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INTEGRATION OF RISK MANAGEMENT INTO META-QUALITY DEPLOYMENT METHOD

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1. Introduction

Successful development of products requires strict orientation towards the requirements of customers and compliance with the preventive quality assurance principles. Attention must be paid to safety, health and ecological impacts of the new product. The key document concerning the safety of machinery is the Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC. The risk assessment must be performed for the whole life cycle of the analyzed machinery and its objective is to ensure reduction of the risks to a tolerable level. Great attention is paid nowadays to the assurance of functional safety of electrical control systems related to the machine safety - SRECS (Safety-Related Electrical Control System). For successful development of a new product it has been possible to use the preventive quality assurance method Meta-Quality Deployment (MQD). The objective of this paper is to update this method by integration of the complete system of risk management.

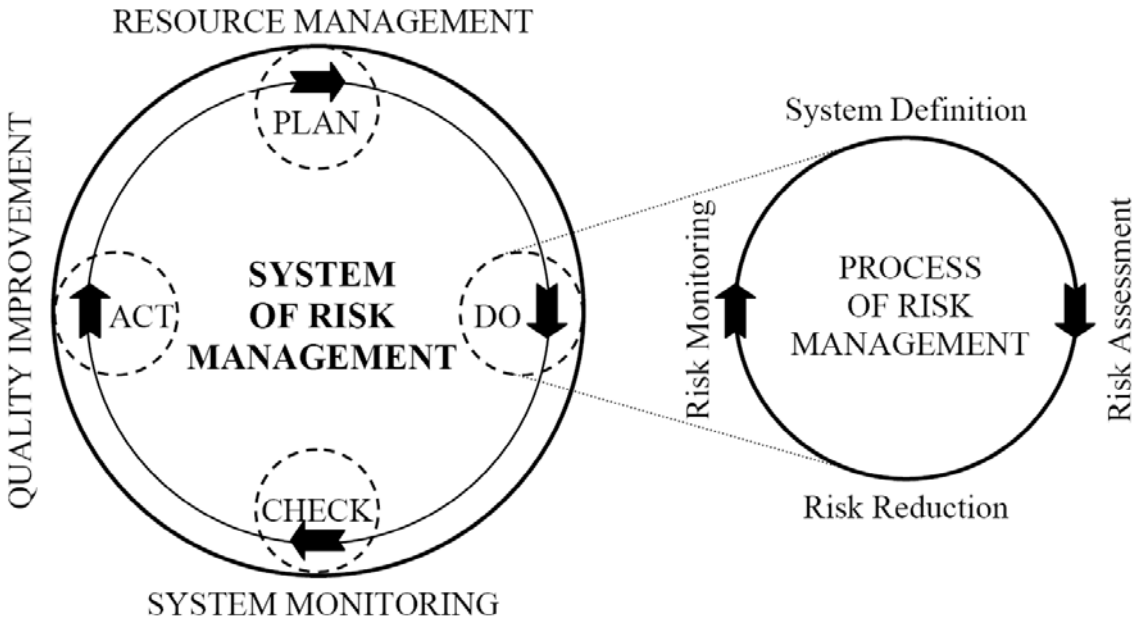

Figure 1. System of risk management elements [Zowa 2006]

2. Risk Management

There are two levels of risk management: strategic and operative (Fig. 2.) Strategic management defines and controls the risk policy of an enterprise and provides internal rules for operative risk management.

