

RISK ASSESSMENT ON MACHINES WITH CE MARKING AND WITH EMBEDDED INDUSTRY 4.0 ENABLING TECHNOLOGIES

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ABSTRACT

The Machinery Directive 2006/42/EC introduced the obligation for the manufacturer to carry out risk assessment on machines in the design and construction phase according to a structured and iterative process as described in the ISO 12100 standard that also provides the aspects to be taken into account to identify all hazards and the associated risk. However, the rapid technological development that is characterizing the fourth industrial revolution is leading to equipping the machines with increasingly sophisticated sensors and technologies and this implies new assessments on the safety aspects. In particular, new human-machine interaction, smart machines with learning ability, machines equipped with sensors that report in real time their operating and health status thanks to the connection made possible by the Internet of Things, the potentiality of augmented reality, are all aspects that now must be considered. Therefore, the aim of this paper is to show the risk assessment process by proposing the well-suited techniques used in each of its phases and to highlight the new safety aspects to be taken into account when the machines with CE marking are equipped with the Industry 4.0 enabling technologies. Future developments in standardization and research in this direction will be tracked.

Keywords: risk assessment, risk management, machines with CE marking, smart machines, Industry 4.0 technologies.

1 INTRODUCTION

The risk assessment process on machines with CE marking should be carried out by the manufacturer who must take in account the relevant aspects described in ISO 12100:2010 [1], in order to design reliable and safe machines. The risk assessment process described in this standard is in line with the logical structure of risk management standard ISO 31000:2018 [2], in which it is structured in hazard identification, risk analysis and risk evaluation. To this end, the standard IEC 31010:2019 [3] describes a series of risk assessment techniques that can cover several phases of the overall process according to their specificity. Furthermore, the choice of the most suitable tools is a function of a series of characteristics, which must be defined by who is responsible for conducting the analysis. The structured risk assessment process allows the manufacturer to identify the essential health and safety requirements (EHSRs) applicable to the machine based on the identified hazards. However, the incorporation of enabling Industry 4.0 technologies in machine with CE marking, requires a review of the risk assessment process having to take into account the impact of these technologies on health and safety.

The paper is organized as follows. In Section 2 the risk assessment on machines with CE marking is presented according to the ISO 12100 and techniques for each phase of it is proposed among these presented in IEC 31010 standard. Section 3 takes into account the new safety aspects to be considered in risk assessment related to the new Industry 4.0 enabling technologies embedded in machines. In Section 4 future research and standardization in line with industrial revolution are proposed.



2 RISK ASSESSMENT PROCESS

Risk assessment process according to ISO 12100 is shown in Fig. 1, where for each step the more suitable techniques, selected among those in IEC 31010, are indicated. The paper, in fact, is based on integration of the main international standards on risk assessment process and techniques. To this end, Table 1, extracted and adapted from IEC 31010: 2019 “Risk management – Risk assessment techniques”, is proposed as a guidance in selecting appropriate techniques for the risk assessment by showing the degree of applicability at each stage of the process. In particular, only the appropriate techniques to be able systematically and completely carry out the risk assessment process on machines with CE marking during the design phase were reported in this section.

2.1 Determination of limits of machinery

The determination of limits of machinery is the first step of risk assessment process. It consists of defining all the functions of the machine in the whole of its life cycle (transport, assembly, installation, commissioning, use, maintenance, decommissioning, dismantling, scrapping), including human–machine interactions in relation to the functions identified. Also mechanical and physical machine properties and the values of the parameters, on which the safety of the machine depends such as the maximum load for the lifting, the maximum slope on which a mobile machine can be used without losing stability, the types of material that can be processed safely by the machine, must be specified.

The use of the machinery by the operator, therefore, could be described in terms of activities associated with the intended use and reasonably foreseeable misuse of the machinery, considering all the people who interact with the machinery in a work environment. The intended use of the machine must include all the different operating modes and conditions of use. In addition, the designer must identify the reasonably foreseeable misuse of the machinery, thus they must consider the easiest or fastest way to perform an activity that may be different from what is described in the manuals, procedures and instructions.

