

International Conference on Industry 4.0 and Smart Manufacturing

Implications of embedded artificial intelligence - machine learning on safety of machinery

Sara Anastasi^a, Marianna Madonna^b, Luigi Monica^{a,*},^a *Department of technological innovation and safety equipment, products and anthropic settlements, Italian Workers' Compensation Authority (INAIL), Via Roberto Ferruzzi 38/40, Rome 00143, Italy*^b *Operational Territorial Unit - Research, Certification and Verification Area, Italian Workers' Compensation Authority (INAIL), Via Nuova Poggioreale, Naples 80143, Italy*

Abstract

The Artificial Intelligence (AI) and the Machine Learning (ML) is a rapidly evolving technology and up until recently has not been a subject of machinery safety. The purpose of this work is to evaluate how embedded artificial intelligence – machine learning can affect the safety of machinery and machinery systems in the development of their applications. This work can be useful to machinery designers to develop their particular applications as it describes how the new hazards, associated with embedded AI – ML, should be considered within the framework of the risk assessment process. The proposed study underlines the new dimension of complexity linked to artificial intelligence and machine learning that could lead to a revision of European legislation in terms of the introduction and/or modification of essential health and safety requirements (EHSR) in the Machinery Directive, in order to guarantee safety levels at least equivalent to those currently achieved.

© 2021 The Authors. Published by Elsevier B.V.

This is an open access article under the CC BY-NC-ND license (<https://creativecommons.org/licenses/by-nc-nd/4.0>)

Peer-review under responsibility of the scientific committee of the International Conference on Industry 4.0 and Smart Manufacturing

Keywords: Safety of machinery; Artificial Intelligence; Machine Learning; Machinery Directive

1. Introduction

The new manufacturing model, called smart manufacturing, is characterized by numerous physical and digital technologies such as artificial intelligence, cloud computing, collaborative robots, augmented reality, additive

* Corresponding author. Tel.: +39- 0654876410; fax: + 39 0654876413.

E-mail address: l.monica@inail.it

manufacturing and Internet of Things. The term Industry 4.0 is used to describe this new smart factory which involves increases in mechanization and automation, digitization, networking supported by sensors, machines, workplaces and IT systems that communicate with each other [1]. However, the idea of supporting human activities with automation and mechanization as robots and artificial intelligence, like machine learning, is not a recent development.

The origin of Artificial Intelligence can be traced back to the 1950s when the British mathematician Alan Turing proposed the question “Can machines think?” [2]. He stated that if a machine is to be intelligent, then it will need to “learn by experience”, probably with the experiences to which the machine will be subjected.

Only later in 1986, the American mathematician John McCarthy coined the term Artificial Intelligence to describe “the science and engineering of making intelligent machines”. More recently, according to the international standard (ISO/IEC 2382:2015) artificial intelligence (AI) is defined as “the capability of a functional unit to perform functions that are generally associated with human intelligence such as reasoning and learning” [3]. Instead, the term machine learning (ML) refers to a subfield of artificial intelligence and is defined as the field of study that offers computers the ability to learn without being explicitly programmed [4]. According to ISO/IEC 38505-1:2017, machine learning is “the process using algorithms rather than procedural coding that enables learning from existing data in order to predict future outcomes” [5]. As an emerging field in industrial applications, artificial intelligence (AI) techniques have been receiving increasing attention from academia and industry.

In this paper, the focus is on the use of embedded AI in the machinery sector that is developing for different application of advanced systems making the smarter decision. The main processes involved are the optimization of process parameters, the monitoring of the health machine conditions, predictive maintenance and fault detection. These applications lead to the optimization of the machine performance with effects on the overall improvement of the working conditions.

However, AI applications can have an effect on the machine function and thus on machinery safety. The implications of integrated artificial intelligence on machine safety also depend on its practical implementation and therefore on the choices made in the machine design phase, so they should be taken into account in the risk assessment process.

After showing in the second section, the potential of AI applied to machines in the context of the smart factory, in the third section, we will evaluate the impact of new technologies on European legislation. In particular, we will try to analyze risks introduced by AI embedded applications and how this should lead to a modification/introduction of new essential health and safety requirements (EHSRs).

2. Evolution of Machinery Directive concerning the use of new technology

The Machinery Directive (2006/42/EC) is a European Directive that adopts measures to harmonize the legislation of the Member States in order to ensure the establishment and functioning of the internal machinery market. The primary objective of these measures is to allow the free movement of products on the EU market, defining, in an induced manner, a minimum level of safety for machinery. The essential health and safety requirements (EHSRs) of the directive, in fact, establish a level of safety, which all manufacturers are required to follow in order to market their products on the EU market. The establishment of a harmonized regulatory framework for the design and construction of machinery is of vital economic importance to the European engineering industry. At the same time, safer machinery makes an essential contribution to the reduction of the social cost of accidents and damage to health, both in the workplace and in the home [6].