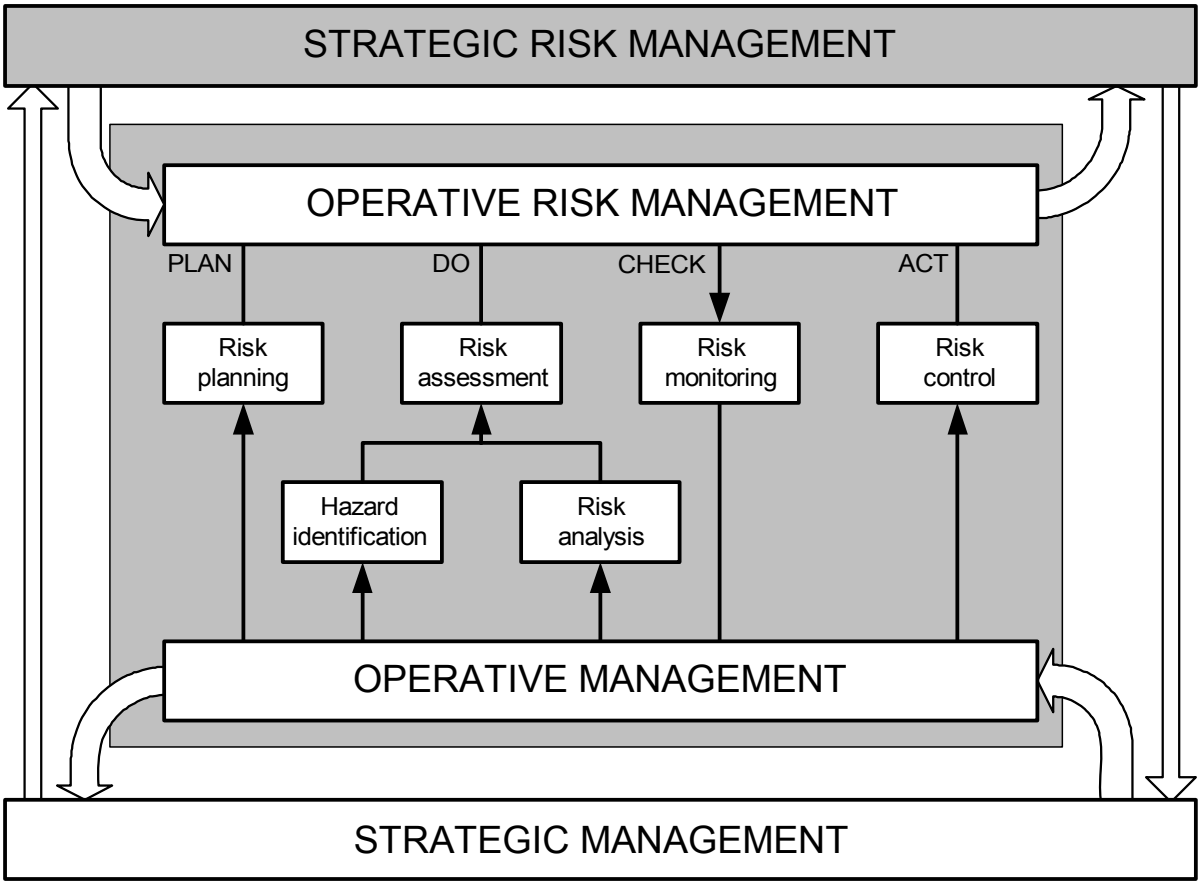

Figure 2. Strategic and operative risk management [Zowa 2006]

The outputs of strategic management may include:

- **Risk matrix**, which classifies the risks as acceptable, acceptable with review and unacceptable.
- **Hazard probability,** which determines the relation between the qualitative and quantitative expression of hazard occurrence (i.e. frequent probability of occurrence corresponds to the frequency of 15 hazardous events per month).
- **Hazard severity**, where qualitative values are matched with quantitative expression (i.e. catastrophic severity may be characterized by death of three or more persons).

Operative risk management is a repeated sequence of actions that can be described in general by the following four steps (see Fig. 2.):

- Plan
- Do
- Check
- Act

Risk assessment (the step “Do”) plays a key role in health and safety assurance of machinery and is defined in EN 1050 (Fig. 3.).

