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RISKS IN PRODUCT DEVELOPMENT: ADVANCEMENTS IN RECENT YEARS

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1. Introduction

With each day products are getting more complex due to market requirements going up which in turn leads to more complex development processes. The ability to meet the end user requirements under constraints of quality cost and time determines how successful product development was. [Lindemann 2006]. Organizations are becoming more and more aware that without the risk management they cannot stay competitive on the market. Although some organizations require identification of needs for risk management processes, many of them still require only basic understanding which is used as needed or occasionally [Škec et al. 2014]. Few years ago standard that defined frame for risk management was published. Standard describes in detail risk management processes that are independent of risk type, nature or whether effects are positive or negative [ISO 2009a]. Along with risk management standard a set of many techniques for identification, analysis, evaluation and risk mitigation were published. [ISO 2009b]. Even before the standards were published there were many risk management process representations [PMI 2013]. Most of the defined processes consist of identification of potential risks. Various techniques are used for risk analysis and final mitigation or elimination. Through the entire process risks need to be monitored and checked constantly to ensure that after mitigation no new risks are introduced.

This article is a review of the available literature in risk management in product development area. The aim is to summarize new methods that improve product development and reduce defects, required time for product export on the market and related costs. Based on the introduced methods and approaches, gaps in currently used literature can be recognized and further research directions are provided.

This review will address the following questions:

- Could some of the existing risk management methods be combined (merged) in order to provide more efficient results in complex product development processes?
- Is it beneficial to implement or connect risk management with everyday usage of CAD systems? Which risk management method(s) could be appropriate for this purpose? In this context would it be interesting to analyze how influential may be risks connected with "bad or not efficient" usage of CAD systems?
- Would it be beneficial to support risk treatment and risk communication with PLM systems?

2. General risk management process

Although risk awareness exists for several centuries, only a few years ago have International Organization for Standardization published a standard that defines risks in project management [ISO 2009a].

Alongside risk management standard, an additional standard that lists tens of methods used in risk identification, analysis, evaluation and risk treatment was published. Even before standards were defined much has been written about risks and a number of models for risk management exist that do not differ much from published standard, in product development or in general project management. Now already well recognized project management process was described by PMI [2013], and another similar model was described by HM Treasury [2004].

Risk management model defined by ISO 31000 is general model and doesn't relate only to specific industry. This process can be applied to whole organization, from strategic management to some specific activity or decision. During the risks analysis, individual risk cannot be viewed separately because individual risk can affect or stem from another risk. In order to better describe process of risk analysis, model is divided into 7 key steps (descriptions quoted or paraphrased from [ISO 2009a]) (Figure 1):

1. Communication and consultation with external and internal stakeholders is not a distinct stage in the management of risk. It is an activity which runs through the whole risk management process. Communication and consultation should facilitate truthful, relevant, accurate and understandable exchanges of information, taking into account confidential and personal integrity aspects. It is important to ensure that all stakeholders understand, in a way appropriate to their role, what the risk priorities are and how their responsibilities fit into process framework.
2. Establishing the context: In this step external and internal parameters which will be taken into account need to be defined. The organization sets the scope and risk criteria for the remaining risk management process. The management of risk should be undertaken with full consideration of the need to justify the resources used in carrying out risk management. The context can involve goals and objectives, responsibilities, risk assessment methodologies and the way of performance and effectiveness evaluation.

