New Approach for Risk Analysis and Management in Medical Engineering

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SUMMARY & CONCLUSIONS

Risk management in its current form does not fulfill today's requirements for enterprises in risk-sensitive industries. Risks resulting from well-known boundary conditions, such as shorter development times, a higher number of variants or global markets can just be identified inadequately by existing methods. In particular the increased product complexity, e. g. in the medical engineering branch, makes it difficult for companies to assess risks correctly and individual persons are less able to judge a product thoroughly.

To improve the risk management process the iFEM-method (innovative function effect modeling) was developed, which is a new approach to identify and assess risks. First of all, critical risk areas are identified by the creation of a tree that visualizes the actual state of a complete technological system. After that, these critical risk areas are analyzed by an object model and a function-effect model. The result is a comprehensive risk inventory in which the cause and assessment for each of the risks have been defined. These results can be directly addressed through an effective risk mitigation.

The validation of iFEM was carried out in an enterprise from the medical engineering industries. The results were structured and documented so that the information could be used to improve the method. iFEM is a suitable method to model an overall system for the multidisciplinary analysis of a complex product. It permits a common understanding of a system and combines manufacturing and operational processes with system functions and inherent risks. The benefits of iFEM are the systematical risk identification of inconsistencies and expansion of employee's system understanding.

1 INTRODUCTION

Due to the increasingly dynamic markets and complexity in the business environment the risk management becomes more and more important for successful enterprises [1]. Shorter product development cycles, a higher product variety and an increasing complexity of products force German enterprises to take greater risks in order to remain their competitiveness [2]. That is the only way that they can compete in international markets, especially against enterprises from the Asian region, because these vendors sell the same technologies much cheaper [3]. German enterprises can compensate for this competitive disadvantage by product innovations, which naturally present high risks [4]. In particular, the risk situation for producers of risk-sensitive products, such as in the medical engineering branch, became considerable worse in recent years [5]. The practice in the field of health care demonstrates that medical mistreatment occur frequently. In Germany, each year approximately 40,000 medical mistreatments allegations and 12,000-proven mistreatments occur. These mistreatments are often caused by risks which were unrecognized in spite of an existing risk management system.

The costs, which occur by risks not recognized early can take a immense dimension and in extreme cases, threaten the survival of a business [6]. Field and product recalls are getting more common and decrease the margin of an enterprise dramatically. But not only the warranty and goodwill costs as a result of an unrecognized risk have to be considered. Especially the loss of image due to negative media coverage and the necessity to issue recalls have a long term negative impact for companies. [7, 8]. Through consistent and effective risk management, some of these negative events can be avoided.

Very often residual risks appear, which were undetected by a risk management system in the development and production phase. The reason for that is often a lack in control of the complexity of an analysed system, its operating conditions and the resulting interactions between its components [9]. A high rate of preventable errors in connection with the use of technical systems can be attributed to human error [10]. In today's risk management methods these interactions are inadequately represented [11].

It is clear that enterprises act currently in a stress field, which is characterized by different risks. The task of a risk management system must be to identify these risks reliably, analyse them accurately and define concrete and innovative measures for its mitigation and elimination.

Therefore the developed iFEM-method aims at the risk analysis of complex products supported by appropriate sub-methods. These methods allow identification and analysis of interactions between different sub-systems

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2 THEORETICAL BACKGROUND

The effective implementation of a risk management system, for example in the medical engineering branch, requires a systematic process oriented model as well as an appropriate support by methods and tools. Therefore, the relevant state of research related to process models and risk management tools will be described.

2.1 Process models for risk management

Hoffmann, Haller and Mensch developed general risk management models, which must be adapted for specific tasks.

