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A KNOWLEDGE FRAMEWORK FOR SAFETY ANALYSIS OF USER-INDUCED CHANGES

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Keywords: change management, safety analysis, knowledge framework, user-driven customization

1. Introduction

In the last years the demand for individual products increased and the focus of value creation shifted more and more to customers or users [Reichwald and Piller 2006]. This on one hand shifted the creation of variants to later stages in the development and manufacturing process but also introduced new concepts of customization and user-involvement. Examples are user-driven customization, user co-creation or user innovation [Franke and Piller 2004], [Reichwald and Piller 2006], [Roth et al. 2016b]. These concepts induce engineering changes (EC) through the users, which in case of user-driven customization are shifted to the end of the product development.

On the other hand, complexity of products and constraints is also increasing. This especially applies for safety regulations. In combination with the previously mentioned trends and late user-induced changes, this leads to increasing efforts and new challenges [Lindemann et al. 2008], [Leveson 2012], [Roth et al. 2015a].

Yet, current practices of safety analysis mainly rely on experience and review-based methods [Sierla et al. 2012]. And also the consistent and integrative documentation of safety analyses and connected knowledge is not always given [Roth et al. 2015a].

With these manual efforts and inefficiencies, individual products of user-driven customization cannot compete with mass products. To overcome this, a knowledge framework is needed which helps to analyse user-induced changes and identify their impact on product safety. This could close the gaps between designers and safety experts as well as simultaneously reduce the manual efforts involved.

However, existing research on engineering change management (ECM) is mainly concerned with the management of change and rework processes. Also the idea of user-induced changes in a user-driven customization setting is not considered. Therefore, this paper researches the question (RQ1): How does a knowledge framework to identify and evaluate the safety impact of user-induced changes look like?

To answer this, the paper as its main contribution conducts an extensive literature review of existing publications on ECM. It from a product perspective analyses the model domains and basic methods, the approaches and methods build on. The findings are then consolidated with a similar analysis of model-based safety analysis methods to derive the sought knowledge framework.

The paper in the following first introduces the basic terms and concepts of both, safety analysis and ECM. It then introduces the research methodology and elicits basic requirements on the framework. Then the results of both literature analyses are presented before the consolidated framework is derived. The paper then concludes with a discussion and an outlook on future research and applications.

2. Background of safety analysis

This section introduces the background of safety analysis. It therefore, defines the key terms and presents

the traditional and most common methods of safety analysis.

2.1 Safety, hazards and failures

The main objective of safety analyses is the analysis, assessment and improvement of the safety of a system or product. In this context the following definition of MIL-STD-882E is chosen according to which safety is a system's "(…) freedom from conditions that can cause death, injury, occupational illness, damage to or loss of equipment or property or damage the environment." [DoD 2012]. This mostly complies with Neudörfer, who defines safety as an immaterial system property, which describes that in the expected product life cycle hazards are limited to an acceptable risk [Neudörfer 2014].
These hazards are a threat to safety. They are a "(…) real or potential condition that could lead to an unplanned event or series of events (…)" [DoD 2012], resulting in the occurrence of the events stated in the definition of safety above [DoD 2012]. Events which lead to the occurrence of these hazards are the failures of functions or components.

2.2 Traditional methods of safety analysis

To ensure system safety a wide variety of safety analysis methods exists. E.g. Berres et al. examined in their survey which methods in aerospace engineering development processes are applied [Berres et al. 2014b]. Other analyses can be found in [Leveson 2012], [Jensen and Tumer 2013] and [Roth et al. 2015a]. The most common methods are the deductive Fault Tree Analysis and the inductive Failure Mode and Effect Analysis. In the following both are described briefly.