The lack of concentration and carelessness, the adoption of the “line of least resistance” as well as the behavior deriving from pressures to keep the machine running in all circumstances, the instinctive reaction in case of malfunction or failure during the use of the machine are all examples of reasonably foreseeable misuse. The machine manufacturer is not expected to take into account all possible misuses of the machine. However, some types of misuse, intentional or involuntary, are foreseeable on the basis of the experience of users of the same type of machine or similar machines, related to the investigations on accidents, incidents or malfunctions history and knowledge of human behavior [1].

2.2 Hazard identification

The most important phase of the risk assessment is hazards identification because it is not possible to intervene to avoid or reduce the effects of unidentified hazards. The systematic identification of hazards, of the hazardous situations and/or hazardous events related to human–machine interaction, allows predicting possible accidental scenarios. For this purpose, it is necessary to identify all phases of the machinery life cycle, modes of operation, functions and tasks associated [4].



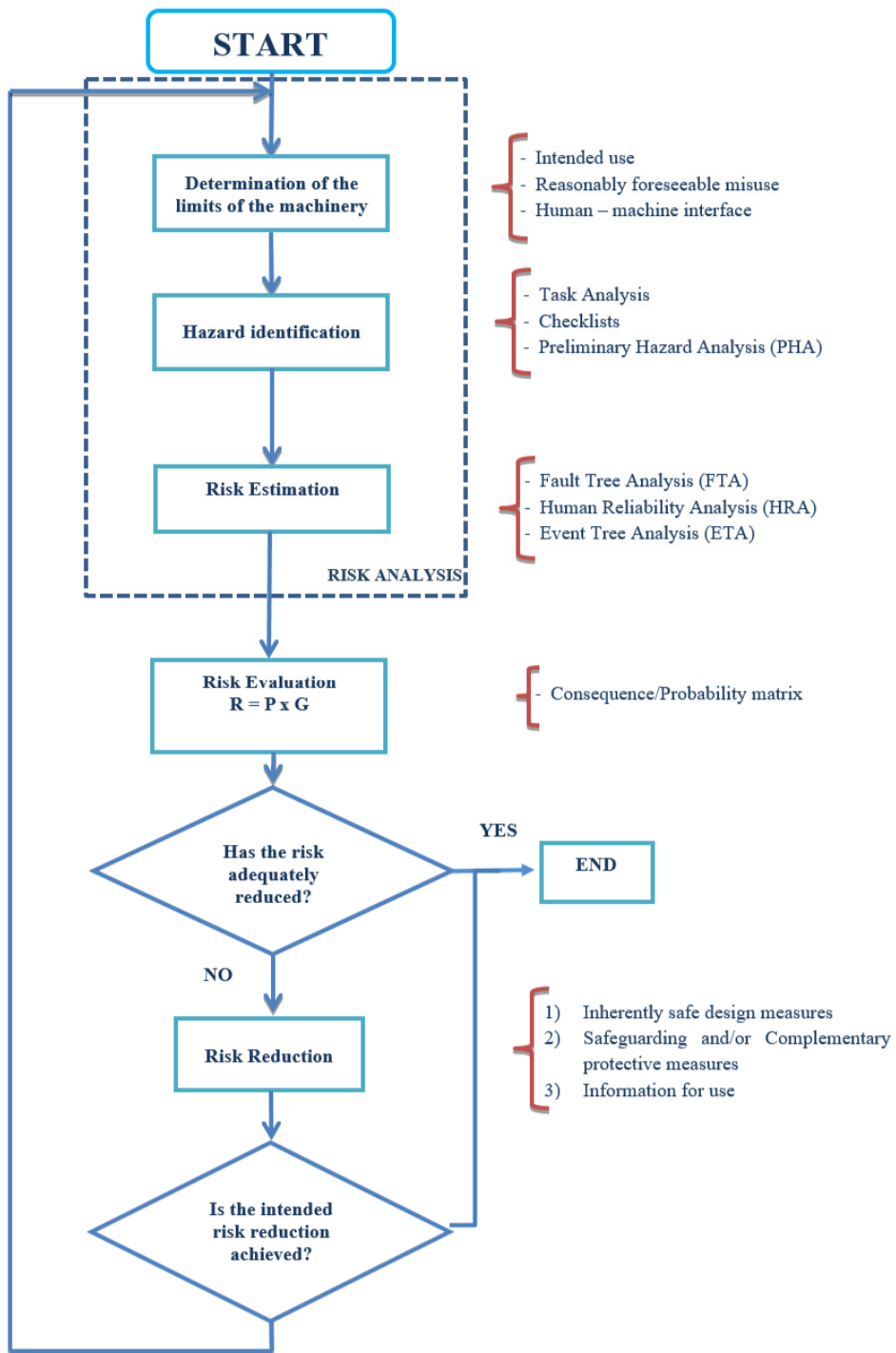


Figure 1: Risk assessment process on machines with CE marking according to ISO 12100.

Table 1: Applicability of risk assessment techniques to the ISO 12100 process. (Source: Adapted from IEC 31010:2019 [3].)

Techniques	Risk Assessment			
	Risk Analysis			Risk Evaluation
	Hazard Identification	Consequence	Probability	Level of risk
Checklists	Strong Applicable	Not Applicable	Not Applicable	Not Applicable
Event tree analysis	Not Applicable	Strong Applicable	Applicable	Applicable
Fault tree analysis	Applicable	Not Applicable	Strong Applicable	Applicable
Human Reliability Analysis	Strong Applicable	Strong Applicable	Strong Applicable	Strong Applicable
Consequence/Probability matrix	Not Applicable	Applicable	Applicable	Strong Applicable

