Risk-based thinking in the Production Process Using the Methods of Quality Assurance Matrix and the FMEA Process

Lucie Hrbáčková
Thomas Bata University in Zlín
Faculty of Management and Economics
hrbáčková01@gmail.com

Abstract: The present article has focused on risk-based thinking in the production process according to the updated ISO/FDIS 9001:2015 Quality Management System – Requirements. One of the crucial changes of this update is incorporation of the risk-based thinking into quality management system of organizations. This article deals with this current issue of correct understanding of the actions to address risks in the processes that influence the customers. On the basis of a new updated standard and case studies focused on application of the method of the FMEA Process (Failure Mode and Effects Analysis) as well as the method of Quality Assurance Matrix in the production process, suitability of using these methods for risk assessment in the production process was assessed. The result is utilisation of these methods of FMEA and QAM for identification, analysis and risk assessment in the production process taking into consideration requirements of the respective standard.

Key words: Risk-based thinking, ISO /FDIS 9001:2015 Quality management system – Requirements, Actions to address risks, Production process

1. Introduction

Both in the production and non-production enterprises new quality targets that are based on the corporate strategy are annually set up and are then divided into the main and side corporate processes in the form of the key matrices of those processes. When analysing and optimizing the business processes, there are changes of application of those procedures and methods. The main impulse for such changes are the outer environment changes particularly in development of the information technologies, increased demand on quality of the products or services as well as requirements on fast supplies or shortening of the product innovation times.

Several outer factors playing a role in the continuous improvement of the processes are new trends of the International Organization for Standardization. In September 2015 there was an update of the ISO /FDIS 9001:2015 Quality management system – Requirements. Every organization implementing the quality management system based on this International Standard shall address risks and opportunities associated with its context and objectives. A new element risk-based thinking in the procedural approach has the goal of achieving improved results and preventing negative effects. Management of the processes can be achieved using the PDCA cycle.

On the basis of direct questioning in the selected companies in the Plastics Cluster Zlín it was found out that the companies used FMEA and QAM methods for identification of the potential nonconformity in the production process. By means of the case studies it was verified if those methods are suitable for risk assessment in the production process and the companies could use them as a preventive tool to avoid negative effects.

The FMEA method (ČSJ, 2008) is the one used particularly in the pre-production phases regarding the preventive removal of possible defects and errors. This method enhances identification of the most critical and most probable errors in the product or in the process. This article depicts the FMEA-process. FMEA-Process investigates all potential defects of the process of production and assembling and their causes and determines necessary remedies such as, for instance, those applied during construction of FMEA. The working team is managed by the employee of the particular production department, department of technical preparation of the production, quality assurance department or department of the industrial engineering. The method QAM – Quality Assurance Matrix - is a method used by the company BOSH. This method has to quantify the level of the periodic quality provision of the production processes as well as verify the reliability of the existing controlling means in the process operations (BELU, 2012). Comparing to the FMEA, it can be applicable in already implemented production.
The aim of the present article is to assess suitability of the methods FMEA-Process and QAM for risks assessment in the production process. The issue that is currently on the agenda of many companies certified with the ISO 9001 standards is that the update of the standard ISO /FDIS 9001:2015 is too general. Such companies will have to seek a kind of solution and reconsider what methods and tools are suitable for risk management.

In the subsection of the Introduction the terms risk analysis and risk process management are analysed in relation to the international standards and BPM approach. The chapter Risk Assessment in the Production Process has focused on assessment of the methods FMEA-Process and QAM for the particular production process after case studies for the particular production process. As a conclusion the article’s author has conducted evaluation of usage of the two selected methods for risk management in the production process.

1.1 The International Standard and the Analyzing of Process Risks

In the ISO 9001:2008 standard (CSN EN ISO 9001, 2009) there are chapters 8.5.2 Corrective Actions and 8.5.3 Preventive Actions that deal with the management process of non-complying product and prevention of repeated occurrence of the current or potential non-compliance as demonstrated in the Figure 1. An update of the ISO /FDIS 9001:2015 (ISO /FDIS 9001, 2015) standard has not specified any more the requirement on the preventive measures but the purpose of the quality management is to work as an preventive tool with the objective to prevent or decrease unfavourable impacts. A new way of thinking based on the risk analysis requires an approach focused on evaluation of the internal as well as external risk and opportunities. As can be seen in the Figure 1, the risk analysis of the process being assessed shall be executed before its initiation in order to eliminate any possible failure during its implementation. With incorporation of the Actions to address risks into the production process we will not achieve 100 % prevention of failures due to repeated arise of the loss caused by the technological means (i.e. loss resulting from implementation of the production) as well as the loss resulting from any possible fault of human factor or unplanned defect of the machine.