However, the development of increasingly intelligent machines, with enabling industry 4.0 embedded technologies, could have an impact on the way products are manufactured. This leads to a new dimension of complexity of the machinery safety so that the Machinery Directive could move to innovative EHSRs to guarantee safety levels at least equivalent with these current achieved.

The manufacturer carries out the risk assessment for the machinery at the design stage according to the ISO 12100 standard, in compliance with the essential health and safety requirements (EHSRs) defined in the Machinery Directive. For example, with the rapid development of Industry 4.0 technologies, the machines that perform a task autonomously are designed with AI algorithm and new cognitive demand is required in human-machine interaction [7] [8].

From a regulatory point of view, the manufacturers have not referenced on how to integrate AI systems in their risk assessment process of the whole machines. These technologies integrated into the machines imply that new aspects are taken into account in the risk assessment and, consequently, a review of the current Essential Health and Safety Requirements (EHSRs) or the introduction of new requirements. To this end, in the last section, the implications on safety aspects, in terms of impact on Essential Health and Safety Requirements (EHSRs) are analyzed.

3. AI/ML applications in smart factory

The continuous advance in Industry 4.0 technologies, which involves intelligent devices and sensors connected via the Internet of things (IoT), allows the development of new applications of AI/ML algorithms. The machines are equipped with hardware and software components for data communication and manipulation [9]. From a data science perspective, this new paradigm allows extracting relevant knowledge from monitored assets thanks to the application of machine learning and optimization methods. One of the main features of AI/ML in this context is to effectively predict abnormal behaviors in industrial machinery, tools and processes: the system learns from experience, making itself capable of carrying out inductive reasoning and elaborating general rules defined by associating input to correct output. In this context, IoT plays a crucial role in capturing a huge amount of data by several physical objects devices that should be analyzed in real-time to acquire useful knowledge [10]. Furthermore, the integration of advanced sensors with Artificial Intelligence, IoT and Cloud Computing technologies in industrial robots involves intelligent decision-making, forecasting and maintenance skills with advanced autonomous behaviors that contribute to improving production and help and collaborate with workers in carrying out their duties [1]. In this context, also machine manufacturer begins to equip machines with smart devices to support migration to Industry 4.0.

3.1 Examples use of embedded AI-ML in machine applications

Mobile robots are widely used in Industry 4.0 applications, above all, they increase efficiency and flexibility in logistics, assembly, production and in the processes in which replace human resources in repetitive and heavy tasks. There are several types of mobile robots; the most common are autonomous mobile robots (AMRs) and automated guided vehicles (AGVs) although so far, there is no clear distinction. In general, an AGV is, by definition given in ISO 3691-4 (2020), a motorized truck designed to operate automatically to transport loads [11]. Instead, an AMR can move independently and perform different tasks based on customer specifications. Navigation through its environment, is provided by sensors mounted on the robot. However, using mobile robotics in industrial applications increases safety requirements due to the coexistence between moving machines and humans [12]. They are able to operate in uncontrollable and unknown environments, which are often shared with humans, and often they will be required to collaborate with each other, and even with humans, to perform complex tasks.

A mobile robot with embedded AI-machine learning calculates the best route guidance through the plant and optimizes the speed within given limits, but on the routes, people are present in a causal way.

In order to address the increasing complexity and ensure safety issue of mobile robots, the robotics and automation industry is working towards the establishment of new international safety standards through the International Organization for Standardization (ISO) for robots and robot systems integration. The currently developed standards in this sector are ISO18497 [13] standard for the safety of highly automated agricultural machines and ISO 15066 [14], which focuses on the collaboration between people and robots, as existing safety standards are focused on safety achieved by isolating the robot from people [15].

For example, in autonomous driving, the machine learning algorithm uses, in real-time, the vehicle's operating data (speed, engine consumption, shock absorbers, etc.) and those collected by sensors that scan the surrounding environment (road, signs, other vehicles, human presence etc.) to optimize the route and the acceleration and speed parameters to complete its task. The algorithm, based on the input data (external environmental conditions, including human behavior), optimizes the operating parameters to achieve the objective in an optimal manner.

In addition, Machine Learning algorithms for an autonomous configuration of this machine require the development of new evaluation, testing and verification methods. AI applications for safety components require

testing to demonstrate that error rates fall within the Performance Level (PL) ranges specified in standard ISO 13849-1 [16] to ensure the safety of the component's behavior in line with Machinery Directive requirements. However, the applicability of this standard to AI algorithms has not been demonstrated, so it should be necessary to adapt the recommended test methods and PLs to AI.