The hazards identification, therefore, allows understanding what could happen or, in any case, what situations could occur and be such as to affect the machine operation and the health and safety of persons who operate on it. The applicable methods in this first phase of the process are mainly evidence based such as Checklists or systematic approaches conducted by a team of experts through inductive techniques such as Preliminary Hazard Analysis (PHA) (see Table 1). PHA is a qualitative technique for identifying hazards relatively early in the design process [5], that aims to identify, in structured and systematic manner, the hazards, hazardous situations and events that could represent risks to personnel or equipment. The conduct of this preliminary analysis requires information on the machine, its operations and human-machine interactions. The result of the analysis consists in the elaboration of a list of hazards related to the materials used, to the people working on it and to the environment in which the machine is utilized. The Checklists method is one of the most simplistic and main tools of hazard identification [4]. They are based on experience that can be used to help in identifying risks. The level of starting information or data needed is high while the level of experience required for correct use is intuitive [3]. Annex B given in the ISO 12100 standard can be used as a generic checklists as the starting point for identifying relevant hazards on the machines [1]. In particular, the first step is to identify the phases of the machine life cycle, the parts and/or functions of the machine (*origins of hazards*). The second step is to define the tasks to be performed by people interacting with or near the machine or the operations to be performed by the machine, in each of selected phases (*hazardous situations*). The third step is to identify for each task operation in each particular hazardous zone, the relevant hazards and the possible hazardous situations (*hazardous events*) [4].

2.3 Risk estimation

Risk estimation concerns the development and the understanding of the risk, as it provides considerations on the potential consequences that could occur as a result of certain accidental event as well as the estimate of the associated probabilities.

Risk assessment consists in defining the elements of risk for each identified hazard, hazardous situation and hazardous event: the likely severity of harm and the probability of its occurrence. Risk estimation techniques can be qualitative or quantitative Qualitative

methods are generally expressed as a level or index, while quantitative methods are used to estimate the frequency or probability of harm occurring.

