be evaluated by looking at the level of severity and costs using the MAFMA method, which is calculating the costs that arise from the severity value contained in the highest RPN value. Then in the fourth stage, namely risk treatment using risk mitigation. After that, the risk management team will evaluate and monitor changes in performance and the success of the implementation of risk measurement towards improving the quality of products for creative economy actors/small and medium enterprises.

4 Result and Discussion

The process of risk management entails implementing policies, procedures, and practices in a systematic way to manage risks. This involves activities such as communicating and consulting with stakeholders, defining the context, assessing, treating, and monitoring risks, as well as documenting and reporting the process. The procedures, programs, and practices that SME's uses to achieve their goals are referred to as processes. A well-designed risk assessment process enables the team to identify emerging risks early on and create and implement suitable risk mitigation solutions before they harm the SME's. Figure 1 is the concept of the ISO 31000 framework regarding risk.

Figure 1 shows the basis for implementing a risk-based integrated management system and management system that adopts ISO 31000. The impact of risk on an organization can have a positive and/or negative impact, according to the organization's objectives and different aspects.

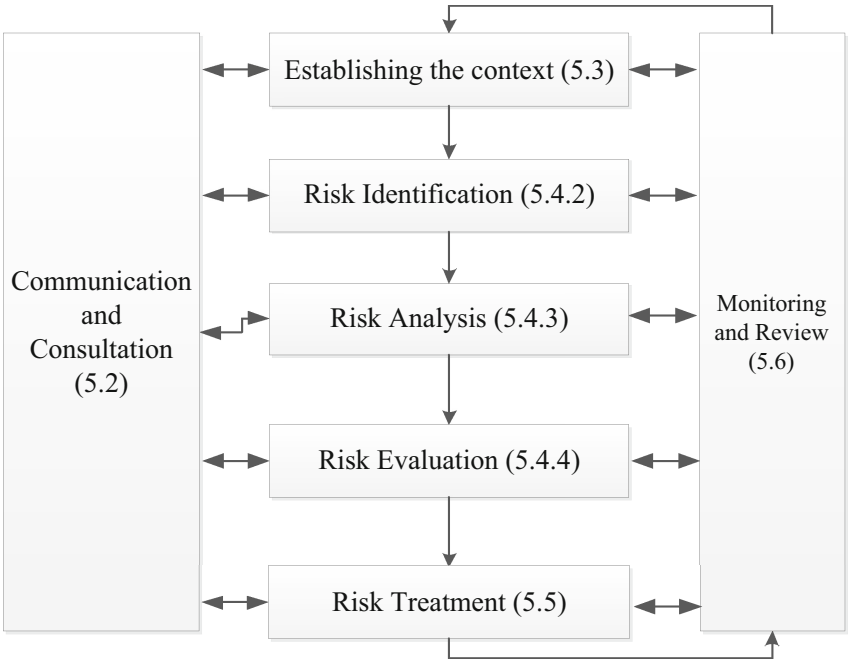

Fig. 1. Risk Management Process based on ISO 31000 [1, 2]

The application of an integrated risk management framework can improve company performance by reducing expenditure and reducing external capital costs, increasing capital efficiency, promoting and coordinating various risk management activities and creating risk awareness that accelerates valid strategic decision making in the operational process [24].

4.1 Risk Identification

At the risk identification stage, several things will be carried out, namely:

a. Identify the team of a risk committee

At this stage is to form a team to measure the risks that occur throughout the business process of small and medium enterprises. This team will be tasked with identifying risks that exist throughout the business process, then measuring risks that have the potential to have an impact on product quality and the company to evaluate and report the results of risk management and communicate to all entities in the company.

b. Identify variables and indicators

The stage of identifying variables and indicators regarding the risks contained in SMEs is carried out by literature studies and discussions with several creative economy