2.2.1 Fault tree analysis (FTA)

The FTA is a well-established and standardized method for safety analysis of systems (IEC61025). With its deductive character it identifies possible causes and their contributions starting from an undesired top event. The results are displayed in a tree, where Boolean logic gates model the interferences of causes. Elements within the branches are so-called intermediate events and the elements at the bottom of the tree are basic events which are usually single component failures [IEC 2006b], [Majdara and Wakabayashi 2009].
The traditional FTA, thus is able to evaluate the impact of one failure on multiple events (common cause). Also analytical methods allow to precisely evaluate the trees, which includes the identification of so-called minimal cut sets [IEC 2006b]. Yet, the FTA involves high manual efforts and expert knowledge [Majdara and Wakabayashi 2009], [Sierla et al. 2012]. Additionally, very detailed information is required to assess occurrences. This limits the FTA's applicability in early stages [Roth et al. 2015c].

2.2.2 Failure mode and effect analysis (FMEA)

In comparison to the FTA, the FMEA has an inductive character and its main objective is to identify and assess possible failure modes [IEC 2006a]. It occurs in various phases of development and abstraction levels. Common types are the functional or the systems FMEA, the design FMEA and the process FMEA [IEC 2006a]. The FMEA includes five steps: preparation, failure analysis, risk assessment, calculation of the risk level and, if necessary, deduction of countermeasures. A common extension is to deduce an overall criticality of the failure modes (FMECA) [IEC 2006a].
The failure analysis identifies potential failure modes of the product and their resulting consequences. For these modes, their probability, severity and detection are assessed. Based on that the risk level is calculated and, if necessary, measures to reduce the risk are deduced [IEC 2006a], [Ben-Daya 2009].
The traditional FMEA thus, is able to analyse and improve product safety during the whole development process. Yet, it does not consider common causes, and like the FTA involves high manual efforts and expert knowledge [Maurer and Kesper 2011], [Jensen and Tumer 2013].
As recommend in standards [IEC 2006b], the deductive FTA should be combined with inductive methods like FMEA to ensure comprehensive safety analyses. The link between these methods are the basic events of the FTA: each of those shall be represented by a failure mode in the FMEA [IEC 2006b].

2.2.3 Summary of traditional safety analyses

From the previous paragraphs it is obvious that the manual efforts and required experience are major limitations of traditional methods. In the context of customizable products, these disadvantages gain in weight [Roth et al. 2015a]. This induces a need for a framework to efficiently handle the safety analysis of user-induced changes due to customization.

3. Background - knowledge and information models for changes

As described in the introduction, a concept of user-driven customization will directly induce changes in the product through the users. These changes have to be handled. The approach to meet classical ECs in development is ECM. The following introduces its main concepts and methods.

3.1 Engineering change (EC) and change propagation (CP)

EC has been discussed widely in literature during the last decade. However, the definitions of EC are not fully consistent [Jarratt et al. 2011]. We in this paper follow the consolidated definition of [Jarratt et al. 2005]: "An engineering change is an alteration made to parts, drawings or software that have already been released during the design process."

While ECs occur frequently during the design process, the actual challenge there arises from the interactions between the system elements. Due to these interactions, changes to one part in complex products usually lead to necessary changes to other parts. This might induce additional changes and is called change propagation [Eckert et al. 2004].

Integrated products with high complexity and coupling bear a higher risk of CP than lesser complex products [Fricke et al. 2000], [Jarratt et al. 2011]. Therefore, when analysing changes, it is necessary to consider change networks instead of change chains [Eckert et al. 2004]. This underlines that both factors, complexity and product architecture, have a significant influence on engineering changes [Jarratt et al. 2011].

Possible consequences of these changes are major rework cycles in the development process [Maier et al. 2014] and information deficiencies between the involved domains and individuals [Fricke et al. 2000], [Jarratt et al. 2011]. These and other challenges are addressed by ECM.

Returning to the user-induced changes in user-driven customization, it becomes clear that the centre of interest lies on the product related aspects of changes. Thus, process and organizational aspects are neglected in the following.