Fig. 1: The scheme of incorporation of the risk analysis as a preventive tool (the author)

By means of risk assessment in the production process we are able to decrease the costs of internal as well as external quality loss since detecting any possible unfavourable effects happens already prior to the implementation and not once the defects arise and thus it brings costs to the company in the amount of production already in the process. In the production processes we may understand the danger as defined in the international specification OHSAS 18001:1999 as a source or situation able to cause harm expressed in the monetary or other units (Ševčík, V., 2009). According to this way of thinking it is a situation when there is non-compliance with the requirements on the product leading to the customer satisfaction (CSN EN ISO 9001, 2009).

ISO 9001:2015 standard does not require implementation of the risk management process; neither it specifies any formal methods for risk management. This standard allows the organisation to understand the expectations and needs of all parties involved and to understand the strategic direction, concept as well as objectives of the company. On the basis of this information it is necessary to implement the management system with the objective to reinforce favourable effects, prevention or decrease of the unfavourable effects and reaching improvement. The organisation shall plan the actions to address these risks and opportunities in the form of integration and implementation of the actions into its quality management system processes and shall evaluate the effectiveness of these actions. The approved measurement for remedy should have proportionate impact on the product’s compliance. (ISO /FDIS 9001, 2015)
1.2 Risk Management

When implementing the procedural approach it is necessary to dwell on the risk management principles. Within all corporate processes risk management is their inherent part, it improves decision-making process and enhances the continual improvement of the organisation (ČSN ISO 31000, 2010). When implementing the risk management into the organisation directed by processes, it is appropriate to follow the given model in the Fig. 2. Risk management process.

![Fig. 2: Risk management process](ČSN ISO 31000, 2010)

Business process management (BPM) is a field of improving corporate performance by managing and optimising company's business processes (Burton, 2001). In BPM Life Cycle a phase of Design of processes is defined. The clear model of processes should be created in the Process Modelling (Tuček, D.&Basl, J., 2011). The authors in the article Methodology for Modelling and Analysis of Business Processes (Repa, V., Bruckner, T., 2015) wrote about a focus on the negative feedback in the processes in order to meet process goals. Aris Platform (2012) offers some different models. A business control diagram in the Figure 3 represents a potential risk for a process or function as well as risk control methods. A risk represents a possible danger in the already defined process. Risk control is a general way of eliminating or minimizing risks. Risk solution means implementing risk control for a risk. The FMEA and QAM methods rank among the controlling methods in the production process. (Aris Platform, 2012)

![Fig. 3: Example of a business controls diagram](ARIS Platform, 2012)


2. Risk Assessment in the Production Process

In this chapter the reason for selecting the two methods of FMEA-Process and QAM for risk assessment in the production process is clarified. Utilisation of those two methods is evaluated according to the case studies in the given company. The methods are discussed from the perspective of risk identification, analysis and evaluation. In the last sub-chapter of the risk assessment the approach of both methods is evaluated to compare the results of risk analysis with risk criteria. On the basis of the direct questioning 10 production companies of the Plastics Cluster in the Zlin Region have been addressed. The following direct question was asked: "Which methods or tools do you use in order to prevent occurrence of non-compliant product?" 5 companies out of 10 answered that they use the method of the construction FMEA for identification of any possible defects during development of new products. The only one company uses the method Quality Assurance Matrix in the production process for the defects arisen during the production process. Both methods are used in the production process or the process of design and development of new products. The author of the present article considers comparison of these two methods to be a benefit for risk assessment in the selected production process. Risk assessment means identification, analysis and evaluation of risk. The companies certified by the ISO / FDIS 9001:2015 standard shall implement activities that ensure identification of the external as well as internal risks in all process significant for the customer. During the production process the highest values for the customer is created and in this phase 80 % of the defects arise. Focus on activities that define, analyse and assess the risks is inherent part of risk-based thinking. Risk assessment as a preventive tool for prevention of occurrence product's nonconformity shall be implemented by the owners of the processes during development of the new product. As part of the case studies the process of injection moulding was discussed. The specialized team performing the risk assessment of this process comprised 6-8 employees. These employees were from the field of quality, production and technology.