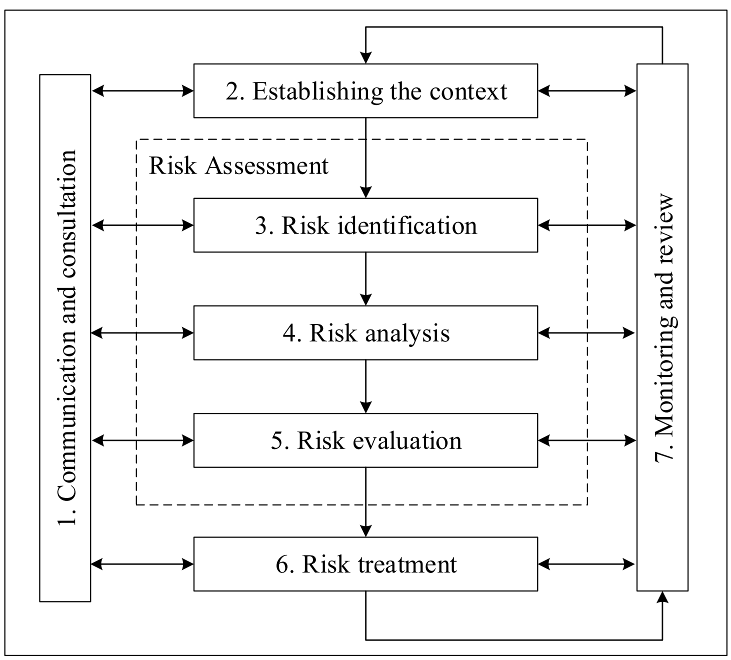

Figure 1. Risk management process [ISO 2009a]

3. In order to manage risks, the organizations need to know what risks it faces. Risk identification is the first step in risk assessment process. There is no right way to identify all risks, but documentation of risks is crucial to effective management of risk. The result is a list with all identified risks with their sources, areas of impact, events and their causes and potential consequences.
4. Risk analysis is a stage between identification of risks and their evaluation. The Aim of this stage is to get more detailed information about risks. For every risk, its causes and sources are

considered and probability and impact it has on execution of events is calculated. Risk analysis can be undertaken with varying degrees of detail, depending on the risk, the purpose of the analysis, and the information, data and resources available. Analysis can be qualitative, semi-quantitative or quantitative, or a combination of these.

5. Risk evaluation: Depending on the probability of risk consequences and by comparison with established criteria, risk need treatment or it can be tolerated. Since risk analysis is a cyclical process, in some circumstances, the risk evaluation can lead to a decision to undertake further analysis.
6. Risk treatment: In this step, decision how to treat risk needs to be made. This can include the following: avoiding the risk, removing the risk source, changing the likelihood, changing the consequences, sharing the risk with another party and retaining the risk by informed decision.
7. Monitoring and review: Every step in risk management process is monitored and reviewed. The aim of this step is analyzing and learning lessons from events (including near-misses), changes, trends, successes and failures. The results of monitoring and review should be recorded and reported as appropriate.

3. Findings of the literature

Although lately no significant methods like brainstorming or checklist have been found, a lot of small but essential steps have been made in this area. Some of them will be presented below.

3.1 Recommendations for risk identification method selection

Many methods that differ by complexity, implementation, need for experts and implementation duration among others are available for risk identification [Grubisic et al. 2011]. Authors therefore propose a model that would help in the selection of most suitable methods for risk identification for new product development project. Method selection is based on 3 criteria: product design and project management maturity levels, product innovation degree and project team. In proposed model it is assumed that degree of innovation and team profile will have a positive effect on the risk identification success.
Authors state that model as it is recommends continued improvement of risk management process.
In order to choose a right risk management approach (analogical, heuristic or analytical), it is recommended that project manager defines level of maturity of product process development and project management, originality of the product and the team profile.
Based on the model for choosing risk identification method authors make recommendations for the selection approach (Table 1) [Grubisic et al. 2011].

Table 1. Classification of the risk identification approach for the selection of the method [Grubisic et al. 2011]

Criteria / Typology	Product Design and PM Maturity	Product Innovation	Project Team
Analogical	3	Adaptable/Alternative	+
Heuristic	1	Innovative/ Adaptable	++
Analytical	3 Product design and PM - Key PM Processes and Focus Areas	Innovative	+++
	4 PM - Organizational		
+++ very important ++ important + less important			

3.2 Risk breakdown structure

As presented, the result of risk identification phase is an extensive list of risks. This list is not structured and therefore isn't of much help to project manager, for this purpose Risk Breakdown Structure (RBS) is used. RBS is defined as "A source-oriented grouping of project risks that organizes and defines the total risk exposure of the project. Each descending level represents an increasingly detailed definition of sources of risk to the project.” [Hillson 2002].

[Škec et al. 2013] created RBS for product development where he divided all occurring risks on internal and external. Internal risks are divided on four categories: Management, Financial, Technical and Organizational. External risks are divided on following six categories: Market, Regulatory, Financial, Partnership, Social and Nature. Each of those categories is further divided on several subcategories. After structuring, risks were mapped on two most common development process types: spiral and sequential.

3.3 Interaction-based clustering

[Vidal et al. 2009] state that risk classification by nature or by value is traditional and propose interactions-based clustering. Authors say that risks are related with complex relations which were not considered during traditional risk structuring.

