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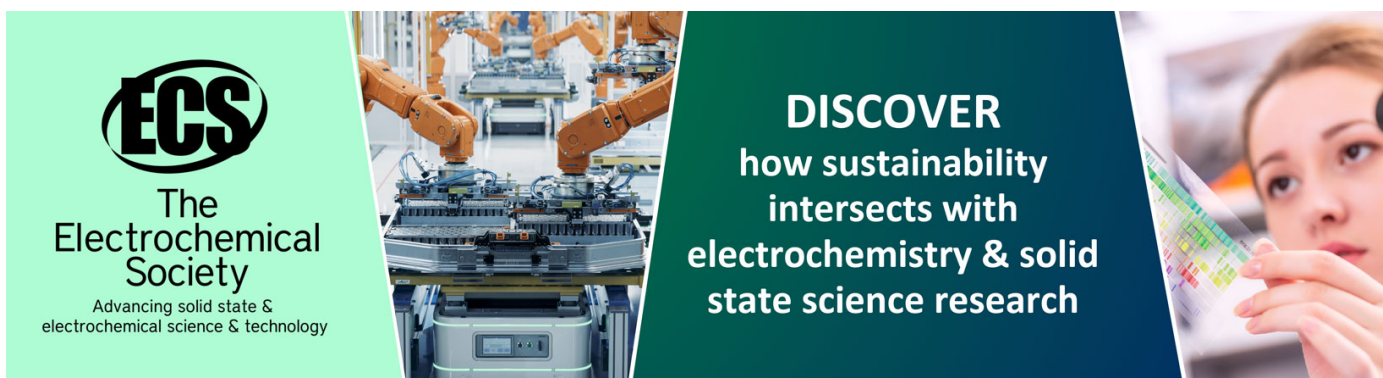
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Risk Assessment and Calibration of Risk Matrices Aspects

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Abstract. Modern quality management systems, including ISO 9001 standard based, are widely used by companies. Availability of ISO 9001 certificate and quality management system, that runs like well-lubricated machine, gives the company the tool to concentrate on customer needs, to keep the high quality standard of all processes in the company, to collaborate with reliable partners and as a result to offer the high quality products and services. There is a tendency that management systems are becoming more risk thinking based and refer to risk management standard ISO 31000. Risk management standard stands for managing risks with consequences related to safety, economic performance, environmental and other outcomes thus support company continuous improvement.

For machine industry risk assessment is crucial as this is a part of CE marking documentation. According to EU legislation, to sell the machinery within European Economic Area, CE marking of machines showing the machine correspondance to Machinery directive requirements is mandatory. Risk assessment in machine industry is applied for evaluation of the risks associated with corresponding hazards to guarantee the safety of design, production process and machinery produced. Risk assessment is conducted to evaluate machine design, exploitation or manufacturing process risks. For production process risk estimation the risk levels of subprocesses should be considered.

There are no available risk assessment industry standards. Risk matrices developed by companies are used to analyse and estimate risks for correct decision making and risk reduction. Unfortunately faulty risk matrices cause difficulties during risk estimation process and lead to inappropriate safety measures application. Risk matrices use numerical values and consider minimally hazardous event severity and probability of hazardous event levels. Numerical values of risk levels are listed in the risk matrices during risk assessment. Unfortunately calibration information with defined numerical risk tolerance criteria is often missing. Miscalibrated risk matrices lead to critically wrong decisions on risk elimination issues. This paper describes the aspects of risk matrices calibration and highlights the importance of risk tolerance definition applied during risk assessment.



1. Introduction

Most companies, that stand for high quality products and international collaboration, implement quality management systems (QMS) including ISO 9001 standard based QMS. Risk based thinking is one of the main issues of the latest versions of QMS and it is applied to provide high standards of safety and quality of processes and products of the company. Therefore, risk management standards including ISO 31000 are getting high priority. According to risk management standards all kind of risks related to safety, economic performance, environmental and other outcomes should be managed to guarantee company continuous improvement. For risk levels estimation and elimination risk assessment different techniques listed in risk management standard ISO 31000 can be used. However often risk and hazard definitions are mixed up. Hazard is an issue that can cause any harm, for example health loss, social and economic disruption or environmental degradation. Risk definition is more complex as it defines the probability that hazard will lead to some consequence. As the consequence can be positive and negative, risks also can have positive and negative influence on the process or issue being managed, investigated. During risk estimation and risk assessment hazards or hazardous scenarios are listed. Hazard probability of occurrence and severity of consequence levels are considered for risk level estimation. Risk elimination methods and safety measures are offered. Risk assessment can be divided by stages. Final risk assessment is performed after risk elimination techniques are applied and should reveal low risk levels for most issues.

