Risk assessment of machinery supported by the Bayesian approach

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ABSTRACT

Meeting safety requirements and conducting a conformity assessment is an obligatory process for machinery developers and manufacturers in the European Economic Area. Risk assessment of machines within the framework of the conformity assessment procedure is performed based on the harmonized standard ISO 12100 and the technical report ISO/TR 14121-2. These documents offer a basic description of approaches for machinery risk assessment. The ISO 12100 standard provides machinery designers and manufacturers with information for machinery to comply with essential requirements stated in Directive 2006/42/EC on machinery. With the development of digital technologies and the introduction of the new Machinery Regulation (EU) 2023/1230, the need to consider the requirements of the EN ISO 13849 control system safety standard and the EN IEC 62061 Safety Integrity Levels (SIL) standard has emerged. However, making decisions about the risks of machinery as a complex system is not an easy task. The ISO 31000 risk management standard recommends applying the theory of probability for uncertainty consideration when assessing risks. Bayesian analysis is one of the methods for applying a probabilistic approach and considering uncertainties to support decision-making when assessing machine safety risks.

1. Introduction

Starting in the year 2027, the Machinery Directive (2006/42/EC), used by engineers to guarantee the safety of machinery, will be amended by the new Machinery Regulation (EU) 2023/1230. The main goal of the new machinery safety-related document is to provide essential health and safety requirements for machinery, including machines with emerging technologies. The Machinery Regulation was developed considering the latest digital technologies used in machinery, such as Wi-Fi, Internet of Things, communication of robot systems, Artificial Intelligence, radio frequency devices and more. Protection against corruption as well as safety and reliability of the control systems dealing with cybersecurity also become essential in the conformity assessment process. The Machinery Regulation, as provided in its Annex I, presents a revised list of machinery categories and related products that require the mandatory participation of a third party in the conformity assessment. One of the main changes in the Annex I machinery list is the inclusion of self-learning machinery that uses systems based on machine learning behavior and safety components with fully or partially self-evolving behavior, ensuring safety functions [1].

New types of risks caused by the application of emerging technologies arise, and these risks should be considered in the risk assessment of machinery during the design process. The amendment of the Machinery Directive leads to the need to review the harmonized standards linked to this directive. New harmonized standards such as EN ISO 13849-1:2023 for control system safety and the related EN IEC 62061 Safety Integrity Levels (SIL) are becoming increasingly important.

Unfortunately, basic harmonized standards used for the risk assessment of machinery, such as EN ISO 12100, the technical report ISO/TR 14121-2 and other harmonized standards related to the Machinery Directive, are still being reviewed and developed. While these harmonized standards are being updated and reviewed, machinery design engineers need effective tools and methods for a reliable machinery risk assessment procedure. So far, the methods applied in machinery design risk assessment do not consider all the safety aspects required by the Machinery Regulation nor do they offer an integrated approach to risk estimation. Some machinery design risk assessment methods stated in the harmonized standards seem to fail when the risks of the systems consisting of multiple components are investigated. Often, the reliability and safety of complex systems is estimated based on the probability of failure and the corresponding safety integrity levels (SIL) of subsystems and individual components. For machinery as a complex system, reliable risk assessment and risk level estimation methods are required. Not only should the basic severity of harm and the probability of its occurrence be considered, but also the probability of failure of machinery components based on SIL as well as the software probability of failure should be estimated. The probabilistic approach suggested by the ISO 31000 risk management standard, which involves applying the theory of probability to assess uncertainty in evaluating risks, is becoming increasingly popular. One of the probabilistic approaches offered by the ISO 31000 risk management standard is Bayesian analysis.

The Bayesian approach has been successfully used by researchers to investigate probabilities of failure and estimate risk levels in various fields. The risk of oil spills in the marine environment has been found to require an integrated approach when investigating complex impacts. Applying Bayesian Networks (BNs) as a probabilistic approach supports decision-making in complex system risk estimation when environmental and socio-economic impacts should be considered [2].

BNs have also been applied to jet engine design, manufacturing and maintenance risk assessment with a focus on the assembly processes [3]. Not only operational but also software and hardware reliability are analyzed, and the corresponding risks are assessed in this research. The importance of software risk estimation is highlighted as software plays a crucial role in identifying failure risks during the assembly process. Software risk estimation is a high priority as software failure or improper functioning increases the risk of the whole system failure drastically.

Another research [4] employs the Bayesian approach for assessing delay risks in tunneling projects. The authors find BNs to be a useful method for predicting the time and cost overruns; however, developing optimal strategy for decision-making algorithms is still required for cost, effectiveness and duration criteria considerations.