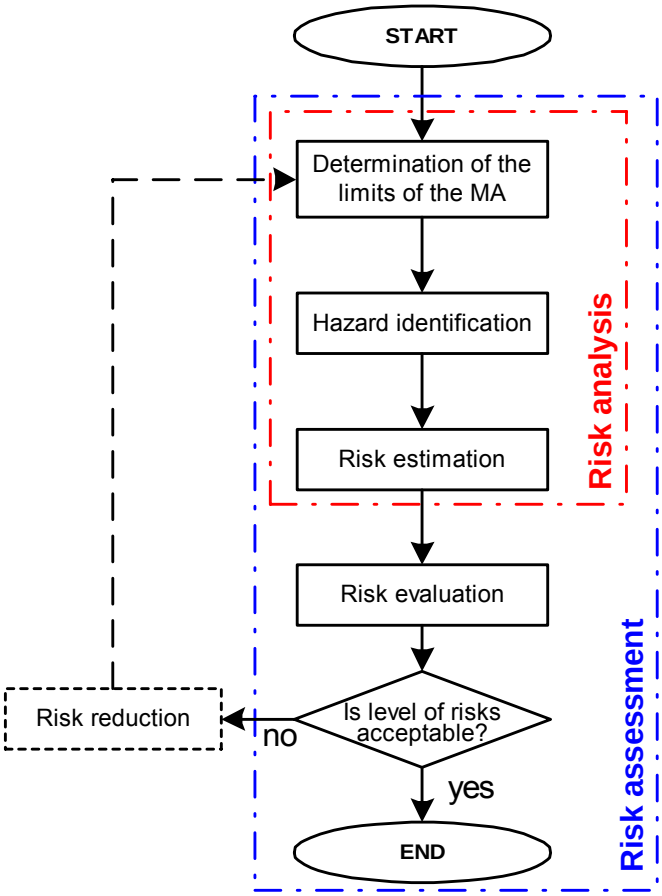

Figure 3. Repeated procedure to ensure machinery safety in accordance with EN 1050

According to interpretation of Directive 2006/42/EC of the European Parliament and of the Council, the manufacturer is obliged to perform risk assessment of machinery (thereinafter referred to as “MA”) that is being put on the market or into operation. The output of this process is the following documentation:

- Block diagram of MA
- List of sources of relevant hazards
- Hazard analysis of MA
- List of identified significant hazards
- Risk degree estimation of significant hazards
- Risk evaluation (review of existing safety measures)
- List of preventive measures (with determined priorities) proposed to reduce the risks
- List of hazards with residual risk

On the basis of a detailed block diagram showing interactions between all components it is possible to work out a list of sources of relevant hazards related to individual components of the machinery.

Table 1. Sources of relevant hazards

Component of the system	*Position of the component within the system*	*Type of hazard according to EN 1050*
Spindle drive engine	Drive housing – machine face	mechanical, electrical, heat, unexpected activation, unexpected overspeed
Etc…		

It is advisable to perform risk analysis of machinery in accordance with standards EN 1050, EN ISO 12100-1, EN ISO 12100-2 and, if possible, also with application of the harmonized standard of C type for the specific machinery. The output of the risk analysis is a review of identified significant hazards as well as a list of serious hazards (Tab. 2.).

Table 2. List of serious hazards

Machinery:		**Compiled by:**		**Approved by:**	**Date:**		
According to EN1050	**HAZARD**	**EN ISO 12100-1:2003**	**EN ISO 12100-2:2003**	**DESCRIPTION OF HAZARDOUS EVENT**	Corresponding B-type standard	Corresponding articles of C-type standard	**Total number of hazards**
Hazards, hazardous events							

Estimation of severity of all hazards registered in the “List of serious hazards“ may be performed with the use of a form. If the same hazard arises at more places within the machinery, the risk estimation must be performed for all places of occurrence in separate forms.

The form used for risk estimation should include:

- Identification of MA;
- Phase of MA life cycle relevant to the estimated risk;
- Operation state of MA relevant to the estimated risk;
- Persons exposed to hazard;
- Description of the hazard;
- Estimation of the risk prior to application of protective measure (EN 1050);
- Selection of category for safety parts of control (EN 954-1);
- Description of preventive measures (constructional, technical, performed by user);
- Determination of requirements for Safety Integrity Level (EN 62061);

- Estimation of the risk after application of protective measure (EN 1050);
- Estimation of acceptability of the residual risk.

3. Application of the System of Risk Management in Product Development

The purpose of the system of risk management is to ensure the success of the newly developed product on the market. To be allowed to appear on the market, the product must meet strict safety, hygienic and ecological requirements. The producer is obliged to declare the conformity with these requirements and to guarantee the safety of his product.

From the formal point of view it seems effective to integrate risk management of a newly-developed MA into the method of preventive quality assurance known as Meta-Quality Deployment (Fig. 4.).