For company context and economic performance risk estimation preliminary hazard analysis (PHA) is often used (see Table 1). Risk matrices usually consider only three risk levels low, medium and high. Probability of occurrence of hazard or issue is considered in percentage. Severity of consequence is presented in form of the economic impact. It should be also stated in the matrices to whom the risk is assigned, expected results, uncertainty, opportunity to eliminate the risk and also cost of risk elimination. The hazards or issues listed are divided onto internal issues related to company environment and external issues that depend on political, social, ethical, technological and economic environment the company is operating in. For example, external issues include changes in the legislation, certification and standardization (see Table 1).

Table 1. Example of PHA risk assessment matrices

Hazards/ Issues (Internal / External)	To whom risk are assigned	Results to expect	Uncertainty or reasons of hazard	Proba- bility of occu- rence	Conse- quence or economic impact	Risk level (low, medium, high)	Opportunity or risk elimination	Cost of risk elimina- tion
Lack of multi- skilled workforce (Internal)	Company	Competent workforce	Company all present workforce is not skilled enough	30% - 60%	in €	Medium	Creation of multi-skilled teams	in €
Noncon- formance to standards within industry (External)	Company, Clients, State and EU	Well informed about changes in standardi- sation	Standards are being updated and changed frequently	0% - 30%	in €	Low	Designers participate in conferences on standards update	in €

In machine industry risk assessment is performed by companies for safety of manufacturing processes and safety of produced machines. Risk assessment is one of the main parts of machine design process and it is the first stage of design process. Risk assessment report is included in CE marking technical file documentation. Within European Economic Area CE marking of machines is mandatory and shows the machine correspondence to Machinery directive requirements. There are no standards for risk

assessment procedure. Companies mostly use self-composed risk assessment matrices with references to ISO 12100:2010 Safety of machinery - General principles for design - Risk assessment and risk reduction standard and ISO/TR 14121-2:2012 Safety of machinery - Risk assessment - Part 2: Practical guidance and examples of methods (see Fig. 1).

Severity (Se) levels from 1 to 4 starting from light and ending with irreversible injury are defined. Likelihood parameter is divided by three: frequency, probability and avoidance. Frequency (Fe) levels vary from 1 to 5 and correspond to the hazard occurrence duration time starting from interval more than 1 year and ending with the interval 1 hour or less. Probability (Pr) of occurrence varies from 1 to 5 and corresponds to negligible up to very high probability of hazard occurrence. Avoidance (Av) parameter vary from 1 - likely, 3 - possible and to 5 - impossible level. Risk level (RC) is the sum of all likelihood parameters. Combining severity (Se) and risk level (RC) parameter values the risk index (RI) level is determined (low, medium, high risk). Numerical values of risk along with risk levels are presented in the risk assessment risk matrices (see Fig. 1). Numerical values of risk give more detailed overview of extent of risk connected with specific hazard.

Hazard Number	Severity	Likelihood				Risk Index RI RC = Fr + Pr + Av and Se level combination
	Se	Frequency Fr	Probability Pr	Avoidance Av	Risk Level RC	
1.	4	3	2	1	6	High risk
2.	2	2	2	1	5	Low risk
3.	2	4	2	3	9	Medium risk

Risk Index RI:	≤ 64	Low risk
	98 ... 512	Medium risk
	$686 \leq$	High risk

Severity Se	Risk level RC:	4	5	6	7	8	9	10
	4	343	686	1372	2744	5488	10976	21952
	3	49	98	196	392	784	1568	3136
	2	7	14	28	56	112	224	448
	1	1	2	4	8	16	32	64

Figure 1. Example of Initial risk estimation and evaluation; Method: Hybrid ISO/TR 14121-2:2012.

To provide reliable risk assessment data, risk matrices should be calibrated. Decision of the risk acceptability is made based on risk matrices results. Majority of companies do not consider risk matrices calibration and do not define numerical risk tolerance criteria. Without calibration criteria wrong decisions on risk elimination issues are made. For successful risk matrices calibration process the risk assessment techniques should be applied in the early design stage before whole system structure is designed.

2. General aspects of risk matrices calibration

Risk matrices are widely used as a method for risk assessment procedures. However, risk matrices methodology has its limitations in risk management decision making [1]. The example of the simplest risk assessment matrix is shown in Table 2. In the risk matrix the boundary conditions value for probability and consequence are either 0 and 1. Three levels of risk considered: low, medium and high for different probability and consequence quantitative values combinations.

Table 2. A simple 2×2 Risk Matrix [1].

Consequence/ Probability	Low	High
High	Medium (1,0)	High (1,1)
Low	Low (0,0)	Medium (0,1)

Risk matrices appear to be reliable for risk assessment if probability and consequence values are positively correlated, both probability and consequence have quantitative values either (0,0) and (1,1) correspondingly. (0,0) corresponds to minimal or zero probability and consequence and low risk level and (1,1) to maximum both parameters value and high risk level. On the contrary if probability and consequence values are negatively correlated and are placed along diagonal (0, 1) to (1, 0), then no information about greater or lower risk level is available as for both risks “Medium” risk level is assigned and decision error probability increases up to 50% [1]. Such pairs as high probability and low consequence and low probability and high consequence are commonly presented in the risk assessment.