As can be seen, the area of probabilistic approach application is very wide. It can be used as a supportive tool of risk estimation in any industrial process risk assessment and decision-making procedure. The research [5] introduces the principles of BN applications in process industries, focusing on the safety aspects of handling hazardous materials. Risk assessment is introduced as a process that can evolve and adapt to a dynamic environment. Conventional risk assessment techniques fail when updating the probability of failure due to changes in information or conditions.

However, the probabilistic approach described in the above-mentioned research does not concentrate on machinery *design* in order to prioritize hazards or design solutions and does not consider risk assessment as an investigation of the degree of injury or damage to the health of exposed persons, as required by the Machinery Directive, the new Machinery Regulation and safety-related harmonized standards for machinery. Only machinery failure risks or environmental risks are investigated in the research mentioned above.

In this publication, the application of the Bayesian approach for complex machinery *design* risk assessment is investigated. The methodology, the required data considerations and risk assessment steps are described along with the comparison of BNs and the conventional methods for machinery design risk assessment. The aim of this research is to offer a probabilistic approach that can be applied by machine designers to complex and digital technologies, including machinery design risk assessment.

2. Bayesian approach for machinery risk assessment

Emerging technology components involving machinery risk assessment require not only the application of commonly used harmonized standards, such as EN ISO 12100:2010 *Safety of machinery – General principles for design – Risk assessment and risk reduction* and the technical report ISO/TR 14121-2:2012 *Safety of machinery – Risk assessment – Part 2: Practical guidance and examples of methods*, but also control systems safety related standards, such as EN ISO 13849-1:2023 S*afety of machinery – Safety-related parts of control systems – Part 1: General principles*

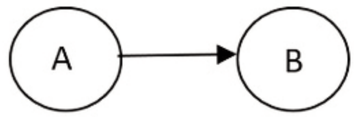

Fig. 1. The simplest BN.

for design. The EN ISO 13849-1:2023 standard provides guidance for designing and incorporating safety-related parts of control systems responsible for safety functions [6]. However, only specific recommendations for machinery design risk assessment procedure are provided by this standard without any detailed information on risk estimation methods. For deeper and more detailed information on component failure probability, the BN approach is suggested for risk assessment in the machinery design process.

The simplest BN represents a graph with nodes and arrows defining the dependency between variables (see Fig. 1). Node A is called a parent and node B is a child. Arrow direction defines the relationship between these nodes. The BN in Fig. 1 is a graphical presentation of factor A (cause) influencing variable B (consequence).

If multiple factors are added to the BN representing the probabilities of machinery component failures and the probability of occurrence of harm and the severity of harm, then the probability of risk acceptance, depending on these factors and the corresponding risk levels, can be estimated. The BN incorporating the requirements of machinery design risk assessment is shown in Fig. 2.

For risk acceptance decision-making, the risk levels should be estimated and evaluated, and the risk acceptance criteria should be calibrated. The permissible probability value for risk acceptance is defined. To illustrate the application of BNs for machinery design risk assessment, a BN graph was created (see Fig. 2). To describe the principles of the BN method and calculate the probability of risk acceptance, specific factors related to the probability data were selected. According to the data presented in Fig. 2, let us assume that the probability of machinery software or component failure is s^0; the probability of occurrence of harm (along with the severity of harm consideration) is h^0; the probability of risk level is r^1 (low), depending on the s and h factor probabilities; the prob-