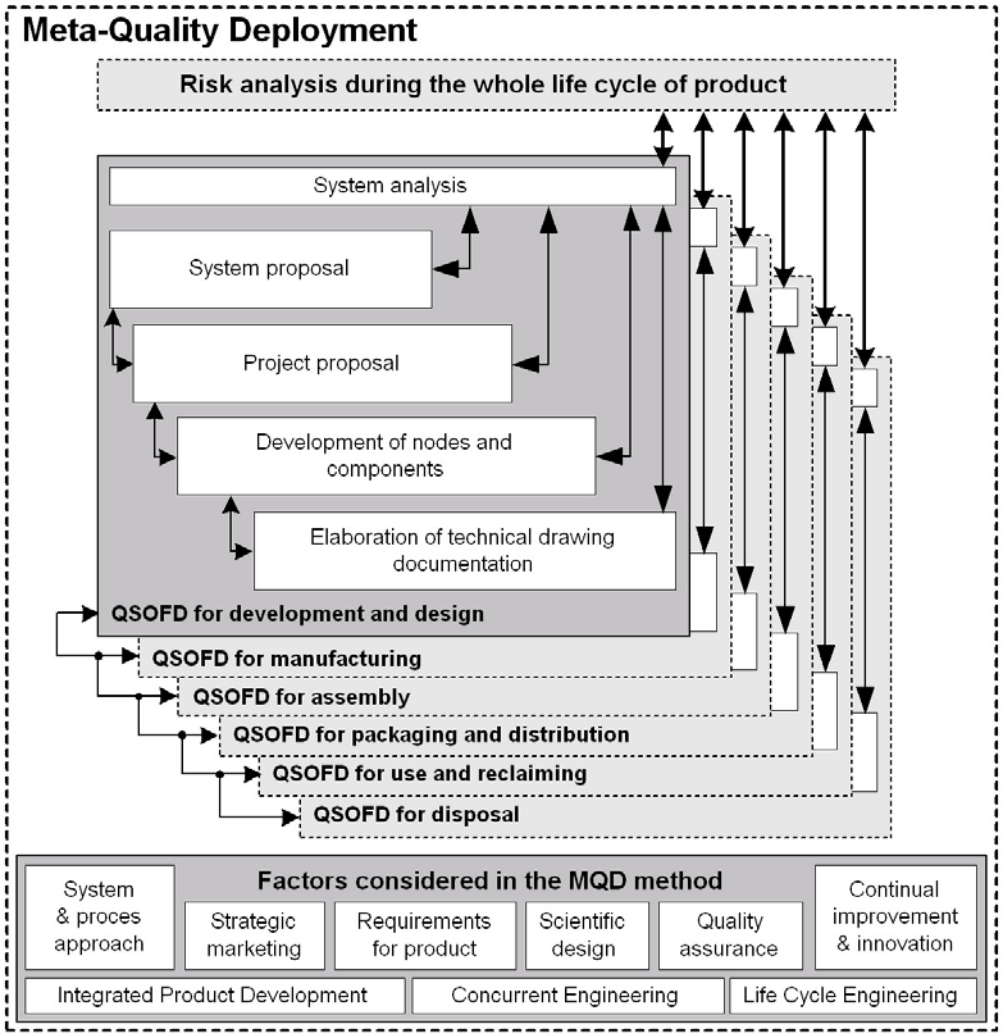

Figure 4. Meta-Quality Deployment method [Blecha 2004]

Linkages between the individual processes of product development included in the MQD method and the inputs and outputs of risk management are shown in Table 3.

Table 3. QSOFD method and Risk Management linkages

MQD	Input / Output	RISK MANAGEMENT
	Risk matrix Hazard probability Hazard severity	← Strategic risk management → Operative risk management
System analysis of MA System proposal of MA →	Functional structure of MA →	Determination of the MA limits
Project proposal of MA →	Block diagram of MA →	List of sources of relevant hazards of MA, Hazard analysis, List of identified significant hazards, Risk estimation
Development of nodes and components of MA ←	List of preventive measures taken to reduce the risk ←	