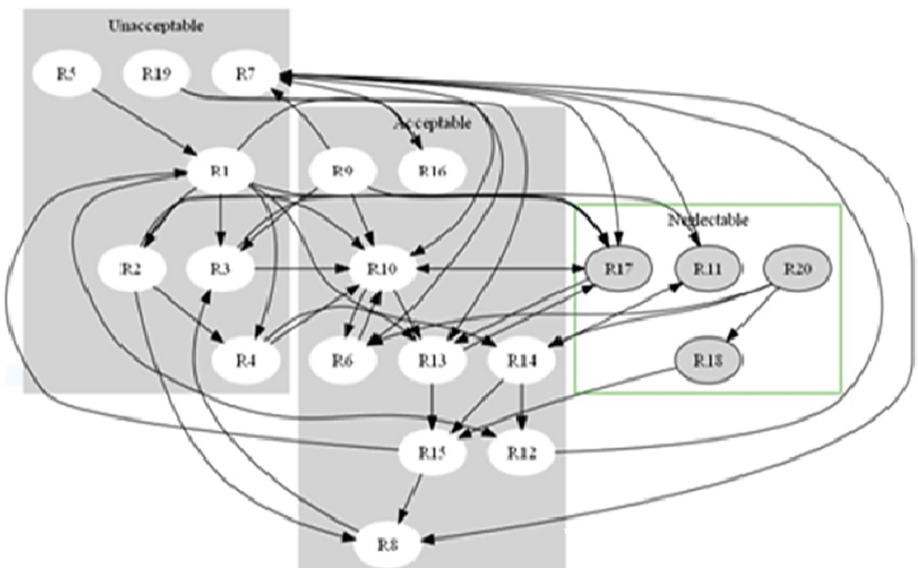

Figure 2. Clustering of projects risks [Marle and Vidal 2011]

They say that existing methods are mainly single-risk oriented and that they are analyzing multiple causes and consequences. Authors made Risk Structure Matrix with the help of identified interactions existing between risks and suggested algorithms for risk clustering [Marle and Vidal 2014].

Authors continued research on the risk grouping with the help of interconnected risk relations by introducing a new approach based on frequency analysis [Marle and Vidal 2011]. As a result frequency matrix was formed. "Frequency matrix indicates, for its non-diagonal elements the percentage of times where two risks Ri and Rj are assigned to the same cluster, and for its diagonal elements the percentage of times where one risk is assigned to a cluster."

After risk grouping depending on their relations and not similarities, authors suggested a method for risk prioritizing using importance measures [Fang and Marle 2014]. Until then, risks were compared independently on other risks and their importance, but here authors measure importance of whole cluster. They further suggest consideration of dynamic situations where risk characteristics and network structure are changing.

3.4 Intelligent risk mapping and sssessment system

In risk management process there is an eternal question which risks to treat first, to spend more resources on risks with greater probability and less impact or to solve risks with greater impact but less probability first [Lee 2014].

Based on well known, standardized risk management process authors formulated comprehensive frame used for intelligent risk mapping during product development process.
The Frame consists of six modules that offer automatic risk identification, their assessment and treatment. Main module is "Virtual Workbench" which offers interactive interaction with the user and allows, among other, choice of actions for treating the risk, as well as representation of risk analysis results. Another module is intelligent "Warehouse" in which is stored all experts knowledge and previous results information, risk factors data and mitigation alternatives. "Context Establishment" module offers automatic context establishment through a variety of structured questions on which user needs to provide the answer. Questions are related to the organization, product and process. "Risk Identification" and "Risk Assessment" modules provide identification of potential risks based on data from knowledge base and assess relative risk impact, weight and probability. "Risk Mitigation" module identifies actions for risk mitigation for most influenced risks. The Module can also assess potential costs for each risk mitigation alternative. Information from knowledge base need to be constantly checked to ensure that provided results are accurate [Lee 2014].