The various methods used systemically to conduct risk estimation can follow a *top down* or *bottom up* approach. The top down approach starts from the potential consequence (harm) and proceeds backwards from the top hazardous event to the hazard situation and thence the hazard itself. The bottom-up approach begins with the analysis of all hazards and considers all the possible developments of a hazardous situation and how this can lead to harm [5].

It follows that the quality of risk estimation depends crucially on the comprehensiveness of the hazard identification. Aspects to be considered during risk estimation are persons exposed, type, frequency and duration of the exposure and the human factors that can influence the risk. In particular, human-machine interface, interface between persons, stress related aspects, ergonomic aspects, those related to fatigue and to limited capacities due to disability, as well as training, experience, the possibility for the operator to defeat or circumvent protective measures and human ability to avoid or limit harm must be taken into account.

2.3.1 Estimation of severity of harm

Each hazard has the potential to result in different severities of harm. Usually, the most severe that can realistically occur (worst credible) must be considered, even if the probability of such an occurrence is not high. The method that well suited to estimate the severity of harm is the Event Tree Analysis (ETA) (see Table 1). It is a bottom up method (inductive approach), that can be used to develop the consequences of an event (hazardous event). It starts with a particular initial event such as a failure and is developed from the bottom-up. The event tree is both a qualitative and a quantitative technique. Qualitatively it is used to identify the individual outcomes of the initial event, while quantitatively it is used to estimate the frequency or probability of each outcomes. An event tree is constructed by defining an initial event and the possible consequences that flow from this. The initial event is usually placed on the left and branches are drawn to the right, each branch representing a different sequence of events and terminating in an outcome. Each branch of the event tree represents a particular scenario and the tree allows estimating the frequency of the outcome for that scenario [5]. A qualitative approach in estimating the severity of harm, uses different severity levels such catastrophic, serious, moderate and minor.

The implementation of this method requires detailed knowledge of the possible initiator failure events and information relating to the behavior of the protection systems. At this end, the historical data is a valid baseline [4].

2.3.2 Estimation of probability of occurrence of harm

For each hazard or hazardous situation (task), the probability of occurrence of harm should be estimated. According to ISO 12100, it is a function of the exposure of person(s) to the hazard, the occurrence of hazardous event and the technical and human possibilities to avoid or limit the harm. Therefore, the estimation should take into account: frequency and duration of exposure to a hazard, persons exposed, machine history, workplace environment, human factors, reliability of safety functions and the possibility to defeat or circumvent protective measures [1].

The Fault Tree Analysis (FTA) (see Table 1) is a useful technique for identifying and analyzing the factors that can lead to the occurrence of an undesired event, also called *top event*. These factors are related to each other through logical gates in order to show the relationships between them. It starts with the event of interest, the top event, such as hazardous event or equipment failure, and is developed from the top-down. The fault tree is



both a qualitative and a quantitative technique. Qualitatively it is used to identify the individual paths that lead to the top event, while quantitatively is used to estimate the frequency or probability of that event [5]. The advantages of using of this technique are related to its graphical representation that allows easily interpreting and intuitively considering the behavior of the system and related factors. In contrast, a limitation of its application is the static nature that therefore does not allow dynamic analysis. Specific stepwise logic is used in the process, and specific logic symbols and diagrams are used to illustrate the event relationships. FTA is aimed to exhaustively identify the causes of a failure; to identify weaknesses in a system; to assess a proposed design for its reliability or safety; to identify effects of human errors; to prioritize contributors to failure; to identify effective upgrades to a system; to quantify the failure probability and contributors; and to optimize maintenances [6].

Similar to severity, there are many scales used to estimate the probability of occurrence in qualitative descriptions as very likely, likely, unlikely and remote. As empirical data are rare, the process of selecting the probability of an incident is based on brainstorming with knowledgeable and skilled analysts [4].