Risk matrix calibrating allows companies to estimate their risks comparing them to risk reference value, for example, risk considered acceptable by society [2]. The calibration method of risk matrix requires the application of calibration cell in the matrix. The calibration cell corresponds to the highest consequence level (depth, lots of injuries, big monetary loss etc.) and the lowest probability of occurrence. As an example of the calibration cell risk value, risk of death in a motor vehicle accident on the way from and to work over a 25-year working period is assigned [2]. Then the highest board value of risk level is selected, other risk zones can be defined.

In process risk assessment research [3] the concept of matrix allocation is highlighted. According to allocation method the number of hazardous scenarios possible are defined and risk tolerance criteria is divided by the number defined. Furthermore, general facility tolerable risk can be allocated to individual hazardous scenario. If each individual scenario risk criteria has not been exceeded, then general facility risk tolerance criteria will be not exceeded. The number of hazardous scenarios estimation method depends on the process complexity. If process contains of subprocesses general facility risk tolerance criteria allocation should consider total number of hazardous scenarios not only individual process ones [3].

The importance to define difference between individual and group risk is also important. If individual risk represents the probability of occurrence of hazardous situation harm any individual may experience, then group risk is considered as the relationship between probability of occurrence and the number of experiencing a level of harm from hazardous scenario [3].

Failure design analysis along with statistical analysis for efficient risk values determination can be performed. To compose risk matrices having allowable residual risks and presenting optimal quantitative distributions of the risk, the optimal design approach methods should be integrated with risk assessment techniques.

3. Calibration aspects of machine safety risk assessment matrices

For successful machine manufacturing risk assessment of design and production stages along with quality control should be performed. Due to absence or lack of statistical data on machines accidents more subjective and qualitative not quantitative methods are often used in risk assessment matrices by

companies. The worst-case scenarios or the highest severity hazards are often supposed to have low probability. Integrating the optimal design and manufacturing methods, failure analysis methods with risk assessment tools in the early stages of design and manufacturing process will guarantee allowable residual risks along with effective quantitative distribution of the risk. Design for Manufacture and Assembly (DFMA), Failure design method such as Failure Mode and Effects Analysis (FMEA) and Failure Modes, Effects and Criticality Analysis (FMECA) with aid of statistical tools like decision trees, vector quantization and rough sets ensure risk matrices contain optimal quantitative distribution of risk.

DFMA process is successfully used for optimizing the manufacturing and assembly process. Integrating DFMA process flow charts, that divide manufacturing and assembly processes into steps, with risk assessment matrix along with red, yellow and green colors or numerical risk estimation values for risk acceptability control is the first step to risk matrix calibration and tolerable risk evaluation. The most critical safety aspects can be spotted on the very first design stage of manufacturing and assembly process. Each manufacturing and assembly concept stage can be evaluated with response to the complexity, cost and risk level. As a result, most simple, cheaper and low risk concepts are defined.

For machine or technical system potential failures identification and elimination FMEA and FMECA techniques are used [4]. FMEA was initiated by SAE reliability engineers and is widely used for mechanical systems reliability control [2]. Current standards are available that provide guide for failure and effect analysis: SAE ARP 5580 Recommended failure modes and effects analysis practices for non-automobile applications; SAE J1739 Potential Failure Mode and Effects Analysis in Design and Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes; IEC 60812 Procedures for failure mode and effect analysis. FMEA and FMECA differ by criticality aspects for reliability estimates and criticality is estimated in conjunction with risk assessment. Bottom-up approach initiates the part failure mode and its failure effect from lower level to higher level in the system. The top-down approach in the contrary investigates the main system functions and functional fails and is performed in the beginning of design process. Failure mode, failure effect and risk assessment severity, probability and risk level parameters are considered during failure mode analysis. Based on the failure analysis results more effective and optimal risk evaluation criteria and risk tolerance criteria can be obtained.

4. Conclusions

However, risk matrices are popular tools among companies and are often used for design, manufacturing processes, products, company economic performance hazardous scenarios probability of occurrence, consequences and risk evaluation and estimation, there are some limitations and uncertainties that can arise during that risk assessment method application. Calibration of risk matrices requires additional analysis tools application. Integrating efficient design, manufacturing process tools and failure mode analysis approaches with risk assessment procedures lead to more optimal quantitative distribution of the risk levels and more reliable risk assessment results.

References

- [1] Cox L A Jr 2008 What's Wrong with Risk Matrices? *Risk Analysis* **28**, No. 2, 497-512
- [2] Clements P 1996 Sverdrup System Safety Course Notes
- [3] Baybutt P 2015 Calibration of risk matrices for proc. safety *J. Loss Prev. Process. Ind.* **38**, 163-8
- [4] Rausand M 2011 Risk Assessment Theory, Methods, and Applications Hoboken NJ Wiley