3.2 Information models for engineering change management

The previous section pointed out the importance of consistent information and the analysis of CPs, when handling changes. Therefore, various methods and tools, which develop or build on information models, are published. To classify those, Ahmad et al. [2011] conducted an extensive literature review and extracted the focus as well as the domains these publications use. They identified four relevant domains for ECM: requirements, functions, components and processes. They found that only few methods and tools use single domain models while most publications include cross-domain models to manage engineering change. They also identified that the majority of these publications aims to support the change management processes and only a smaller part focuses on design and product aspects. [Ahmad et al. 2011]

A similar approach is followed by Helms et al. [2014]. They classify methods predicting engineering change propagation according to their purpose, the situation, their effects and their underlying methods. There, a variety of purposes and situations is identified. However, many of the methods focus on specific aspects and for example mainly predict undesired propagations or evaluate change influences [Helms et al. 2014].

4. Research methodology

To answer RQ1 (see introduction), it is split into four sub-questions. The first sub-question RQ1a is: What are the requirements on a knowledge framework which integrates the aspects of ECM and safety analyses in the context of user-driven customization? The integration of these two aspects requires to

research the existing state of art in both fields. This results in the questions: Which methods and knowledge frameworks for ECM (RQ1b) and safety analysis (RQ1c) exist and which model domains do they use? Thereby, the main focus is laid on ECM frameworks. Using the results of these questions, RQ1d researches: Which are the consolidated domains of acknowledge framework to handle user-induced changes and their safety impact? The overview on these research questions and the connected research methodology is visualized in Figure 1.
The following sections will explain the specific methodology to answer each of the sub-questions and directly present the obtained results.

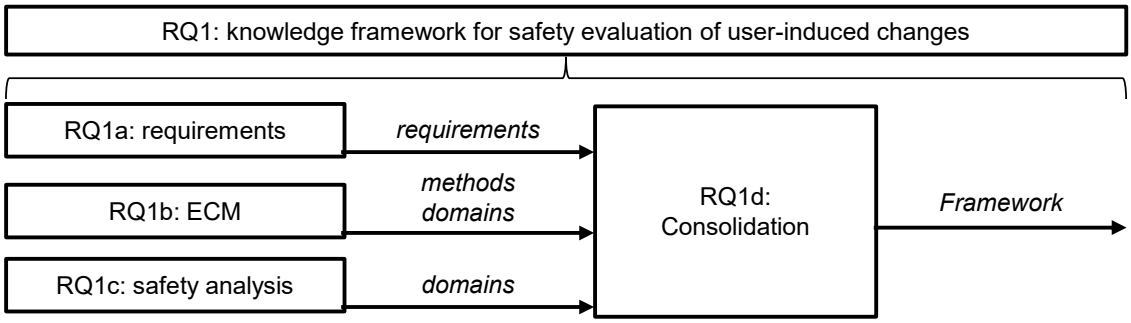

Figure 1. Overview of the research methodology

5. Requirements on a knowledge framework (RQ1a)

As described in the introduction, the realization of a user-driven individualization approach arises the need to combine the evaluation of CP and the analysis of these changes' safety impact. This section therefore, derives basic requirements on a framework, which integrates both perspectives in the context of user-driven customization.
First, general requirements on a support for user-driven customization were extracted from previous studies [Roth et al. 2015a], [Roth et al. 2016b]. These general requirements then were further specified to be valid requirements on a knowledge framework. From a safety perspective the following five general requirements on a support in the context of user-driven customization shown in Table 1 can be identified.
The need of a consolidated knowledge framework is identified in multiple studies. For example Roth et al. [2015a] demand for a model which documents and explicates all relevant product and safety information.

Table 1. General requirements on safety-oriented support for user-driven customization

no.	title	explanations
R1	improvement of efficiency and automation	User-driven customization leads to small batch sizes up to fully individual products, which will lead to increasing efforts to evaluate the user-induced changes in terms of safety [Roth et al. 2015a], DESIGN. To compete with mass products, these efforts have to be reduced by increasing efficiency and automation [Roth et al. 2015a].
R2	support safety-oriented product preparation	Especially efforts for the product preparation (safety, product structure, etc.) will increase due to user-driven customization. Therefore, safety-oriented support methods have to help during the task clarification to prepare the product including all necessary safety considerations [Roth et al. 2015a], DESIGN.
R3	support balancing of safety considerations and degrees of freedom	The challenge during product preparation for user-driven customization is to provide a solution space which is a priori as safe as possible, but does not limit the user in his creativity. Therefore a support tool has to evaluate the safety impact and propagation of the offered degrees of freedom [Roth et al. 2015a].

