Application of Process Failure Mode and Effect Analysis for Quality Risk Assessment of the Storage and Conservation of Tobacco Strips

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Abstract. This paper demonstrates the process failure mode and effect analysis techniuqe be implemented in the quality risk assessment of the storage and conservation of tabacco strips in a cigarette manufacturing enterprise. We presents the process of risk identification, risk analysis, risk evaluation and risk response. During risk analysis, potential failure modes, potential effects of each failure mode and potential causes are identified. Risk priority number for each failure is calculated, which is a product of the severity of the failure, the probability of occurrence of the failure and the difficulty of detection of the failure. These risk priority number values are used to rank the failures. Among those, there are 4 items with a total score larger than 126. This paper finally figures out the key factors that have large influences on the potential failures, and makes control plans to help achieve quality improvement. This paper can be referred to undertake qulity risk assessment for managers and engineers in manufacturing industry.

Keywords: Risk Assessment, Process Failure Mode and Effect Analysis, Quality Management.

1   Introduction

Quality risk assessment are effectively utilized in many areas of industry and engineering [1,2]. It's demonstrated that the effective application of quality risk management is valuable for a quality system. In recent years, different techniques based on failure mode and effect analysis have been implemented [3,4]. Process failure mode and effect analysis (PFMEA) is a widely used technique that helps to figure out the potential failure modes and potetial causes. With risk priority number (RPN), we could find out the key factors related to the main failures, which is quite helpful for taking measures in practice. This paper presents a case of PFMEA implementation in a cigarette manufacturing enterprise which is referred to as Company Z. In this study, we demonstrate the application of PFMEA for qualtiy risk assessment of the storage and conservation of tobacco strips in Company Z.

Company Z, founded in Zhangjiakou, China in 1990, is a cigarette manufacturing enterprise. In order to finish the quality risk assessment work, a high quality team composed of managers and engineers is formed. There are 20 members involved in the quality risk management work. They are responsible for risk identification, risk analysis, risk evaluation and risk response. They seek to figure out the key factors that may have a large influence on the potential failures, and help to make control plans to achieve quality improvement in Company Z.

The quality team in Company Z conducts quality risk assessment of the entire production process. In this paper, we take the storage and conservation of tobacco strips as an example to show how the risk assessment is done in the company. In practice, storage and conservation of tobacco strips is of the most importance in tobacco logistics. Maintaining healthy tobacco is essential for systematically improving the quality of cigarettes, reducing defects cost and meeting customer satisfaction.

2   Risk Assessment

Quality risk assessment is a systematic process for the risk identification, analysis and evaluation [5]. The emphasis on risk identification, analysis and evaluation are probably different from case to case [6,7,8,9,10]. Failure mode and effect analysis is widely used in these cases, which can be referred to for our quality team to undertake quality risk assessment. In this section, we present a case of risk assessment in Company Z.

2.1   Risk Identification

Storage and conservation of tobacco strips is one important process to maintain high quality tobacco for the following process in the production line in Company Z. The qualtiy team in Company Z brainstorms and finally figures out 7 potential failure modes as shown in Table 1. Sometimes, the tobacco temperature is too high. Temperature and humidity don't meet the requirements. Pests are found in stored tobacco. Living pests are around in the warehouse. Excessive aging happens to the tobacco leaves. Water content is too high. And occasionally tobacco boxes are damaged.

2.2   Risk Analysis

PFMEA is a powerful technique that has been used for risk analysis in manufacturing industries. PFMEA provides an effective way of figuring out potential failure modes and the likely effects of failure. Once failures are established, potential causes are to determined. PFMEA provides a way to understand the processes. Based on PFMEA technique, we can easily rank the failure with consideration of RPN values. We can summarize the important failure modes, the effects and causes.

Using PFMEA, we identified 7 potential failure modes which are shown in Table 1. The quality team members from several different departments brainstorm the potential effects of each failure mode and potential causes which are listed in Table 1. Various causes that may influence the storage and conservation of tobacco strips are

analyzed with the consideration of humans, machines, materials, methods and environments. After deep discussion and further analysis, 18 items are determined for further analysis subsequently. Among those 18 factors, for example, insufficient ventilation, high ambient temperature, and direct sunlight may cause high tobacco temperature, which will result in the mildew of tobacco strips. Incomplete pests control may cause pests in stored tobacco or living pests in the warehouse, which will result in the decline in tobacco quality and potential quality hazards. Storage conditions not qualified may result in low quality of tobacco strips or mildew of tobacco strips. Even non-standard operations may cause tobacco strips damaged. As we can see in Table 1, those 18 factors in total include storage conditions, pests problem, temperature problem, humidity problem, non-standard operation, etc.

Table 1. Process failure mode and effect analysis.

Potential failure mode	Potential effects of failure	Potential causes	Item
The tobacco temperature is too high	Mildew of tobacco strips	Insufficient ventilation in the warehouse during natural aging	1
		High ambient temperature	2
		Direct sunlight	3
Temperature and humidity don't meet the requirements	Low quality of tobacco strips	Storage conditions	4
Pests in stored tobacco	Decline in tobacco quality and potential quality hazards	Pests in allocated tobacco	5
		Pests in new tobacco	6
		Incomplete pests control	7
Living pests in the warehouse	Decline in tobacco quality and potential quality hazards	Pests around the warehouse	8
		Pests eggs exist	9
		Pests exist in handling tools	10
		Incomplete pests control	11
Excessive aging of tobacco leaves	Decline in tobacco stips quality	Tobacco kept in warehouse for too long	12
High water content	Mildew of tobacco strips	Insufficient ventilation	13
		Water leak problem	14
		Storage conditions	15
Damaged tobacco boxes	Tobacco strips damaged	The operation of holdint car is not standardized	16
		The use of packing belt is not standardized	17
		Unreasonable stacking	18