The risk analysis by Hoffmann [12] starts with the identification and assessment of risks before these risks are summarized in a risk inventory. In the second phase of this risk management approach a decision about the principles of acting, reducing, avoiding or insuring must be carried out. The next step is to establish a risk policy that contains decisions about risk objectives and strategies as well as risk costs. All these decisions are implemented in the fourth phase and controlled in terms of their effectiveness and their economic benefits. [12]

The concept of an integrated risk management by Haller [13] is divided into a three-stage process. In the phase "clarification of expectations" a risk policy is formulated. The second phase, "assessment of the risk situation," contains the identification, analysis and assessment of possible risk impacts. In the third phase, decisions have to be made about the implementation and control of risk reducing measures. The concept covers basic elements of a risk management system but is not directly implementable as a detailed solution. [13, 14, 15]

The risk management framework by Mensch [16] is based on a risk definition which considers the risks of wrong decisions reasoned by a lack of information. The approach focuses on the informational aspects of decisions and claims the consideration of risks in every business decision. So risk management is an integral part or a dimension of leadership in all business functions. [16]

2.2 Tools for risk management

Failure Mode and Effect Analysis (FMEA) allows a systematic analysis of a product or a process at the early stages of development to initiate different avoiding measures [17, 18, 19]. There is a distinction between the system-FMEA product and system-FMEA process, in which possible errors in processes for product manufacturing are analyzed [20]. Disadvantages of FMEA are the high effort of execution and the complexity of analysis, which increases significantly with the complexity of the analyzed system [21, 22]. A reduced effort of execution can be achieved by the use of an appropriate software support [23, 24]. Another disadvantage of FMEA is that complex causal chains cannot be mapped by the defined sequence to determine "error, fault effect, cause of error" [25]. Another point of criticism is the subjectivity of risk assessment. The result of the FMEA only reflects the subjective assessment of the experts involved and in particular the risk priority number cannot be considered as an absolute measure of risk [18, 19]. The isolated application of FMEA does not lead to an objective quantification of risks and solutions to eliminate causes of errors. However, it allows a systematic and structured collection of explicit and implicit available knowledge about possible errors. [19, 23; 26]

Fault tree analysis (FTA) is - beside the FMEA – is one of the most common methods of quality management. The core of the method is the creation of a fault tree based on a previously performed system analysis. Based on one error, all possible failure combinations are collected that may have caused the error. The conclusion of the FTA is the analysis of the found correlations regarding to the probability of failure occurrence. [18] Like the FMEA, the FTA does not cover complex relationships between sub-systems.

2.3 Central deficits and need for action

Out of the described deficits, a need for tailored tools and methods arises for the increasing complexity of products and technologies. Therefore, an innovative risk management model must represent non-linear cause-effect relationships. New approaches with a high innovative potential are required to overcome the limitations of previous approaches for risk mitigation. The isolated consideration of a technical system can contain the risk of failing to identify critical risks. Especially in the development of medical devices, interdisciplinary teams of medical scientists and engineers are common. For the majority of engineers, it is difficult to imagine themselves in the work practices of medical scientists and vice versa. Therefore, the new method has to serve these different ways of working, thinking and visualisation to support the identification of product and application risks.

3 THE INNOVATIVE FUNCTION EFFECT MODELING (IFEM) AS A NEW APPROACH FOR RISK IDENTIFICATION AND ANALYSIS

The four modules risk identification, risk analysis, risk mitigation and risk control are the elements of a risk management process which runs continuously in an organization. For the identification and analysis of risks in a complete system, the six-stage innovative function effect modeling (iFEM) was developed and validated. The iFEM approach will be described in detail in the following sections.

3.1 Modeling the complete system

Based on the complexity of a technological system, the aim must be to decompose a complete system into smaller sub-systems, to identify the sub-systems with the highest risk and to analyse these targeted on possible risks. Therefore, the interactions between sub-systems have to be also considered, so that possible risks arising from them can be included in the risk inventory of the complete system. This must be mapped with an appropriate modeling method, which is provided by the Theory of Constraints (TOC) in the form of a tree to visualize the actual state of a system [27].