2.3.3 Estimation of the probability of human error

It is well established that human actions play a big role in accidents. The human reliability analysis (HRA) is used to take into account this aspect. The HRA techniques allow estimating human error probability by describing the physical and environmental conditions in which the operator performs his tasks on the machine and by taking into account their skills, abilities, and cognitive effort. The error probabilities, obtained by applying a human reliability analysis technique, can also be used in other risk assessment techniques such as Event Tree Analysis (ETA) and Fault Tree Analysis (FTA). An HRA technique that is well suited for this purpose is the Cognitive Reliability and Error Analysis Method (CREAM) [7]. This technique, based on task analysis and focusing on the operational context, allows a precise, in-depth and above all dynamic representation of human-machine interactions.

This technique, used in a reactive way, allows the manufacturer to identify those tasks that present a greater probability of error, thus becoming the subject of a more in-depth assessment in order to be able to implement protective measures already in the design (inherently safe design measures) [1].

2.4 Risk evaluation

After estimating the severity and probability, the level of risk is determined using mainly a consequence/probability matrix. How the risk element of severity and probability are combined varies according to the risk matrices utilized, which differs according to the number of levels chosen to classify each risk element. Probability and severity levels generally vary from three to ten, with a prevalence of three, four and five levels. The output of this assessment generally varies from low to high risk. Risk evaluation consists in comparing this risk-assessed value with the risk acceptability criterion established a priori. Risk evaluation, therefore, allows the designer to establish whether a risk reduction is necessary and, where possible, to apply the appropriate protection measures. Therefore, the designer will have to check whether, as a consequence of the application of the new protective measures, new hazards have been introduced or other existing risks have increased. Consequently, if new hazards have occurred, they must be included in the list of identified hazards and, consequently, appropriate corrective measures must be applied (iterative process).



2.5 Risk reduction through the application of the iterative three-step method

The risk reduction is achieved by reducing, separately or simultaneously, the two elements of the associated risk, respectively, the probability of occurrence of harm or limiting its severity. To this end, the risk reduction measures must be applied following the hierarchical order of protection measures. The achievement of an adequate risk reduction is developed through the three-step method [1]; this implies that the protective measures must be applied in the following sequence:

Step 1 – the hazards elimination and the risks reduction obtained in the design phase by replacing materials and substances with less hazardous ones or applying ergonomic principles (*inherently safe design measures*).

Step 2 – the risk reduction obtained through the application of complementary protective measures such as to adequately reduce the risks associated with the intended use and reasonably foreseeable misuse (safeguarding and/or complementary protective measures);

Step 3 – if it is not possible to reduce the risk through inherently safe design measures or through the adoption of complementary protective measures, the residual risks shall be identified in the information for use.

The protective measures integrated into the design constitute the first and most important step of the risk reduction process and consist in eliminating the hazards at the source or reducing the risks by modifying the design characteristics of the machine and/or the interaction between the exposed persons and the machine itself. If the hazards cannot be eliminated in the design, the risks should be reduced by intervening in the physical aspects or in the man–machine interactions. In particular, in order to reduce the probability of human error in the use, it is necessary to take into account the ergonomic principles in the design to minimize mental stress and operator effort.

The ergonomic aspects that must be taken into account in machine design are the following:

- body sizes likely to be found in the intended user population, strengths and postures, movement amplitudes, frequency of cyclic actions;
- all elements of the operator–machine interface (controls, signaling or data display elements) shall be designed to be easily understood.

Furthermore, the machine manufacturer must also define the reasonably foreseeable misuse by using technical means to avoid it. If there is still a residual risk of foreseeable misuse which cannot be completely avoided by technical means, special warnings must be put on the machine and in the instructions. It is also necessary to inform users whether special training is required and whether a personal protection equipment is provided.

The instructions must be considered as a very important complement to the protection measures, in particular as regards the possible misuse of the machine.