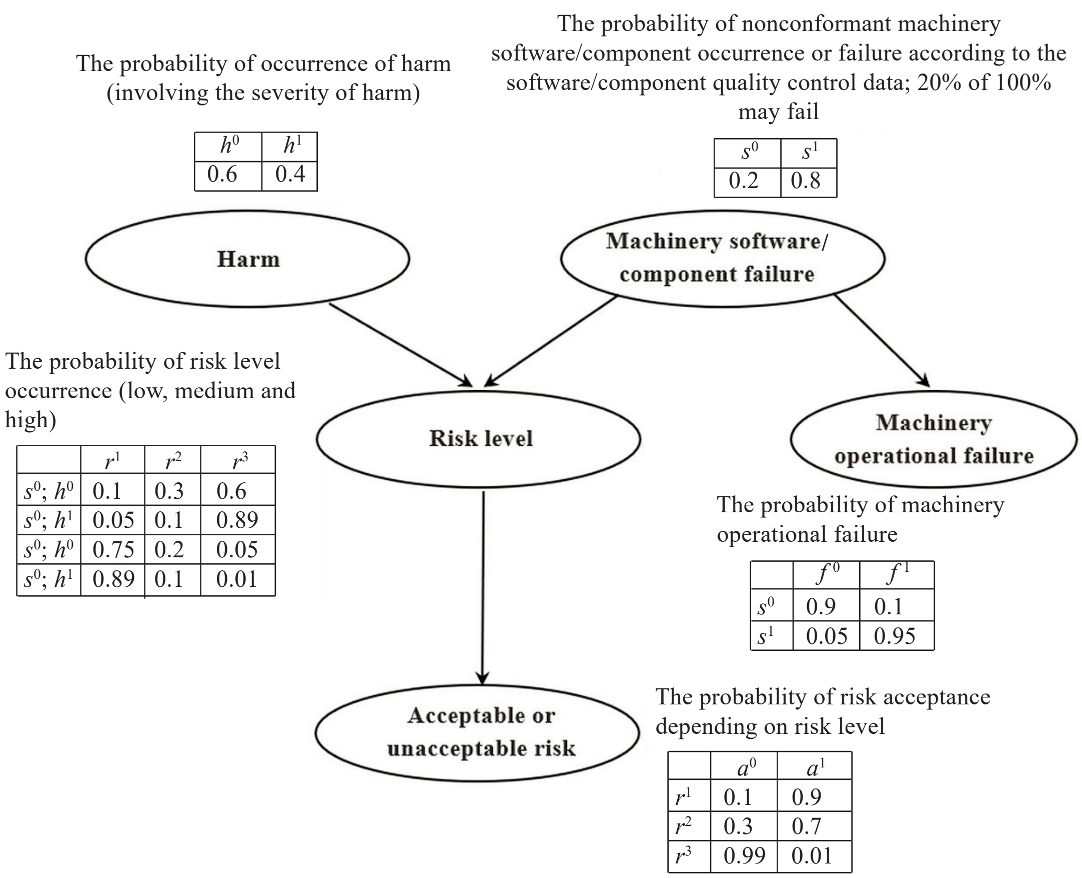

Fig. 2. An example of machinery design risk assessment based on the BN incorporating the probability of machinery component failure, the probability of occurrence of harm and the severity of harm.

ability of machinery operational failure is f^1, depending on the software or component failure; and the probability of risk acceptance is a^1, depending on the risk level. The calculation and result of the risk acceptance probability can be presented as:

$$P(s^0, h^0, r^1, f^1, a^1) = P(s^0)\,P(h^0)\,P(r^1 \mid s^0, h^0)\,P(f^1 \mid s^0)\,P(a^1 \mid r^1) = 0.2\cdot 0.6\cdot 0.1\cdot 0.1\cdot 0.9 = 0.00108.$$

As shown in the calculations below, the probability of getting a low and acceptable risk level for the probability values of factors s^0 and h^0 is low compared to the risk acceptance probability value for factor s^1 under the same conditions:

$$\mathrm{P}(s^1, h^0, r^1, f^1, a^1) = 0.3078.$$

It should be noted that the probability of machinery component failure, including software failure, must be estimated based on quality control data, test report results and expert opinions. The estimation of the probability of occurrence of harm and the severity of harm should be based on the available harmonized standards and technical reports related to machinery design risk assessment mentioned previously. For a more detailed approach, additional factors can be considered and links between factors can be defined. A complex relationship between the factors in BN leads to the need for BN software application. A popular software for BN design is MATLAB. The software allows it to go deeper with probabilistic analysis and continue with BN optimization. An automated learning approach can be further applied using software for BN design.

Before creating the BN presented in Fig. 2, the steps of the BN-based machinery design risk assessment should be defined:

1. Factor (impact) identification – node identification on the BN graph
2. Identification of factor relationships – identification of arrow directions on the BN graph
3. Developing of the BN graph using software (for example, MATLAB)
4. Review of machinery component quality control data, test results and expert opinions for collecting reliable data on the probability of failure (subsystems, components, software-related, etc.)
5. Estimation of the probability of occurrence of harm and severity of harm. Application of harmonized standards for machinery safety
6. Expert approval of the probability data
7. Calculation of risk acceptance probability values (consequence)
8. Analysis of results
9. Optimization on BN (correction of factor probabilities, changing relations between factors, adding factors to BN), possible application of an automated learning approach.

In this publication, only the concept of the BN-based approach to machinery design risk assessment was presented, highlighting the need to incorporate the probability of occurrence of harm, consider the severity of harm and define risk as the degree of injury or damage to the health of an exposed person.