3.5 Specification risk analysis

[Wagner et al. 2008] found that when it's talked about risk management in product development, specification phase is not sufficiently supported. Therefore they designed method that analyzes potential risks of not achieving product specifications. Method is based on Failure Mode Effect Analysis adjusted for product requirement analysis. Authors state that this method was created for the application during embodiment design phase when numbers of product architectures are taken into consideration.
After team members selection further progress with 10 step procedure can be made [Wagner et al. 2008]:

1. Review the Candidate Product Architecture
2. List the Specifications and Decide Which Ones Will Be Analysed
3. Rate the Accessibility of Information
4. Rate the Feasibility
5. Rate the Contingency
6. Calculate the Risk Priority Number
7. Prioritize the Specifications
8. Develop Corrective Actions, Assign Responsibilities, and Set a Schedule for the Implementation
9. Implement the Corrective Actions, Update the Ratings, and Recalculate the RPN
10. Reflect and Decide about Future Proceeding
11. Also are listed all of their methods [Wagner et al. 2008]:
    - Identification, assessment and product specification ranking
    - Avoidance of product defects and possibility of a systematic approach for the development of appropriate risk mitigation actions
    - Reduction of cost and required time in later development phases

3.6 Development processes and risk management

In product development there are numerous approaches of which are most common: Waterfall model, Spiral development, Design for Six Sigma and Lean product development [Bassler et al. 2011]. Authors mutually compared different development processes in relation to the risk management approach and uncertainties in product development. For Waterfall model they said that it is focused on minimizing of uncertainties in system integration and comprehension of user requirements with extensive up-front planning while the first and fourth risk-driven design principle (Table 2) is not addressed. The Spiral model emphasizes reducing of uncertainties related with stability of user requirements. Spiral product development process is complex and therefore only partially reduces company-internal uncertainties. Authors conclude that this process is more suitable for complex project with poorly defined user requirements. Design for Six Sigma is very good at addressing all of the four principles, unlike spiral model and it is not intended for elimination of biggest risks first but for support of the most profitable project. Authors note that DfSS process due to its complexity requires a lot of expertise in risk management as well as a lot of development sophistication. This process directly addresses risk management in requirement phase. Authors state that Lean process doesn't address risk management directly but that decisions should be made based on checklists and matrixes that facilitate construction evaluation. But unlike other approaches, in Lean suppliers are involved in development process in early phase. Authors conclude that all development processes except DfSS need improvements in terms of risk identification and quantification [Bassler et al. 2011].

Table 2. Overview of risk management of different PD approaches [Bassler et al. 2011]

Risk-Driven Design Principles	Waterfall/ Stage gate	Spiral	Design for Six Sigma	Lean PD
1.) Creating transparency regarding design risks				
Explore and identify knowable uncertainties	○	○	●	○
Quantify resulting risks	○	◐	●	○
2.) Making risk-driven decisions				
Go/no-go decisions, quality checkpoints	●	◐	●	●
Resource allocation to retire biggest risks first	○	●	◐	○
Objective setting associated with risk assessment	○	◐	●	○
Entrepreneurial decision making based on risk-return analysis	○	○	●	○
3.) Minimizing uncertainty in design				
New (component) technology	◐	●	●	◐
System integration	●	◐	●	●
Quality of understanding customer requirements	●	◐	●	●
Stability of customer requirements	○	●	◐	○
Company-internal	●	◐	●	●
Competitor	○	○	○	○
Supplier	○	○	◐	●
Market	○	○	○	○
4.) Creating resilience in the design system				
Responsive design system	○	●	◐	●
Critical buffer in design system	○	○	◐	○

● ... Strongly addressed ◐ ... Weakly addressed ○ ... Not addressed

3.7 Creativity and risks

For the success of a product that is being developed on the market with good engineering knowledge certain dose of creativity is also required. [Sperandio et al. 2009] says that innovation is a function of creativity and therefore success or failure depends on creativity. Authors created new procedure for risk management in NPD that takes creativity into consideration They divided creativity on creativity of the individual and creativity of the organization in which individual is working. By combining these two points of view authors created success or failure probabilities of creativity graph (Figure 3).