Table 1. Variables and risk indicators in the Creative Economy/SME

No	Variable	Indicator
1	Raw Material Ris	a. Fluctuating raw material prices
		b. Lack of supply of raw materials
		c. Quality of raw materials is not good
		d. No alternative raw materials
2	Production Process Risk	a. Production results are not good (defective/failed products)
		b. Damage to machinery or equipment during the production process
		c. There is a work accident
		d. Cleanliness and discomfort of the work environment
		e. Incompatibility of product quality with product standards
3	Demand Risk	a. Fluctuating demand
		b. Product order cancellation
		c. Product delivery delay
		d. Product sales returns
		e. There are business competitors
4	Shipping Risk	a. Transportation mode accidents
		b. Product delivery delay
		c. Fluctuating shipping costs

actors / SMEs in Sidoarjo Regency. Table 1 regarding the variables and risk indicators found in the creative economy/SMEs. These variables and indicators will then be compiled in a questionnaire which will then be distributed to business actors (SMEs) to find out the risks contained in the business processes of small and medium enterprises. By knowing the risks that exist throughout their business processes, business actors can take several actions that can reduce and prevent risks that occur from impacting other processes.

c. Identify the higher risk level based on the highest RPN value with DFMEA method

After collecting data by distributing questionnaires to SMEs, the next step is to calculate the RPN using the DFMEA method. This calculation will get the highest RPN value. RPN calculation is obtained by the formula:

$$\text{RPN} = \text{Severity} \times \text{Occurance} \times \text{Detection} \tag{1}$$

$$\text{RPN} = \text{S} \times \text{O} \times \text{D} \tag{2}$$

4.2 Risk Analysis

The purpose of risk analysis is to provide information to business actors in making decisions including priorities, alternatives in risk treatment, the balance of costs and benefits. The risk analysis starts from the calculation of the highest RPN value. An analysis of the causes of the highest RPN value will be carried out using the Root Cause Analysis (RCA) method. Root Cause Analysis (RCA) is a process of identifying factors that cause variations in performance or predisposition to undesirable outcomes [5, 25]. The results of the root cause analysis will determine the root cause of the problem with the highest RPN value. At the risk analysis stage, it will help determine the risks that have the greatest consequences or have an impact on other processes. This will provide a better understanding in understanding the impact of risk, or the likelihood that occurs to make team decisions in controlling risk.

In other words, that this risk analysis is to determine the level of risk that has an impact on other processes with the formula:

$$\text{Risk} = \text{consequence} \times \text{likelihood} \tag{3}$$

When conducting a risk analysis, there are several elements to consider. These include identifying existing strategies and controls that help to minimize negative risks and enhance opportunities, determining the potential consequences of negative impacts or opportunities (whether they are positive or negative), assessing the likelihood of negative consequences or opportunities occurring, estimating the level of risk by combining the consequence and likelihood assessments, and identifying any uncertainties in these estimates. Different analysis techniques can be used, such as brainstorming, root cause analysis, fault tree analysis, and the 5 whys.

4.3 Risk Evaluation

At this stage, it is important to do so to determine the level of seriousness of the risks faced by business actors. Business actors determine the level of risk that is still acceptable and does not have an impact on other processes. Risk evaluation will be considered by calculating the costs incurred to minimize the risk so that it has an impact on product quality. By calculating costs using the MAFMA method, the cost of risk is obtained by calculating the severity level at the highest RPN value with the costs contained in the activity or failure mode that occurs at the highest RPN value.

4.4 Risk Treatment

At this stage, it will be carried out to control risks and minimize and reduce bad consequences or reduce likelihood and occurrence. This will affect the costs incurred when implementing all strategies to reduce risk. At this stage, risk mitigation and risk prevention policies will be carried out.

4.5 Monitoring and Evaluation

At this stage, a cost and benefit analysis will be carried out to determine the level of success in managing risks that affect the products of business actors, as well as knowing the extent to which this risk management can be reduced and prevented which has the possibility of having an impact on the quality of risks and other processes.