R4	provide transparency and documentation	The documentation of propagation and safety analyses has to be complete and consistent [Fricke et al. 2000], [Roth et al. 2015a]. For each individual product full traceability has to be ensured.
R5	provide interface for toolkit integration	The realization of user-driven customization requires a continuous integration of the users DESIGN. This is mainly done by web-based toolkits [Roth et al. 2015b].

To evaluate occurring changes, the possible propagations in the model have to be identified by suitable methods. Therefore, often matrix- or database-based methods are used [Helms et al. 2014]. From safety perspective for example Jensen et al. build a model-based design framework and identify an additional need to explicitly include safety aspects [Jensen and Tumer 2013]. Also others demand for a model, which is enriched with additional safety information to enable faster reaction on modifications [Berres and Schumann 2014a].
Moreover, the requirements R2 to R4 all induce that a knowledge framework for user-driven customization has to connect and integrate all relevant aspects. In particular it requires the integration and connection of CP with safety aspects. This in summary results in the four framework-specific requirements shown in Table 2.

Table 2. Specific requirements on a framework for a safety-oriented support of user-driven customization

no.	specification	parent
Req1	The framework shall be model-based and computer processable.	R1, R5
Req2	The framework shall integrate all relevant domains and dependencies to determine change propagations.	R2, R3, R4
Req3	The framework shall integrate all relevant domains and dependencies to provide safety analyses.	R2, R3, R4
Req4	The framework shall integrate and connect change propagations with safety aspects.	R2, R3, R4

6. Methods for ECM (RQ1b)

In section 3.2 we introduced two extensive literature studies on ECM methods. However, both followed specific aspects and had a special focus. Therefore, to cover the latest publications and to tailor the literature review according to the focus of this paper, we conducted a further literature study: The keywords "change" and "propagation" have been searched in the following sources: design society (including the conferences DSM, ICED, DESIGN and further) and in relevant journals (Res in Eng. Design, Journ. of eng. Design, IEEE Trans. on Eng. Mgmt. and Systems Engineering). This search identified 617 publications in the years 2000 to 2015. From these publications the titles were screened on if they use the keywords in the sense of EC. This reduced the number of relevant publication to 106. For these 106 publications the abstracts were analysed to identify the scope of the paper. According to this scope the articles were classified in relevance. If the document addresses aspects of CP within the product and its elements, it was assigned to the "high relevance" class. If it focussed on other perspectives of CP, but is connected to product aspects, the "medium relevance" class was assigned. Other publications were assigned to the "no relevance class".
In total, 48 highly and 18 medium relevant publications remained. Those were analysed to identify and document the domains included in the methods and models as well as used other basic methods.
As the focus of this literature review slightly differed from the works of [Jarratt et al. 2011] and [Helms et al. 2014] the results also vary a little. Though, still a large overlap can be found. The results were clustered according to the classes defined by Helms et al. [Helms et al. 2014]. If necessary they were refined. Figure 2 provides an overview of the distribution of these classes. It can clearly be seen that the school of EDC Cambridge with its Change Prediction Model (CPM) and its extensions published most in the field of EC. Some other classes defined by the existing reviews were not identified, as they have a different focus and they are out of scope of this analysis. In the following each class will be described briefly.