2.1 Risk Identification

It is a process of finding, recognizing and describing risks. Risk identification involves finding the risk sources, events, their causes as well as their potential consequences (CSN EN 31 000). It is possible to define the internal as well as external risks of potential occurrence of threat in the production process; it may be on the basis of former experience of the specialized employees, brainstorming, records from the internal audits or current reporting. The event or in other words "threat" means occurrence of internal or external complaint.

When implementing the FMEA Process we define the process functions, manifestation of the possible defect, possible consequence of the defect and its possible cause. As evident from the Table 1, the injection moulding process was assessed. One of the manifestations of the possible defects was non-compliance with the mechanical characteristics of the mouldings. The consequence of this non-compliance is the nonconformity product. The potential cause of this defect was: drying of the material – caused by the human factor, temperature of the machine – caused by the human factor and defect of the material at the producer. On the basis of the team's expertise, brainstorming and reports from the internal non-quality of a similar product any possible risks that could cause any possible defect at the process of injection moulding were assessed.

**Tab. 1: Risk definition according to the FMEA Process method** (the author)

<table>
<thead>
<tr>
<th>Process functions</th>
<th>Manifestation of the possible defect</th>
<th>Possible consequence of the defect</th>
<th>Possible cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection moulding</td>
<td>Mechanical characteristics of the mouldings</td>
<td>Defect to take effect at the customer Fragility - material degradation</td>
<td>Drying of the material – caused by the human factor</td>
</tr>
<tr>
<td>process</td>
<td></td>
<td></td>
<td>Temperature of the machine – caused by the human factor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Defect of the material at the producer</td>
</tr>
</tbody>
</table>

When filling out the QAM form it is necessary to add the process step that is the same as at the FMEA Process – injection moulding, see the Table 2. Furthermore, this method assesses the errors (risks)
and the causes of such errors. Description of the risk means for this method to identify any possible errors. There is not any focus on the results of the possible defect.

Tab. 2: Definition of the risks according to the method QAM (the author)

<table>
<thead>
<tr>
<th>Step of process</th>
<th>Description of the error - risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection moulding</td>
<td>Unsuitable mechanical characteristics (Wrong set drying parameters / Wrong melting temperature - the human factor)</td>
</tr>
</tbody>
</table>

For detailed findings, recognizing and describing of the risks the author recommends using the FMEA Process method that ensures more detailed evaluation of:

- Expression of any possible defects,
- Possible consequence of the defect,
- Possible cause of the defect.

This more detailed elaboration of the specialized team is helpful during analysis and assessment of defects, i.e. risks.

### 2.2 Risk Analysis and Evaluation

This part focuses on the process of comprehension of the nature of risk and on determination of the level of risk (CSN EN 31 000). Risk analysis provides the basis for risk evaluation (CSN EN 31 000). In the production environment risks are considered to be any defects that could arise when transforming the input into the output.

The method of FMEA Process determines in the analysis of the defects the probability of the occurrence of defects, significance of the defects for the customer as well as detection of the defect arisen. When using the method of FMEA Process subjective assessment of the individual categories—occurrence, significance and detection of the defect - was carried out. It was observed in the case studies that when assessing probability of the occurrence, the quality team employees put higher significance to the occurrence of the defects than the employees of the production team or the technological team. Other different values were evident from the evaluation of the significance for the client that was conducted by the specialised team. The criterion of the defect detection was uniformly assessed by the team. This criterion is focused on assessment whether the defect can be detected.

The QAM method used for determination of the level of the defect at the selected process step assesses probability of the occurrence and so-called Quality-Tor that is supposed to ensure detection of the defect. In the Table 3 we may observe QAM Matrix of the process of the injection moulding. One of the Quality-Tor elements is the input check, material releasing, release of the form, release of the 1st piece, setting up the injection moulding parameters, setting up the handling robot, measurement of the moulding, visual control at the workplace, visual control by the operator, 100% check. The described defect is not controlled by each gate quality. In order to determine probability of the occurrence and assurance of defect detection it is recommended to follow the values indicated in the FMEA Process.
Tab.3: Quality Assurance Matrix for the process of injection moulding (the author)

<table>
<thead>
<tr>
<th>Step of process</th>
<th>Description of the error - risk [the causes]</th>
<th>QUALITY TOR</th>
<th>RISK CRITERION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection moulding</td>
<td>Unsuitable mechanical characteristics (Wrong set drying parameters / Wrong melting temperature - the human factor)</td>
<td>Gates detecting errors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unsuitable mechanical characteristics (Defect of the material at the producer)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In the Table 4 we may compare the criteria for determination of the level of the risk resulting from the methods of the FMEA Process, QAM and risk definition according to the specialised literature. The risk (Ševčík, 2013) shall be expressed as a combination of the consequences and probability of the occurrence.