3 IMPLICATIONS OF INDUSTRY 4.0 TECHNOLOGIES EMBEDDED ON THE MACHINES ON RISK ASSESSMENT PROCESS

The manufacturer carries out the risk assessment for the machinery at the design stage by determining the application of the essential health and safety requirements (EHSRs) defined in the Machinery Directive. The risk assessment process is conducted according to the ISO 12100 standard, as presented in the sections above. However, with the rapid development of technology, the machines are equipped with sophisticated sensors and smart devices that



report in real time their operating and health status and allow them also to communicate by means of Internet of Things (IoT). These technologies embedded in machines involve new aspects to be taken into account in the risk assessment and consequently the review and/or the definition of new essential health and safety requirements. To this end, some of Industry 4.0 enabling technologies associated with *Human Robot Collaboration (HRC)*, *Artificial Intelligence (AI)* and *Augmented Reality (AR)* are considered below in terms of implications on safety aspects. In Table 2 the implications of the selected enabling technologies on the machine risk assessment in terms of impact on essential health and safety requirements (EHSRs) are reported.

Table 2: Implications of enabling technologies on the machine risk assessment in terms of essential health and safety requirements (EHSRs).

Enabling technologies	Impact on EHSRs of machinery directive
Human robot collaboration	1.3.7 Risk related to moving parts
	1.1.6 Ergonomic principles
Artificial intelligence – Machine learnings	1.6.1 Machinery maintenance
Augmented reality	1.6.1 Machinery maintenance
	1.2.5 Selection of control or operating mode
	1.7.4.2 Contents of the instructions

3.1 Human robot collaboration

The new scenario of Industry 4.0 production sees the emergence of a new form of human–machine interaction that is a real collaboration: the robot at the service of human that facilitates their tasks making them even more ergonomic, fast and accurate. Consequently, human safety is the main concern in this new physical interaction between human and robot as it determines a new class of risks. Therefore, the safety concept was previously based on the elimination of the contact between man and robot by providing protections or protective devices in the design to avoid accidental contact with the moving parts (*EHSR 1.3.7 Risks related to moving parts*) (see Table 2). This implies that robots are equipped with different types of sensors to ensure human safety during the physical human robot interaction. The robot will be able to detect human face, any object carried by human hand, to define in which directions the force should be applied and what are the dangerous directions for human safety. The force sensor will help the robot to react to the motion of the human hand during the assembling task. Also, a skin sensor will prevent any collision between the human and the robot arm [8]. The essential health and safety requirement related to ergonomic principles (*EHSR 1.1.6 Ergonomics*) should be adapted to consider the human robot coexistence in a shared space (see Table 2). Consequently, the risk analysis must consider the entire robotic system, including the terminal organs, the cell layout and also the cognitive demand in the new human–machine interaction [9].

3.2 Artificial intelligence

In the new industrial paradigm and, in particular, as regards the machinery sector, artificial intelligence (AI) techniques are increasingly being applied. Defined as the ability of a machine to perform functions generally associated with human intelligence such as reasoning and learning, an AI application integrated on a machine can have an immediate effect on its function and therefore on its safety.

According to the literary review, the AI techniques becoming more and more attractive and powerful for machinery fault diagnosis [10]. This impacts on third paragraph of EHSR 1.6.1 (see Table 2) that requires machinery to be provided, where appropriate, with the means of connecting the necessary diagnostic fault-finding equipment.

3.3 Augmented reality

Augmented Reality (AR) is an enhanced version of physical real environments with superimposed computer generated images. It differs from virtual reality that requires an entirely virtual environment. It uses existing real environment and simply overlays virtual information on top of it. Augmented reality is one of the cutting edge technologies involved in the Industry 4.0 particularly as it offers many advantages in maintenance such as in reducing execution times and in minimizing human errors and allows the operator to act in dynamic and unforeseen situation safely also by means of smartphones, tablet, etc., with digital information (sound, video, graphics, etc.) [11].