The Change Prediction Model (CPM) uses matrices to map dependencies between product components and based on that predicts the risk of further propagation through the product. It thus helps to evaluate and compare engineering changes [Clarkson et al. 2004], [Helms et al. 2014].
The Change Modelling Method (CMM) unites the CPM with the House of Quality (HoQ). It allows to obtain possible propagations of change options and supports their selection [Koh et al. 2012], [Helms et al. 2014].
While the above described methods only consider dependencies between components, the Functional Analysis of Change Propagation (FACP) integrates a functional view. Thus, changes can be considered in terms of function and form simultaneously [Flanagan et al. 2003], [Helms et al. 2014].

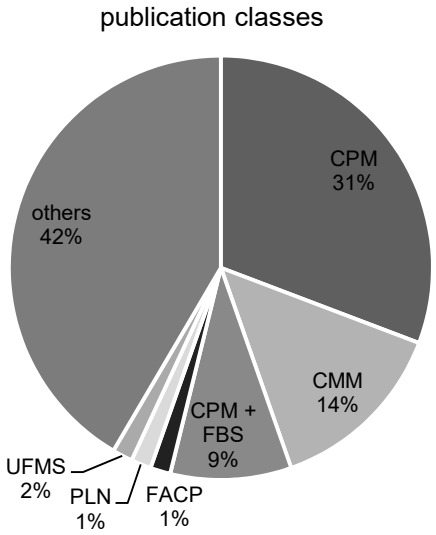

Figure 2. Classification of relevant ECM publications

The functional perspective is also integrated by the FBS Linkage Model (CPM+FBS). It integrates Function Behaviour Structure (FBS) in CPM to predict and analyse engineering changes [Hamraz et al. 2012].
The Unified Feature Modelling Scheme (UFMS) models associative engineering relations. It thus strives to control information consistency during various lifecycle stages to make EC processes more effective [Ma et al. 2008], [Helms et al. 2014].
The PLN-based method (PLN) considers linkages between parameters. Based on a parameter linkage model an algorithm identifies the optimal propagation path [Yang and Duan 2012], [Helms et al. 2014].
The class of others collects different publications and methods, which could not be assigned to a new or specific existing class. One example is the multilayer network model, which unites the product view with organization and individuals [Pasqual and Weck 2012].
The analysis of involved domains and methods is presented in Figure 3. It can be clearly seen that components are the central element of models and methods for ECM. This is not surprising, as usually the product structure is defined in components or assemblies and the development activities are structured accordingly. Furthermore, requirements and functions are often used approaches as well. Moreover, some publications use design parameters or product properties. And even though, publications which only focus on processes were not analysed, the domains of processes and resources still play a role in the identified methods and models. Additionally, it is remarkable that flows and faults only play a marginal role in the ECM models.
As already seen during the classification, CPM plays a central role in ECM publications. But the basic method on which the vast majority of all published methods and models build are matrices. Thus, matrices and CPM dominate the ECM methods. Further methods are used to supplement or extend these basic methods. The most important examples are Propagation Trees, the FBS, the contact channel model (C&CM) and the Quality Function Deployment (QFD).