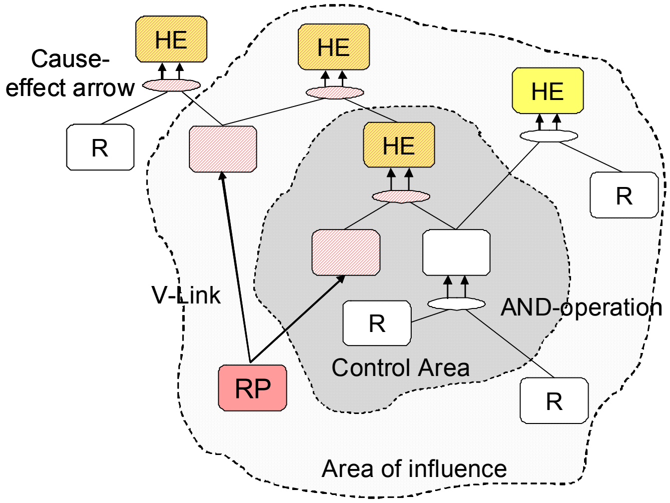

Figure 1: The actual state of a system visualized in a tree

This tree has to be created by an interdisciplinary team in a workshop and consists of different components. It is modeled by boxes and arrows, which each have a different meaning. The cause-effect arrow indicates a sufficient causal link between individual components of the system. This connection can be characterized by "is cause for" [28]. The ellipse indicates an AND-operation, so that each of these causes is necessary to achieve the effect. Harmful effects (HE) are any problems or effects, which are inherent in a system and have a negative effect on the system. The goal is to identify these effects by the tree. One example for a harmful effect is "system fails" or "system's output is reduced". A core problem is a bottleneck of the system that produces many harmful effects simultaneously. The elimination of a core problem leads to the elimination of many risks and so to the greatest possible improvement of the system. A core problem often arises from V-links between separate branches.

If the tree to visualize the actual state of a system has been created, the system can be specifically checked for risks or risk areas. Therefore it is not important that the effects of a risk are mitigated, but rather that their causes be eliminated. First it must be the aim to eliminate as many causes of harmful effects as possible. [28] If this is done "simple" roots can be considered in a risk analysis.

3.2 Modeling of risk areas by using an object model

If some risk areas are identified in the tree, which contain essential risks of the system, an analysis of cause-effect relationships in these sub-systems has to be done. Therefore, a object model has to be used.

An object model has three different elements, which can be connected by various links to each other. The product is the central element in the model, that plays the leading role. Around the product components will be arranged, which help to ensure that the product can fulfill its functions. These are specifically created sub-systems to interact with the product. The surrounding system are elements which were not specifically created to interact with the system, but are an integral part of the complete system. [29] In order to visualize the system as interactions between different objects these interactions have to be shown in their different interaction forms in the model. Therefore different arrows exist. A normal straight arrow represents a satisfactory and requested interaction between the individual objects. A dashed arrow represents a requested interaction, which is inadequate classified in its intensity, quality or expression. A curved arrow represents an interaction in the system that is not requested. The model is created in a workshop with system experts and is used in the further application of the method to identify the functions of the subsystems that have been previously classified as risky. [29]