This enabling technology embedded on machine could affect some essential health and safety requirements of Machinery Directive. In particular, it could have implication on *EHSR 1.6.1 – Machinery maintenance* (see Table 2), as the first paragraph of Section 1.6.1 states important general principles for the design of machinery to ensure that maintenance operations can be carried out safely. Augmented reality applied for maintenance purposes must be integrated into the machine design so as to provide an appropriate safe operating mode in the control system which requires different protective measures and/or work procedures having a different impact on safety (*EHSR 1.2.5 – Selection of control or operating mode*) (see Table 2). The relative safe method to be employed for maintenance operations by means of augmented reality must be clearly specified and explained in the instructions, so this technology affects also the *EHSR 1.7.4.2 – Contents of the instructions* (see Table 2).

4 NEW RESEARCH DIRECTIONS AND FUTURE DEVELOPMENTS

The machine safe use is the result of the combination of the risk assessment carried out by the manufacturer according to the Machinery Directive and that of the user who takes into account the conditions and characteristics of the working environment in which the machine must operate and the interference with other equipment. However, safe machine design is the primary protective measure to be taken, in order to avoid accidents or malfunctions that could undermine the health and safety of workers. In order to achieve this purpose, the design should aim to make the machine robust and resilient.

Some authors distinguish robustness from resilience based on the magnitude of the disturbance: for a robust system, the physical structure of the system is still intact, whereas for a resilient system, the physical structure is damaged. So according to Westrum [12], robust systems deal with regular and, at a certain level, irregular threats, whereas resilient systems manage unknown situations (unexpected or unprecedented disturbances).



Resilience concept applied to Human–Machine–System (HMS) [13] means that after any disturbance (human errors, technical failures, environment events), the HMS is capable of recovering and stabilizing at another “acceptable” performance level which is a suboptimal performance due to controlling unknown situations. The HMS is robust if it is capable of returning to the initial nominal performance after “known disturbance situations”.

After these considerations, the paper showed how the structured risk assessment process according to the 12100 standard makes the manufacturer able to design a robust machine.

In fact, the manufacturer must determine all machine intended functions, the malfunctions and failures based on data about accident and/or incidents of similar machinery and all unintended behavior of the operator or reasonably foreseeable misuse of the machine based on experience of human behavior with similar machines, if it is easily predictable.

However, this design does not take into account the response of the human–machine system after unexpected malfunctions and failures.

According to Steen and Aven [14], resilient systems are able to adapt to unplanned events, to anticipate failures, to control disturbances, to react and to recover from these events, to learn from their reactions to unplanned events. Thus, Zhang and Lin [15] defined some principles on which the design of resilient systems could be based, such as:

- a certain degree of functional redundancy,
- a controller for redundancy and learning management,
- a sensor for monitoring the whole system’s performance,
- a predictor for predicting potential threats or analyzing potential vulnerabilities of the system,
- an actuator for implementing changes or training.

For this purpose, the technological evolution that is characterizing the Industry 4.0 is well suited to making machines equipped with Artificial Intelligence and Machine Learning technologies capable of creating a resilient human–machine system according to the aforementioned principles.

In particular, many methods or mechanism concerns learning management and training, can be used to make a HSM resilient. It could be achieved embedding artificial intelligence (AI) – machine learning in the machine design process. On the other hand, it could affect machine safety and consequently the risk assessment process according to ISO 12100 as seen above.

It follows that the standardization is trying to take into account the impact of Industry 4.0 enabling technologies on the risk assessment process. The research, on the other hand, is exploring the potential of advanced technologies to improve machine safety.

5 CONCLUSION

According to the above considerations, the risk assessment techniques and their applications continue to evolve according to the new emerging risks associated with the introduction of new technologies. As shown above, the use of Industry 4.0 enabling technologies can affect the risk assessment process in terms of reviewed Essential Health and Safety Requirement defined in the Machinery Directive. Moreover, as the risk assessment process on machines with CE marking is a well-structured process that needs a lot of information to be more reliable, by equipping the machines with smart labels that can keep track of the history of malfunctions and failures as proposed by Gnoni et al. [16], it is possible to provide reliable and often not easily available input information to risk assessment.

In the future, research will consist in proposing a new framework for the machine risk assessment process integrated with the Industry 4.0 enabling technologies.



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