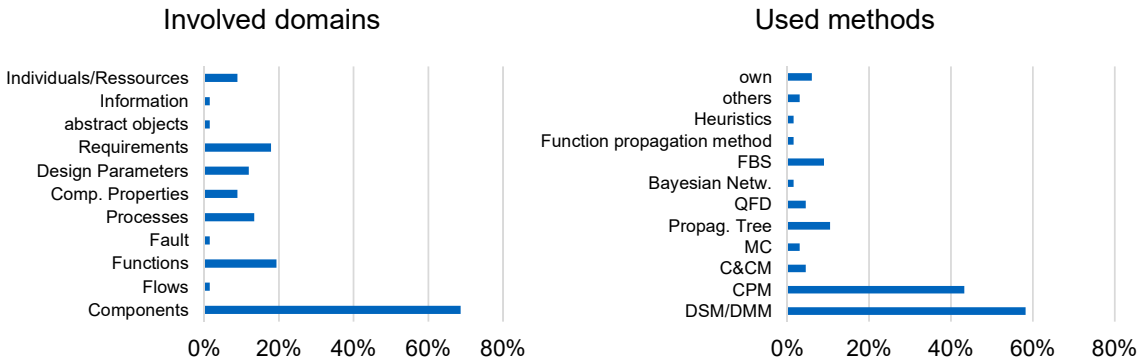

Figure 3. Domains and basic methods of existing ECM methods

7. Model-based safety analyses (RQ1c)

While section 2.2 presented the traditional methods of safety analysis, this chapter analyses existing models-based extensions and methods. Therefore, a minor literature review was conducted. It mainly focused on the systems engineering conferences and journals of IEEE and INCOSE, The selection criteria were, that the methods introduce models or frameworks and simultaneously strive to increase efficiency and automation of the safety analysis. Table 3 summarizes the most recent and relevant approaches in this field.

Table 3. Model-based methods for safety analysis and their included domains

Publication(s).	scope	domains					
		components	functions	flows	hazards	failures	others
[Roth et al. 2015c], [Roth et al. 2016a]	automatic generation of fault trees		x	x		x	
[Biggs et al. 2014]	including safety analyses in SysML	(x)		(x)	x	x	x
[Müller et al. 2016]	including hazard analyses in SysML	x		(x)	x	x	x
[Kurtoglu and Tumer 2007]	framework for early safety and failure propagation analysis	x	x	x		x	
[Maurer and Kesper 2011]	Efficiency improved FMEA through matrix based methods	x	x			x	
[Mhenni et al. 2013], [Mhenni et al. 2014]	Tailored model for safety analysis of mechatronic systems	x		x		x	x

The analysis of the existing models clearly shows that components and functions play a central role. But also failures are a central element of these models. To establish links between the model elements and to consider failure propagations often additionally flows are included in the modelling. Furthermore, depending on the specific scope of the model, other elements (i.e. hazards) are considered as well.

8. Consolidated knowledge framework to evaluate and manage the safety impact of user-induced changes (RQ1d)

To answer RQ1d, the findings of the two previous sections are consolidated. It was clustered in a core and optional elements, which both is described in the following. Moreover, knowledge and assumptions of safety experts in terms of user-driven customization were included.

Out of Figure 3 and Table 3 the domain of components clearly elicit as a central element of a knowledge framework which unites safety aspects and change propagations. Moreover, the domain of functions is involved in many methods of both sides and also should be included in the core domains.
The ECM methods usually establish the links by an abstract propagation, often based on experience. Methods of safety analysis go one step further and usually use material, energy or information flows to establish the propagation links between the system elements. Thus, the domain of flows which represents the more detailed safety view should also be included in the core domains. The same applies to failures. Without including them in the model, a safety analysis would not be possible.
Thus, the core of the knowledge framework displayed in Figure 4 consists of the domains of components, functions, flows and failures as well as their linkages. Possible extensions of that core are the domain of requirements or more specific safety requirements, the domains of hazards or even validation tests.