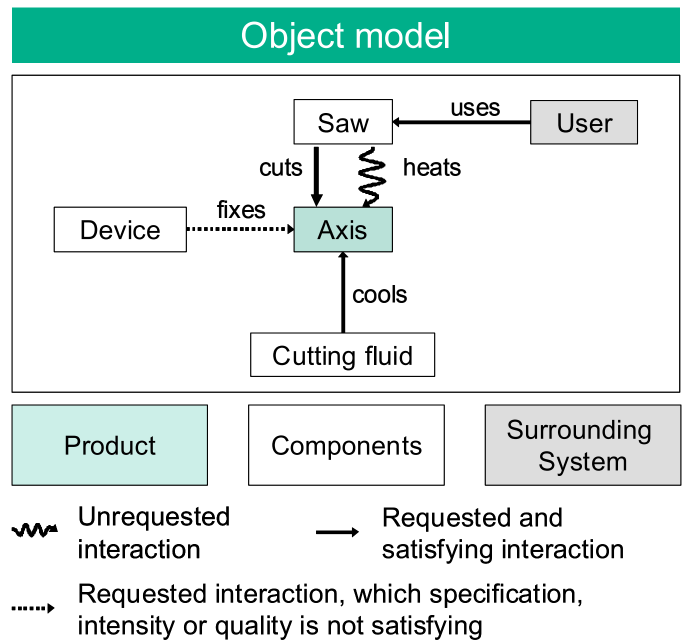

Figure 2:Elements of an object model

3.3 Derivation of the model inherent functions and effects

From the object model the functions of the system can be derived directly. In this context, a function is defined as a connection between a subject which can be set in relation to a specific action with an object. The subject is the active part in this connection, which influences the object by given operations. Subject and object are visualized in a rectangle (see figure 2), as it is usual in the object model. [30] As symbols for the action links the same arrow symbols are selected like in the object model. In this model the arrows are drawn horizontally between subject and object. The description of the action is carried out by a verb, which is arranged vertically centred on the mapped arrow.

By combining the presented symbolism for mapping subjects, objects and actions, it is possible to present a meaningful and unique function in the model. This model is extended by the classification of the functions. Functions that are essential to fulfill the given task are referred as productive functions (PF). They include functions that change the properties of the product permanently. Supporting elements that do not essentially contribute to achieving the objective are considered as auxiliary functions (AF). These are functions that change the properties of the system temporarily to enable other useful functions, to correct harmful functions or to eliminate harmful functions. Functions that have no useful aspect are called harmful functions (HF), which can have a negative impact on sub-systems and deteriorate the properties or performance of the system. [29] After the elements to illustrate functions are presented, the need is to work out the model's inherent effects. For this a division into useful effects (UE), primary harmful effects (PHE) and harmful effects (HE) is given. [29] The effects are derived at a workshop of an interdisciplinary team out of the function model and an analytical view on the system.

3.4 Combination of functions and effects for a function-effect model

According to this arrangement of groups of functions and effects, a model is obtained in which the defined and graphically represented functions and effects are related to each other. Based on the fault tree analysis the symbol of an arrow is used. [31, 32]

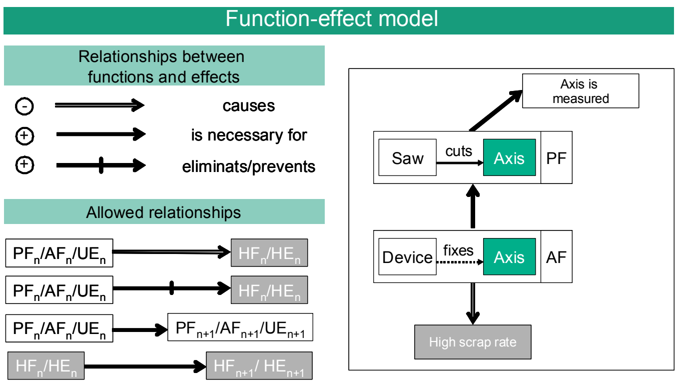

Figure 3: Elements of a Function-effect model

This depicts a causal connection between the individual elements. One way of presenting such an arrow with the corresponding effect description can be deduced from the function-effect modelling. [29] A normal arrow is used to represent a positive dependency. A function "makes" an requested state and is used to achieve the required objective. The opposite pole of this symbolism is realized by a crossed-out arrow. These two forms of representation are appropriate to illustrate positive functional dependencies. But also negative consequences have to be mapped in the model, which result from the interaction of functions or functions and effects. Therefore a double arrow is used. The negative character of the double-arrow icon is concreted by the verb "causes". By applying this relationships assignments permitted cause-effect relationship can be taken in advance. Thus the model development is simplified, because only certain relationships can be useful represented and a variety of false relations can excluded in advance.