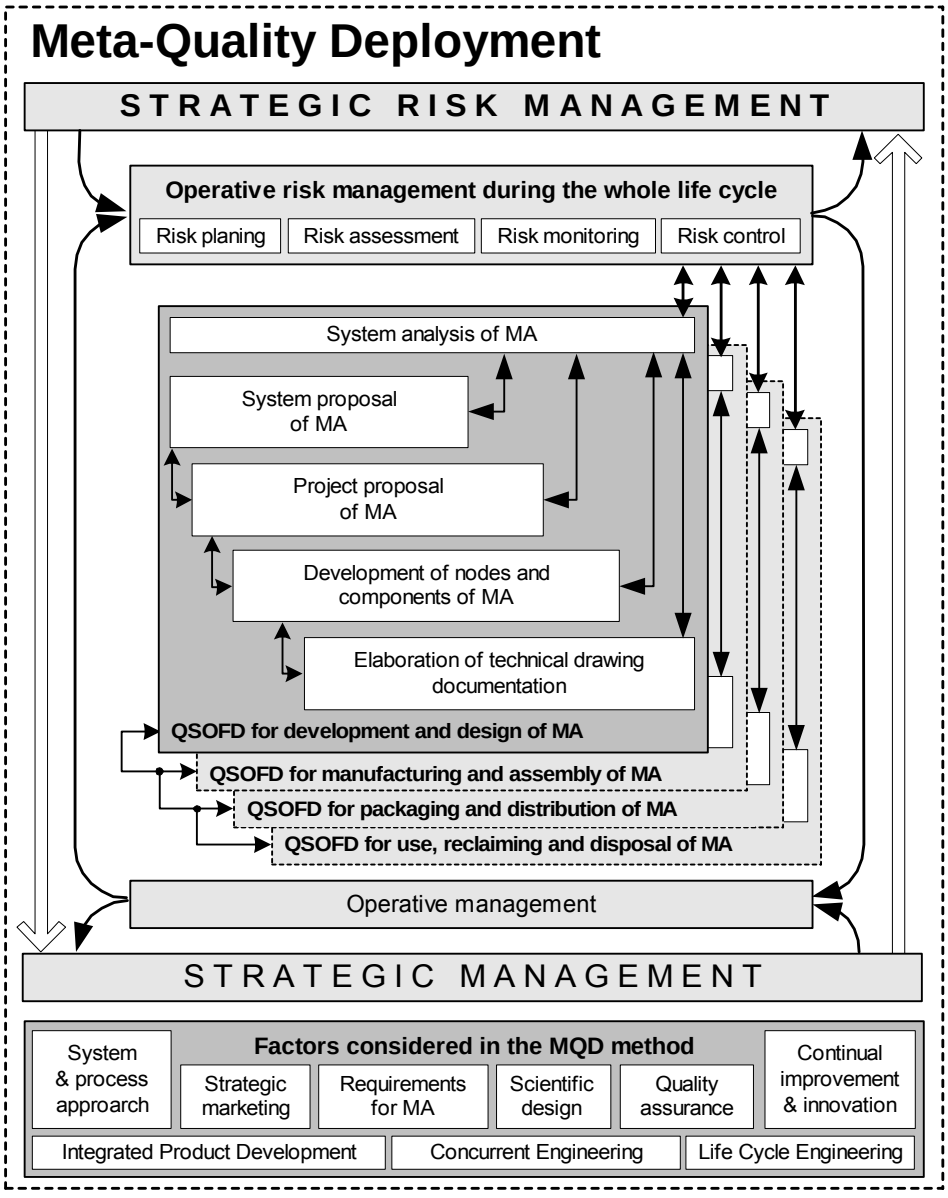

Figure 5. Integration of risk management into Meta-Quality Deployment method

Integration of risk management into the MQD method is very simple. Thanks to the fact that MQD method already works with risk analysis during the whole life cycle of MA, it is only necessary to upgrade this risk analysis to the level corresponding to the present requirements of risk management (Fig. 5.), without the need to modify other MQD processes.

4. Conclusion

MQD is one of the team methods that support Concurrent Engineering, Integrated Product Development and system and process approach to quality assurance [Knoflíček 1996, Marek 1996]. The upgraded MQD method now not only meets the requirements of ISO norms 9000:2000 and 14000:2004 series, but it also helps to realize the basic requirements of the Directive 2006/42/EC of the European Parliament and of the Council.

MQD may be easily complemented with the risk management applied in all stages of the life cycle of machinery or any newly developed product. In this way the upgraded MQD is likely to become an effective tool of Life Cycle Engineering and preventive quality assurance which may assist the team of designers in integrating health and safety into machinery design.

Acknowledgements

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