Risk is commonly defined as the combination of the severity of failure, the probability of occurrence of the failure and the difficulty of detection of the failure. Severity, occurrence and detection rating are got by the quality team. As shown in Table 2,

each item can be judged for it's potential seriousness, and this is done by scoring on a 1 to 10 scale. It's also necessary to consider the probability of potential failure occurring and the detection of potential failure, and these two are also scored on a scale of 1 to 10. In practice, sometimes it's difficult to achieve a share understanding of the severity rating, occerrence rating and detection rating because each member in the quality team places a different probability on each failure. And the subjectivity also impact the decisions that made. At the situation, the rating values are discussed and negotiated by all the quality team members. In future, a data-driven PFMEA could be explored [11]. After rating the severity, occurrence and detection, as shown is Table 2, then RPN is calculated by

$$\text{RPN} = \text{Severity (S)} * \text{Occurrence (O)} * \text{Detection (D)} \qquad (1)$$

According to (1), RPN score is conducted from three aspects: severity, occurrence and detection. The following gives a summary of all S, O, D and RPN scores. Based on the RPN scores, we can prioritize risks.

Table 2. RPN and quality risk level.

Item	S (Severity rating)	O (Occurrence rating)	D (Detection rating)	RPN	Quality risk level
1	5	1	7	25	C
2	5	1	7	35	C
3	5	2	7	70	B
4	4	1	3	12	D
5	9	3	7	189	A
6	9	2	7	126	A
7	9	2	7	126	A
8	9	2	6	108	B
9	9	3	6	162	A
10	9	1	7	63	B
11	9	1	6	54	B
12	7	1	7	49	C
13	3	2	7	42	C
14	3	2	7	42	C
15	3	1	7	21	D
16	2	4	7	56	C
17	2	4	7	56	C
18	2	2	8	32	D

2.3   Risk Evaluation

In practice, we defined 4 quality risk levels (A, B, C and D) as shown in Table 2. There are 4 items with RPN values larger than 126, which are categorized as A. Category A is about pests control, which is the most important aspect of maintaining health tobacco. Item 3, 8, 10 and 11 with RPN values larger than 54 are categorized as B. Item 8, 10 and 11 are also about pests control, which should be pay more attention to. 7 items are categorized as C and other 3 items are categorized as D. Based on the RPN values and different quality risk levels, we could not only rank the risks but also monitor the effectiveness of the following quality risk control plans and measures taken.

3   Risk Response

According to the RPN scores, we defined 4 levels of quality risk, and corresponding control measures to effectively prevent quality risks are formulated according to the qualtiy risk rating criteria. As shown in Table 3, these measures are mainly focus on operational, inspection, and management.

Table 3. Control plans and measures taken.

Potential failure mode	Control plans and measures taken
The tobacco temperature is too high	Temperature and humidity monitoring scheme Ventilation facilities Curtains to avoid direct sunlight
Temperature and humidity don't meet the requirements	Constant temperature and humidity system
Pests in stored tobacco	Pests control plans Regular inspection
Living pests in the warehouse	Trap set in the tabacco warehouse Regular inspection
Excessive aging of tobacco leaves	Controlled by gas regulation
High water content	Sampling inspection
Damaged tobacco boxes	Quality education and supervision

In order to make sure that the temperature and humidity meet the requirements, a constant temperature and humidity system is necessary, and ventilation facilities and curtains are needed. The quality team also make a temperature and humidity monitoring scheme to check whether or not the temperature and humidity are in control. For pests in stored tobacco, pests control plans are made. Trap could be set in the tobacco warehouse to eliminate living pests. Regular inspection is also an effective way to eliminate pests in the warehouse. The situation of excessive aging of tobacco leaves could be controlled by new technology such as gas regulation. Sampling inspection is

a way to monitor the water content. At last, quality education and supervision should be strengthened.

Apart from the storage and conservation of tabacco strips, there are others including inbound, outbound and elevated storehouse storage processes have been analyzed. Table 4 shows the potential failure modes and measures taken.

Table 4. Inbound, outbound and elevated storehouse storage processes analysis.

Process	Potential failure mode	Measures taken
Inbound	Weight discrepancy	Suspend from storage and supplement
	Damaged package	Strengthen on-site supervision and inspect
	Pests eaten tobacco	Don't store normally
	Moldy tobacco	Pick out moldy tobacco and supplement
Elevated storehouse storage	Live pests in the warehouse	Pick out the pests eaten tobacco and supplement
		Set trap and inspect weekly
Outbound	Moldy tobacco	Pick out moldy tobacco and supplement
		Check proportionally and record

4   Conclusions

This study presents a case study of PFMEA implementation in the quality risk assessment of storage and conservation of tabacco strips in a cigarette manufacturing enterprise. The study can be referred to for managers and engineers to undertake quality risk management. In this study, we demonstrate how the PFMEA technique has been applied to risk analysis for identifying potential failure modes, potential effects of each failure mode and potential causes. All RPN values of the 18 items are calculated. Among those, there are 4 items with a total score larger than 126 selected as key factors related to the main failure modes. All of the 18 factors found in the analysis are controlled through control plans to maintain the quality of stored tabacco. Also, there are measures taken to guarantee the inbound, outbound and elevated storehouse storage processes. In practice, the interaction and complexity of different factors haven't been taken into account, which need to be explored in future studies. Furthermore, the sustainable implementation of PFMEA and more techniques could be explored.

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