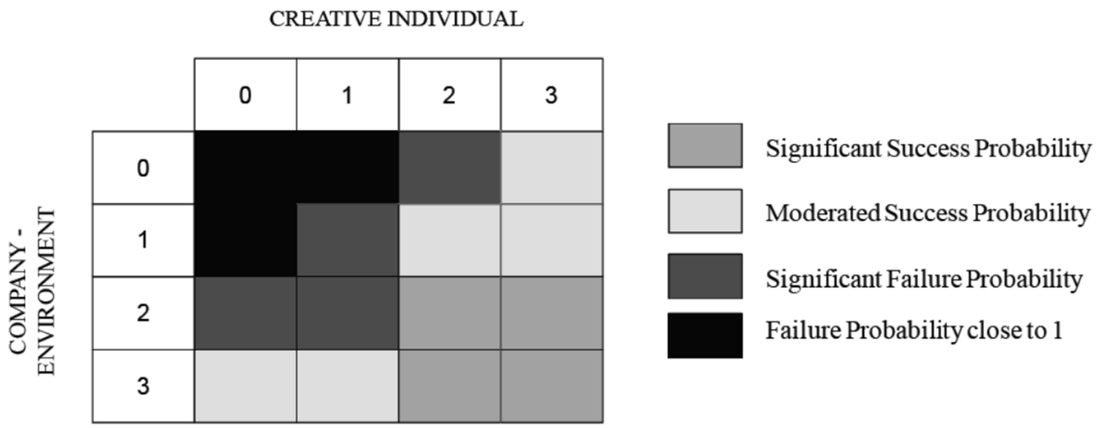

Figure 3. Success or failure probabilities of creativity [Sperandio et al. 2009]

Jerrard et al. (2008) have studied five small creative companies in detail over extended periods of the New Product Development (NPD) lifecycle. Design was a key aspect of company activity and central to the NPD process. Novel risk-tracking participatory methodologies were developed and employed to identify perceived risks at the outset of NPD and to track risk thereafter. Semi-structured interviews were undertaken on regular basis with company personnel responsible for design to provide rich contextual material. Results showed a wide diversity of perceived risk with little commonality amongst the companies – despite shared core criteria amongst the firms themselves, and the new products that were tracked.

3.8 Change Impact and Risk Analysis (CIRA)

One of the key steps in product development is Engineering Change Management [Conrad et al. 2007]. Insufficient information about the possible risks and their effects can greatly harm the organization. Authors have recognized this problem and suggested new approach, The Change Impact and Risk Analysis (CIRA). This approach combines two methodologies: FMEA method and CPM/PDD theory as base for product description. In this approach FMEA is used for assessment of effects, quantification of risks and documentation of the whole change process. Authors state number of the advantages (entire visualisation of the change impact) but also shortcomings of the CIRA (able to analyse single solutions and not a combination of them).

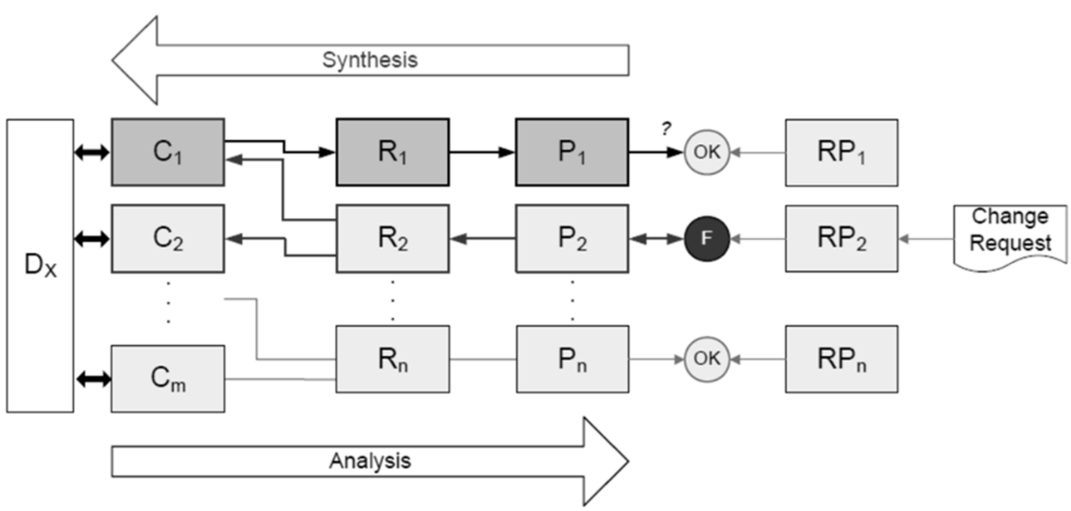

Figure 4. Impact Analysis of CIRA [Conrad et al. 2007]

3.9 Quality of qualitative risk assessment

In risk analysis quantitative and qualitative methods are used. Qualitative methods are widely used as support for making decisions because they can be quickly and easily applied unlike quantitative methods that require more time and more detailed risk information. One of the most widely used qualitative methods is certainly Probability Impact Graph (PIG).

