COMPARISON OF APPROACHES TO MINIMIZING RISKS OF POSSIBLE DEFECTS OF PRODUCED PRODUCTS

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Abstract

Risk management is now often discussed topic, which also appears in the new version of ISO 9001 standard. The risks are no longer seek only in the context of security and finances, as it was before, but there are numerous other areas. One of these areas where there may exist some risks, is the quality of the products. Ensuring the required quality of products is very important. Organizations that have implemented a quality management system according to ISO are obliged to incorporate risk management techniques into their processes. There are many questions, like which risk management techniques, are most effective, or how to evaluate the risks. The aim of this article is partially answer these questions and introduce techniques for risk management in product quality planning for the specific process. This article presents a comparison of different approaches to minimize defects in products in metallurgy. Attention is paid to methods FMEA, HAZOP, HACCP and Quality Risk Management. These methods are applied on the forging process.

Keywords: Risk management, quality management, FMEA, HAZOP, HACCP, forging process

1. INTRODUCTION

Quality is seen in today's rapidly developing world as one of the main requirements of both standards and customers. Quality management is an integral part of developing and improving the quality of both end products and organizations as a whole. In quality management it is very important that emphasis is placed on preventing mistakes that may occur and correctly assessing existing defects. Therefore, it is best to look for potential risks already in the product quality planning phase, which can save large quantities of poor quality products. If we can detect possible risks in pre-production phases, preferably in product and process design and development, we do not need to spend as much resources as we have to deal with these errors during production or through customer complaints. The objective of this paper is to compare three suitable risk management tools for minimizing risks of possible defects of produced products (FMEA, HAZOP, HACCP) and to illustrate use of FMEA as the most suitable tool for this application for die forging process.

2. TOOLS OF THE RISK MANAGEMENT

Risk management principles are effectively utilized in many areas of business and government including finance, insurance, occupational safety, public health. This article mentions methods that can mitigate the potential risk. Each of the methods is different in particular to the area in which it is used, but also to the way in which the risks are assessed. There are selected a few methods - FMEA, HAZOP and HACCP, which are a bit similar in their solutions with the risks.

2.1. FMEA

FMEA (Failure Mode and Effect Analysis), as a prospective risk management technique, has proven to be a useful and powerful tool in defining, identifying and eliminating known and/or potential failures or problems in products, process, designs and services before they occur and reach the customer. The main goal of FMEA is to focus on the most important failure modes according to the limitation of resources, and provide valuable

information for achieving continuous quality improvement. FMEA is a structured and stepwise approach to quantifying the effects of potential failure modes, and usually carried out by a multidisciplinary and team. In the practical application, the following three main phases are often included in the FMEA process: the first phase is concerned with identification of the potential failure modes and their effects of product's components, subassemblies, final assembly and its manufacturing processes; the second phase is concerned with performing criticality analysis to determine the severity of failure modes by evaluating the risk levels of risk factors regarding each failure mode; finally, risk reduction measures of critical failure modes are proposed and implemented to help improve system reliability by failure mode avoidance. The second one of these phases is explored herein, as it is the foundation for developing and implementing risk mitigation strategies. Traditionally, the risk evaluation in FMEA is accomplished by calculating the RPN, which is a mathematical product of the three risk factors: severity of potential failure effects, probability of the failure occurrence and probability of the failure detection. The traditional FMEA often uses a numeric scale from 1 to 10 to evaluate each of the three risk factors. Failures modes having higher RPN values are assumed to be more important and should be given a higher priority for actions. After the relevant modifications were conducted, a reevaluated version of the FMEA could be executed and new RPNs of failure modes would be generated. The cycle would continue until the system reached a level of low or acceptable risk level [1].

2.2. HAZOP

The HAZOP (Hazard and Operability Study) is used to identify hazard scenarios that impact receptors such as people, the environment and property, as well as operability scenarios where the concern is with the capacity of the process to function properly. It evolved from Work Study and Critical Examination. HAZOP studies focus on investigating deviations from design intent. By definition, deviations are potential problems, for example, lack of flow in a transfer line or over pressuring a storage tank. Deviations are generated by applying guide words to process parameters at different locations, called nodes, throughout the process. The process parameters represent aspects of the design intent for the node. The goal in a HAZOP study is to identify all aspects of design intent for which deviations may result in scenarios within the scope and objectives of the study. A standard list of seven guide words is used: No, More, Less, As Well As, Part Of, Reverse, and Other Than. Some practitioners add Early, Late, Before and After, although other practitioners consider these as variants of Other Than. The HAZOP study team chooses appropriate parameters for each node, for example, flow, pressure, temperature, composition, level, addition, cooling, etc. The use of guide words with parameters provides the opportunity, principle, to explore deviations from design intent [2], [3].