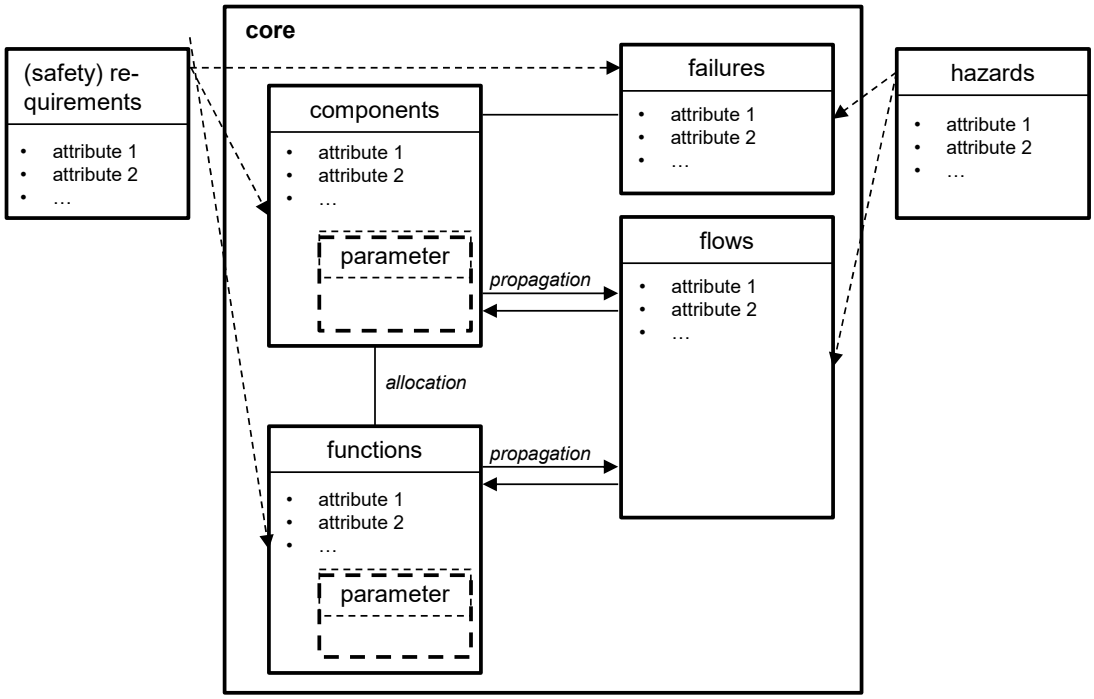

Figure 4. Meta-model of the knowledge framework to evaluate and manage the safety impact of user-induced changes

This knowledge framework and its relations can quickly produce large data volumes. However, it shall be able to be computer-processable and also be compatible with the ECM and safety analysis methods discussed in this paper. This means it has to be compatible with various methods (e.g. DSM, QFD, Propagation Trees, Fault Trees, etc.). To unite those and to remain compatible matrices not suitable as representation. They lose clarity with increasing complexity and interrelations. Instead, a graph-based implementation of the framework is proposed. The graph-based data reduces processing time and makes large amounts of data manageable.

9. Conclusions and outlook

This paper systematically derives and consolidates a framework to model and manage user-induced changes form a safety perspective. It therefore, provides an extensive literature review on existing methods of ECM. Identified publications from a product perspective are classified and structured according to the involved model domains and used methods. By that this paper contributes to the structuring and classification of ECM methods. It answers the research question which methods and information models for ECM exist and which model domains they use. However, the product-centred focus might not be suitable for all applicants so that the validity stays limited to the initial research focus.

In addition, the paper provides an overview on existing model-based methods for safety analyses. It identifies publications and analyses them on involved domains. By that, it answers the research question which methods and knowledge frameworks for safety analysis exist and which model domains they use. This review was performed less comprehensively. The selection of the methods was driven by the authors' experience. This can limit the quality of the results. While this is sufficient to develop the framework, for a general overview and classification, the literature review needs to be extended.
Finally, the paper consolidates the findings and develops a knowledge framework, which satisfies the initially derived requirements. It moreover, suggests a graph-based implementation of the framework. This implementation was realized by the tool Soley (soley-technology.com) and implemented for two consumer goods. The knowledge framework was created for a fully automated coffee machine and a cordless screwdriver. Future work will test the framework on its usability. The first insights underline, that an at least semi-automated processing of the data is needed as the models complexity quickly increases. While the framework can still be manually interpreted for the cordless screwdriver with 20 to 30 components, the coffee machine's complexity with its approx. 200 components or assemblies is too complex for a manual interpretation.
However, only with having the implemented framework no benefit is provided. Further research needs to meet the challenges through user-driven customization and its user-induced changes by connecting the framework with suitable methods. Therefore, interfaces to existing methods have to be developed and it has to be researched how the proposed framework can increase the efficiency of these methods. Moreover, new methods have to be developed which help to realize user-driven customization by providing efficient safety considerations tailored to automation in connection with this knowledge framework. This will include, the assessment of system elements, the identification of possible degrees of freedoms and constraints and the evaluation of their changes.

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