Based on this, a risk management measurement model will be developed that integrates the ISO 31000 concept and Design Failure Mode Effect Analysis. Figure 2 below is a risk management measurement model based on ISO 31000 and DFMEA in the creative economy with a business level at the Small and Medium Enterprise level.

In Fig. 2, the risk management measurement model uses the ISO 31000 framework as shown in Fig. 1 which consists of stages: risk identification, risk analysis, risk evaluation, and risk treatment using the Plan, Do, Check, Action (PDCA) cycle. Meanwhile, DFMEA is one of the risk measurement methods by knowing the RPN which is then used as data to analyze and evaluate as well as treatment which aims to reduce the level of risk and costs and provide increased benefits during implementing risk management.

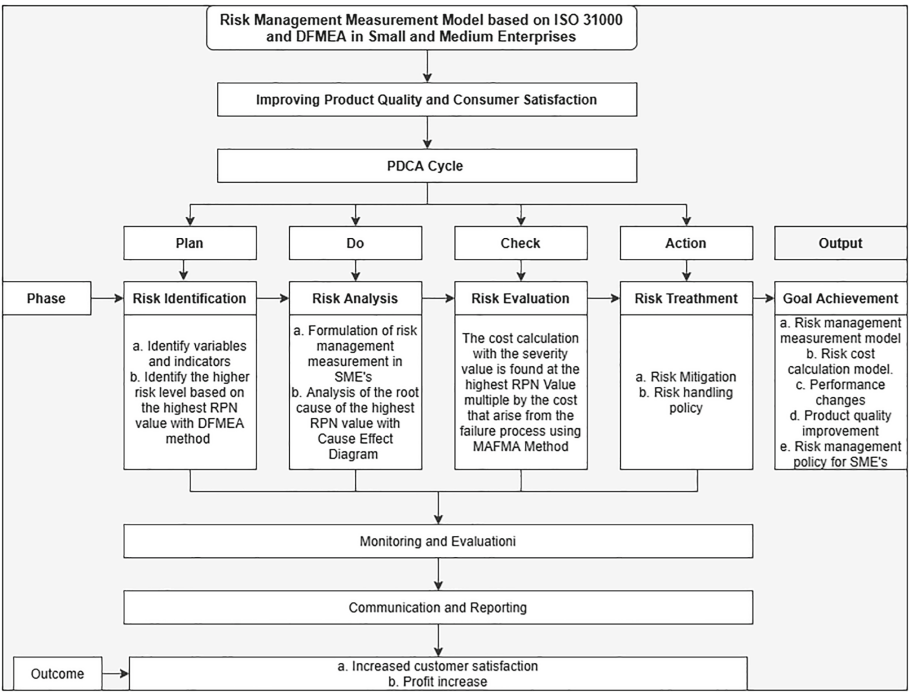

Fig. 2. Risk Managementt Measurment based on ISO 31000 concept and DFMEA

5 Conclusion

This study concludes that the measurement of risk management using the ISO 31000 framework and DFMEA has stages, namely risk identification, risk analysis, risk evaluation, and risk treatment using the PDCA cycle. The variables used in this research are raw material risk, production process risk, demand risk, and delivery risk. The RBQM model by Malikova is the development by Samani et al. (2017), which integrates the Risk Management System into the Quality Management System, also known as the Risk Based Quality Management System (RBQMS) model. This model adds the Quality Management System process to the Risk Management System process. These stages are: 1) Establishing the context of risk management in an organization; 2) Risk assessment, have four stages, namely: risk identification, risk analysis, and risk evaluation, that can apply to each process of the quality management system. This integration will result in risk assessment and further risk management steps. In this case, the risk management system process is considered an organizational improvement process, and risk management applies to the improvement process [3]. In the future, this research can be developed and applied not only in Manufacturing SMEs but also in services according to their business processes in the implementation of each stage. In addition, it can use other methods besides the PDCA cycle, such as DMAIC (Define, Measure, Analysis, Improve, and Control) in six sigma.

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