3. Comparison of the Bayesian approach with conventional risk assessment methods

The BN-based method of machinery design risk assessment has visible advantages over conventional risk assessment methods (see Table 1). It allows for a deeper insight into the factors and impacts investigated in the risk assessment that influence the risk level and risk acceptance probability. While estimating risks using BNs, multiple factors and their failure probabilities can be assessed through defining a parent-child relationship.

It should be noted that in assigning failure probabilities to factors, the requirement for calibration skills and expert competence is stated for both risk assessment methods. Probability values assigned to factors and impacts should be based on product failure probability data obtained from product quality control procedures and from testing. For decision-making, the added value of expert opinions is essential to ensuring the reliability of risk assessment results. An advantage of BNs is also their ability to evolve by easily improving available models when amendments to factor probabilities or conditions are required.

Table 1. Comparison of conventional and BN-based machinery design risk assessment methods

Risk assessment method	Conventional risk assessment method	BN-based risk assessment approach
Assessment of each component failure probability or SIL	–	+
Integrated approach: assessment of probability of occurrence of harm, severity of harm and failure probability of each component or software	–	+
Risk assessment of complex systems with multiple impacts of different origin	–	+
Ability to evolve and change factors and failure probabilities in BNs, based on changes of factors and/or due to new conditions, impacts and relationships	–	+
Need for data calibration	x	x
Need for competent expert opinions on probability values	x	x

4. Conclusion

The probabilistic approach applied to risk assessment procedures allows for an increase in the reliability of results and a consideration of multiple impact factors when dealing with complex systems in machinery design risk assessment. In this publication, the application of the Bayesian Networks (BNs) method in machinery design risk assessment was investigated. A short comparison of the new Machinery Regulation amendment with the Machinery Directive was presented, and the need for more effective and reliable machinery design risk assessment methods was described. The development of improved risk assessment methods is required due to the need to consider machinery-related risks associated with modern digital technologies. This research prioritized machinery design risk assessment procedures, treating risk as the degree of injury or damage to the health of an exposed person, and highlighted the need for estimating the probability of occurrence of harm and severity of harm. The BN-based risk assessment example presented in this research not only addresses harm related aspects but also incorporates the new Machinery Regulation requirements, considering the failure probability of machinery components, software and all applied emerging technologies in risk assessment. The concept of an improved BN-based machinery design risk assessment procedure was presented along with its comparison with conventional machinery design risk assessment methods. The advantages and benefits of the BNs application for machinery design risk assessment are evident due to a more complex and nuanced approach. The developed probabilistic approach-based concept of machinery design risk assessment supports machinery designers and manufacturers who apply conventional machinery risk assessment methods to digital technologies while harmonized standards are being reviewed and amended to correspond to the new requirements of Machinery Regulation (EU) 2023/1230.

Data Availability Statement

All research data are contained within the article and can be shared upon request from the authors.

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Masinate riskide hindamine Bayesi meetodi abil

Alina Sivitski ja Priit Põdra

Ohutusnõuete tagamine ja vastavushindamine on Euroopa Majanduspiirkonnas masinate arendajatele ja tootjatele kohustuslik. Masinate riskihindamine vastavushindamise menetluse raames toimub harmoneeritud standardi ISO 12100 ja tehnilise aruande ISO/TR 14121-2 alusel. Nendes dokumentides on esitatud masinate riskihindamise meetodite põhikirjeldus. Standard ISO 12100 annab masinate projekteerijatele ja tootjatele infot, mis võimaldab tagada, et masinad vastavad masinate direktiivis 2006/42/EÜ sätestatud olulistele nõuetele. Digitaaltehnoloogia arengu ja uue masinate määruse (EL) 2023/1230 nõuete tõttu on suurenenud vajadus EN ISO 13849 juhtimissüsteemide ohutust ja EN IEC 62061 ohutustervikluse tasemeid (SIL) käsitlevate standardite kasutamise järele. Siiski ei ole masinate kui keeruliste süsteemide riskidega seotud otsuste tegemine lihtne ülesanne. ISO 31000 riskijuhtimise standard soovitab riskide hindamisel kohaldada määramatuse arvestamiseks tõenäosusteooriat. Ühe võimaliku meetodina saab kasutada Bayesi analüüsi, mis võimaldab rakendada tõenäosuslikku lähenemisviisi ja võtta arvesse määramatust, toetades otsuste tegemist masinate ohutusega seotud riskide hindamisel.