2.3. HACCP

The Hazard Analysis Critical Control Point (HACCP) system is standing on the knowledge of the critical points, i.e. points where is the greatest opportunity, respectively probability of contamination of the food chain, whether microbiological, chemical or physical. These points become the most important control place that is monitored and evaluated, respectively controlled so that possible contamination was excluded. The success of HACCP is dependent on the expertise of the HACCP approach team management of the organization and all stakeholders. The goal of HACCP team work is the identification of critical points and the definition of potential hazards from the point of view contamination of the food chain. The relevant supervisor is responsible for checking the effectiveness of the system HACCP and its update. The HACCP system should become a natural component of the management system of those parts of the healthcare facility where food is handled. HACCP's proven tool of effectiveness is then audits mainly internal but also external. The elaborated model HACCP system should then to guarantee (in full respect) a high standard of food chain security passing through the health care facilities of the Ministry of Health. All of the mentioned methods can be used for the risks of the quality of the products [4].

2.4. Quality Risk Management

Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the drug product across the product lifecycle. A model for quality risk management is outlined in the **Figure 1**. There can be seen all of the processes in this model, which must be performed, during the risk management with regard to quality of product. There could be also used other models. Quality risk management activities are usually undertaken by interdisciplinary teams. The teams should include experts from the appropriate areas in addition to individuals who are knowledgeable about the quality risk management process. This methodology against for the classic risk management only outlines from all risks the risks related to quality of product. The methods mentioned above are possible to use in this field, mainly in the risk analysis process. It is not the concrete method, but an approach for the risk thinking [5].

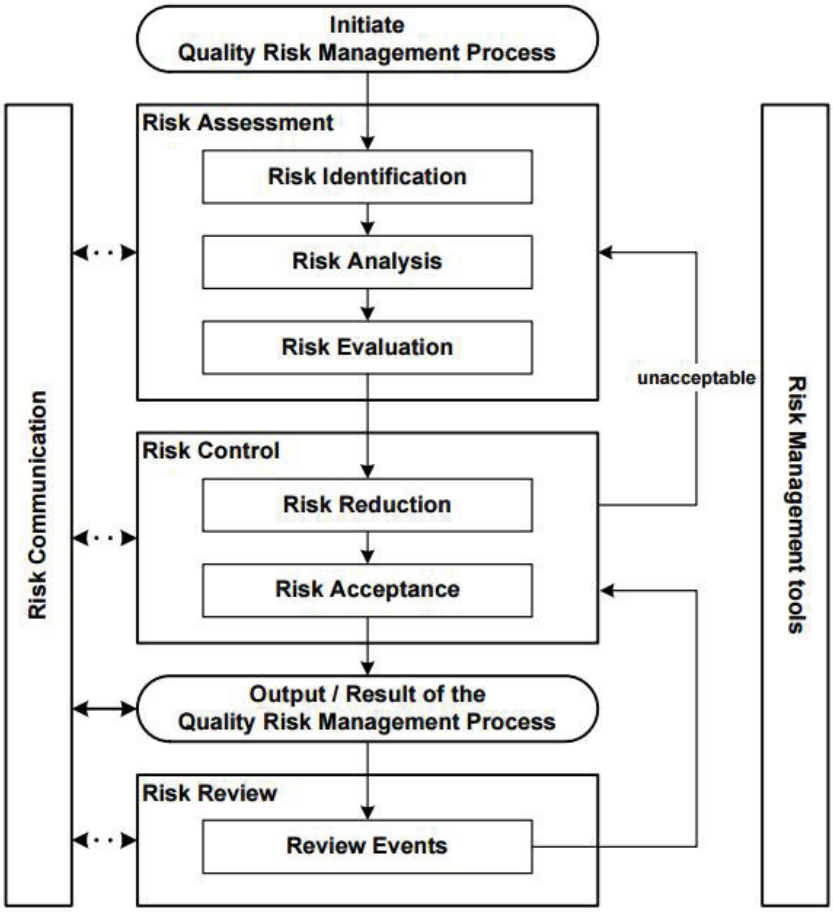

Figure 1 Overview of the quality risk management process [5]

2.5. The comparison of FMEA, HAZOP and HACCP

There are a few differences between mentioned methods. Mainly each of methods is used in the other field, because they are adapted for requirements in the field, for their time options and the level of importance of the risk management in their area. But in this article there is an idea, that each of this method can be used in the product quality planning for their positives. On the **Table 1** it can be seen the main comparison of the solutions at each of the methods. There are visible differences in the solutions, but each of method has own plusses and minuses. For example, in the HAZOP there is a potential problem identified with the guide words, which is not used in any other method. In the HACCP can be seen the term “availability”, which is unique only in this method. The methods HAZOP and HACCP are relatively easy to solve in the team and they are not so time

consuming. But as can be seen on the **Table 1**, no one of these methods is as extensive as FMEA, which contains more requests, without the mentioned exception, and therefore it is more accurate. On the other side this method requires a bit more of time for solution.