3.5 Systematic risk analysis in the developed model

By using this model, it is now possible to visualize the cause-effect relationships of technological systems. First of all risks, which are inherent the functions, can be identified. This is indicated in the function representation by the curved arrow, that identifies an unrequested event. Such a combination leads to the classification of harmful functions.

Not only functions are described and classified in the developed model, but also positive and negative effects. If a negative effect appears in the model, it is an indication of a risk in the system. The aim must be to eliminate this risk to neutralize by peripheral systems.

4 SUMMARY OF VALIDATION RESULTS

The validation of iFEM was carried out in workshops at an enterprise of the medical engineering branch. The case study of the enterprise deals with a unicameral cardiac pace maker. In general the cardiac pace maker is used to stimulate the heart in case of heartbeat slowing down (bradycardia). The high reliability of today's cardiac pace makers supersedes chronic medication. The cardiac pace maker comprises of a lithium battery, a pace maker electrode, control electronics and a programming unit

4.1 Results of modeling the complete system "cardiac pacemaker"

The visualization of risks and their linkages were judged very positively. The possibility to identify linkages and causal chains between the individual risks in the tree were assessed very positively by the participants. In addition, this method offers a good basis to identify risks systematically, because the system is analyzed extensively by these causal chains. The main criticism of the tree related to its high complexity. The degree of abstraction has no limits at the beginning, so the system can be subdivided to any depth. The participants also articulated the need for a prioritization of the risks by severity and occurrence. Another result of the validation was, that a moderator with a broad knowledge of the method is necessary. Working with the model requires a good system knowledge and a high level of abstraction by the participants. The links between the individual risks were assessed very positively. Als schädlicher Effekt des Systems, der im Objektmodell detailliert werden soll, wurde die Verschweißung der Batterie in der Titanschale identfiziert.

4.2 Results for object modeling

The principle of object modeling was understood directly by the participants. The advantages of representation and visualization of the individual relationships were rated as helpful and useful. The structure of the model created a general understanding of the identified problem area in the team. The application has also shown, that for unknown cause-effect relationships an additional connection is needed, to express the need for further tests and analysis. The time expended for the method was evaluated as appropriate by the participants. As a result from the object modeling of the welding process the powder burns on the casing are identified as one of the biggest risks in the system. However in the following function-effect modelling the entire welding process was considered.

4.3 Results for the function-effect model

This method was the greatest challenge for the participants during the validation of iFEM. The creation of a function-effect model was created with great effort, for relationships between functions and effects to be identified correctly and documented by the participants. In particular, the possibility to identify conflicts systematically was highlighted positively by the participants as well as the expansion of the system understanding by this method. Despite the complexity of the method, the participants understood the procedure. The time expended for simple systems was assessed as critical. The opinion of the participants was, that the model is particularly useful for complex systems. The Function-effect-modelling only results, that the entire welding parameters have to be checked. At the end only the checking of the entire welding parameters results from the function-effect modelling.

4.4 Evaluation of iFEM in comparison to classical methods

During a workshop the system-FMEA process [18, 20] and iFEM were compared. The two methods were used on the example of a bike-lighting unit. The aim of the workshop was to evaluate the added value for the industrial practice and the clarity of iFEM. Evaluation criteria were collected, e. g. total number of identified risks, number of identified critical risks, the required time for execution, number of questions by participants or the usability.

The benefits of iFEM are:

- Promoting interdisciplinary exchange,
- Clear result for risk classification and
- Creation of a uniform system understanding.

The following conclusions can be drawn:

The system-FMEA process provides a simple and systematic quantification of process inherent risks. The effort to learn the method is relatively low and a chain-linking of functions and malfunctions is possible. Due to the lack of differentiation of the values of the scale ratios the comparability of risk assessments is complicated, especially if these assessments are done by different people. IFEM is suitable for the interdisciplinary review of a complex product. The modeling of the entire system is possible in order to establish a uniform understanding of the system. Manufacturing processes, management processes and system functions can be linked with iFEM. Both methods require a moderator and need a higher effort with the increasing complexity of the product.

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