Cresswell [2011] says that PIG is literally the basis for risk management in almost every organization. Because "risk = probability x impact", key risk characteristics are limited to its average value. Author states that there exist many better methods with more accurate results, but because of simplicity of application PIG stays the most used method in qualitative risk analysis. Author lists the important shortcomings but also advantages of this method and number of improvements related with this method.

4. Summary and discussion of findings from risk management literature surveys

[Oehmen et al. 2010] say that although risk treatment features prominently in many reviewed papers as an important PD risk management process step, it is difficult to identify concrete examples of actual risk treatment options in PD. No examples could be identified in the literature that showed the assessment of alternative treatment options and a structured selection process.

The authors in [Oehmen et al. 2010] emphasize that the understanding of the risk situation in PD has to be kept current and the risk management process, either in its entirety or parts thereof has to be executed repeatedly at certain intervals. In this way, new information can be integrated into the risk assessment and its accuracy improved. Such a conclusion led us to the proposal that such a repetitive process may be appropriately supported by PLM system workflow procedures.

While many examples of papers dealing with risk identification or analysis were found [Oehmen et al. 2010], only very few address the remaining process steps. The topic of risk treatment is despite its obvious importance only addressed marginally in the literature. Similar situation is with monitoring and review process. Based on all these findings we argue that a new direction of future research may be directed towards implementation of risk treatment, monitoring and review as well as communication and consultation through PLM systems.

Similar conclusions are given in CLUSIF white paper [Clusif 2009]. Authoritative texts in the field of risk management all highlight the importance of risk-related communication. When an organisation commits to serious risk management, it is essential that there should be a shared knowledge and a consensus on the risk situations and that this shared knowledge relies entirely on appropriate communication methods.

[Verbano and Venturini 2013] emphasize a new research stream that studies the implementation of risk management in the context of smaller companies, detailing the first contributions and suggesting future directions. Although the current study provides an input to the field, knowledge of the issues is inadequate at this early stage, and practical and academic studies are still very limited. Many useful implications are expected in the future from this emerging stream, especially in this period of economic recession, where the companies' survival is so threatened and important.

In conclusion of his review [Lleo 2009] emphasize that risk management is not just a technical challenge that requires the attention of a few highly trained quantitative analysts, but it is an organizational challenge in which everyone must participate. This is one more argument in favour of the necessity of permanent communication, monitoring and traceability in risk management process.

Lleo also says that at its base, good risk management needs to be rooted not only in appropriate controls but also in a strong personal and organizational sense of ethics.

An extensive list of remarks for future risk managers and tool developers is given in [Biijl and Hamann 2002]. We would like to emphasize just few key remarks in the context of this discussion:

- A group of people working together does not make a team. An individual working on a project form a threat if a communication is poorly done - again the authors accentuate the communication as one of the key factors in RM processes.
- Look at risk relationships − often a risk driver will impact all facets of risk and the integrated result will be improperly estimated - this remark goes in favour of approach of [Marle and Vidal 2014].

- A method should be: easy to use, fast to use and a method should integrate with existing system development methods - one of the most widespread systems in product development are PLM systems

5. Conclusion

This paper presented a review of the literature on recent advances in risk management in product development. A basis for all methodologies and approaches presented is the risk management process of international standard ISO 31000:2009.

The first part of the paper is about well-known risk management process which consists of the seven major steps. For each of these steps, there are numerous methods, although none of them are dominant in practice.

Presented literature deals with various topics, from managing risks in a specification phase of a product development, intelligent risks mapping to interaction-based risks clustering. Few authors compared common development processes regarding risk management.

It should be noted that this is not a complete review of the literature, but only a small portion in order to show that advances in this research area are significant.

Based on analysis and comparison of papers that present risk management literature surveys we propose a new research area that is rarely covered in literature - a practical implementation of risk management process through PLM systems. Since CAD systems are tightly coupled with PLM systems here we also see the opportunity to analyse risk treatment and monitoring on the level of parts and assemblies during their development. In this context another opportunity could be an analysis of risks that may arise due to errors caused by improper usage of complex CAD/CAE systems' modelling and analysis processes and procedures.

Such an approach need to be validated on several real complex projects in order to gain insight into possibilities of modelling risk management process in the framework of PLM system. Proposed approach should include methods of managing risk in the design process where the focus would be on managing risks arising from engineering decisions rather than from project management issues.

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