Table 1 The comparison of FMEA, HAZOP and HACCP

Item	FMEA	HAZOP	HACCP
Product/Process Requirements	✓		
Identification of potential problem	✓	✓	✓
Identification of possible effects	✓	✓	✓
Identification of possible causes	✓	✓	✓
Preventive measures	✓		
Detection possibility	✓		
Risk evaluation	✓	Deviation from the target	Effect
Risk mitigation actions	✓	✓	✓
Risk assessment after action	✓		

3. APPLICATION OF VARIOUS APPROACHES TO THE FORGING PROCESS

Forging is the process of forming and shaping metal materials with use of hammering, pressing or rolling. There is used the die forging as an example. In this operation, a single piece of metal, normally hot, is deformed mechanically by the application of successive blows or by continuous squeezing. Forged articles range in size from nuts and bolts, hip replacement prostheses and crankshafts to gun barrels. Most metals and alloys can be forged readily and include most steels [6]. The forging process is one of a lot of processes, where it is important to focus on the quality of the final product. Therefore, this article focuses on the use of the mentioned methods for this process.

All three described methods were applied to a particular die forging process for forgings intended for automotive braking systems. HCCCP and HAZOP methods were applied only on potential problems related to the quality of manufactured products.

Processed applications have shown that the outputs of all three analyzes are very similar, although individual methods do not use same terminology. However, the processed applications have also shown that the most information for risk management of potential failures (possible defects) is provided by FMEA. FMEA major advantage is, in particular, the possibility of quantifying the risks of potential failures, which is the basis for setting priorities in designing risk mitigation actions.

Table 2 shows a part of the FMEA application to a die forging operation, where the risks of four potential failures were analyzed. Two of them were related to product dimensions and two to surface defects. As the critical value of Risk Priority Number (RPN) was used common value of 100. The unacceptable risks (RPN > 100) were evaluated for possible not keeping dimension 46.3 mm due to die wearing or due to unsuitable material temperature and for not keeping shift due to incorrect locating of material in the die. In given case proposed preventive actions for risks mitigation were focused to the improvement of failures detection. Concretely, it was proposed higher frequency of measurement of given dimensions.

Table 2 The part of FMEA for die forging process

Process Function / Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Criticality	Potential Cause(s) Mechanism(s) of Failure	Occurrence	Current Process Control - Prevention	Current Process Control - Detection	Detection	RPN	Recommended Action(s)	Respon-sibility Target date	Actions Taken	Severity	Occurrence	Detection	RPN
Forging	Dimension 46,3 is not kept	Nonconforming product	8		Incorrect die dimension	2	Die inspection at shift beginning	Dimension measurement, 3 pieces per shift	5	80	No actions			8	2	3	48
Dimension keeping					Die wearing	3	Die inspection at shift beginning	Dimension measurement, 3 pieces per shift	5	120	Dimension measurement, 2 pieces per hour		Inspection procedure established	8	3	3	72
No scales					Unsuitable material temperature	3	Temperature control in the furnace	Dimension measurement, 3 pieces per shift	5	120	Dimension measurement, 2 pieces per hour		Inspection procedure established	8	3	3	72
No surface defects	Shift is not kept	Nonconforming product	8		Incorrect machine setting	2	Machine setting at shift beginning	Dimension measurement, 3 pieces per shift	5	80	No actions			8	2	3	48
Roughness max 6,3 µm		Problems at assembly			Incorrect material locating in die	3	Staff training before production	Shift measurement, 3 pieces per shift	5	120	Shift measurement, 2 pieces per hour		Inspection procedure established	8	3	3	72
Hardness 238-280 HBW	Scales	Nonconforming surface quality	7		Incorrect technology	3	Staff training before production	Visual inspection 3 pieces per shift	4	84	No actions						
	Surface cracks	Nonconforming product	8		Unsuitable material temperature	3	Temperature control in the furnace	NDT hundred-percent inspection	2	48	No actions						
					Unsuitable chemical composition	2	Certified material	NDT hundred-percent inspection	2	32	No actions						

4. CONCLUSION

There can be seen the short introduction in the article of three useful methods of the risk management, FMEA, HAZOP and HACCP. Then there is a comparison of mentioned methods. In the comparison there is visibly, that the FMEA is the most widespread method against to each other. Therefore, there is an application of the FMEA on the die forging process, where can be seen, how it looks in practical example. In the example is visibly, how the FMEA uses all of the items mentioned in the comparison. FMEA can be recommended for mitigation of risks of possible problems with quality also for other manufacturing processes.

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