Tab.4: Criteria for determination of the level of risk according to risk definition, methods of the FMEA Process and QAM (the author)

<table>
<thead>
<tr>
<th>Criteria for determination of the level of risk</th>
<th>Probability of the occurrence of defects</th>
<th>Significance of the defects for the customer</th>
<th>Possibility to detect any potential defects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>FMEA Process</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Quality Assurance Matrix</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

When defining risk, specialised literature states the probability of occurrence of the given risk and seriousness of the results that may occur and are expressed in the amount of the certain loss. Probability of the occurrence of defects is assessed by the method of FMEA Process as well as QAM. Possibility to detect any potential defects is assessed by both methods. The companies use various quality elements in order to prevent the occurrence of nonconformity of the product at the customer. The method of FMEA process is the only one to evaluate the significance of the defect for the customer.

2.3 Risk Assessment

Risk assessment means identification, analysis and evaluation of the risk. Risk evaluation means comparison of the results of the risk analysis with the risk criteria. The method of FMEA Process determines in the analysis of the defects the probability of the occurrence of defects, significance of the defects for the customer as well as detection of the defect arisen. As part of these assessment categories there is an assessment range 1-10. On the basis of the sum of these categories the risk number so-called RPN is calculated and it could be in the value of 1-1000. The specialized literature (ČSJ, 2008) suggests determining such value defined by the customer as critical RPN. In the case studies the risk value was determined as the value of 100. This risk number is a risk criterion according to which acceptability of the identified risk will be stated. In the Table 5 we can see that the risk number RPN is 160 and the risk criterion is 100. The team has to determine the preventive action.
A risk criterion in QAM is a kind of evaluation of the criteria of defects ‘occurrence and detection of risk is non-acceptable (see the Table 6). In order to determine probability of the occurrence and assurance of defect detection it is recommended to follow the values indicated in the FMEA Process.

3. Conclusion

As part of the risk-based thinking in the processes influencing the customer it is necessary to set up a well-functioning system of the actions to address risk in the organisation. This article has assessed two methods that are used for defining and evaluation of the risks in the production process. The objective was to find out whether these methods are usable for the actions to address risk that resulted from the new requirements of the ISO /FDIS 9001:2015 - Quality management system – Requirements. On the basis of the case studies it was found out that the method FMEA Process is a more complex tool for identification, analysis and evaluation of risks in the production process. It is not sufficient to use the tool FMEA Process solely according to the instructions in the specialized literature; it is necessary to set up the in-house procedure for utilisation of the FMEA tool as a tool for prevention of any errors. This is evident particularly on the subjective procedure during the risk analysis.

It has been evaluated that the FMEA Process method is a more exact tool for identification of risks in the production process from the perspective of recognizing and describing risks. The form of the QAM method does not include assessment of any possible consequence of a defect and these manifests afterwards when determining the risk level. The FMEA and QAM methods are thus contradictory in the analysis and risk assessment when FMEA also assesses (apart from the criterion of occurrence of defects and detection of arise of the defect) the criterion of significance for the customer. This meaning is from the perspective of the approach of the ISO standards the key one. On the basis of different assessment criteria the risk criterion is also different for the assessed methods. When
assessing risks, we compare the results of the risk analysis with the risk criterion and the conclusions are different. In this case, the FMEA method considers more defects as non-acceptable due to assessment of the additional criterion of meaning of the defects for the customer.

If the organisation aspires to ensure a detailed risk analysis not only for the purposes of auditing, it is more suitable to use the FMEA Process method for the actions to address risk. The QAM method is a kind of more interactive method for dealing with the already arisen defects in the production process.

References


Burlton, R., 2001: Business Process Management: Profiting From Process


ČSJ (Czech Society for Quality), 2008: Failure mode and effects analysis (FMEA).Prag: Czech Society for Quality


JEL Classification: D81, L15