In order to regulate the safe use of these innovative technologies, a complete understanding of the system should be had. According to some researchers [17], testing new technologies requires a technical test, through the development of technical Key Performance Indicators (KPIs) and a usability test which, through usability KPIs, allows to evaluate the performance resulting from its use.

4. Implications of embedded artificial intelligence - machine learning on EU product directives

In recent technological development, AI is playing a crucial role in decision-making systems and autonomous processes, with potential consequences in different areas of our life. As with any new technology, the use of AI carries both opportunities and risks. In particular, in this section, we want to highlight the new safety risks for users when AI technologies are embedded in products. To this end, the European Commission recently produced a White Paper on Artificial Intelligence [18], with the aim of developing an “EU regulatory framework for AI” to deal with the lack of explicit safety provisions for products involving AI and that is marketed in Europe. To date, the EU legal framework for product safety consists of the General Product Safety Directive (Directive 2001/95/EC), as a safety net, and a series of specific sectoral directives covering different categories of products ranging from machines, planes and cars to toys and medical devices aiming to provide a high level of health and safety.

While EU legislation remains in principle fully applicable regardless of AI involvement, it is crucial to assess whether it is necessary to properly adjust and/or enforce EU and national legislation to account for the risks associated with embedded AI.

According to the EU Commission's opinion, the legislative framework should be improved to take into account the following aspects:

- *Limitations of the scope of existing EU legislation*: a review of EU product safety legislation for their placing on the market is necessary. For example, current EU product safety legislation requires that software, when it is part of the final product, must comply with the relevant product safety rules. It is, therefore, to be clarified whether the existing rules need to be adapted in the case of a stand-alone software placed on the market or incorporated into a product after its placing on the market, have implications for safety.

- *Changing functionality of AI systems*: the autonomous behaviour of some AI systems during its life cycle can lead to significant product changes that affect safety, which may require a new risk assessment. In addition, human oversight from the product design and throughout the lifecycle of the AI products and systems may be needed as a safeguard.

- *Changes to the concept of safety*: the use of AI in products and services can give rise to risks that EU legislation currently does not explicitly address. These risks may be linked to cyber threats, personal security risks, risks that result from loss of connectivity, mental safety risks of users when appropriate (e.g. collaboration with humanoid robots), etc.

- *Robustness and accuracy*: AI systems must be technically robust and accurate in order to ensure that AI systems are reliable as intended in the design.

The conformity assessment for AI applications could include procedures for testing, inspection and certification of the algorithms and of the data sets used in the development phase. Moreover, it should be part of the conformity assessment mechanisms that already exist for a large number of products being placed on the EU's internal market or where no such existing mechanisms can be relied on; similar mechanisms may need to be established, drawing on best practice and possible input of stakeholders and European standards organizations.

The audit of machine learning algorithms can help the data controller ensure that they are robust (i.e. unbiased and resilient against edge cases and malicious input) and demonstrate compliance with the General Data Protection Regulation (GDPR) requirements. This audit could be carried out by a third party and possibly evolve into a certification mechanism. Standardization is a powerful way of acting to reduce the risks linked with the use of AI in systems, through the publication of a collection of materials to prevent and mitigate the risks of failures [19].

4.1 Implications on Machinery Directive

In this context of the revision of the product directives to take into account the risks introduced by AI embedded applications, we will try to analyze the implications of Machinery Directive (2006/42/EC) in terms of essential health and safety requirements (EHSRs).

First of all, the EHSR 1.1.2 - Principles of safety integration - should be implemented to letter e), which requires that machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely, with the requirement for test procedures for updating and checking the embedded AI system.

If we also consider the growing use in the smart factory of autonomous mobile robots (AMRs) equipped with AI/ML technology, another two requirements should be modified: EHSR 1.1.6 – Ergonomics and EHSR 1.3.7 Risks related to moving parts. So, another point should be added to EHSR 1.1.6 in order to guarantee mental comfort during human-robot interactions as well as not limit human abilities that could lead to reducing productivity and quality of work. The essential health and safety requirement related to ergonomic principles should be adapted to consider the human-robot coexistence in a shared space. Moreover, this new form of interactions between man and robot without material and immaterial barriers leads impact also on EHSR 1.3.7 requiring that moving parts of machinery might be designed to prevent contact risks. The shared space, in fact, could lead to accidents or, where risks persist, must be fitted with guards or protective devices. In fact, the human-robot coexistence materializes without guards or protective devices.

According to the authors, however, AI applications on machines will mainly impact also on the EHSR 1.2.1- Safety and reliability of control systems - especially when the AI application related to safety functions.

In fact, the control system of machinery is the system, which responds to input signals from parts of the machinery, from operators, from external control equipment or any combination of these and generates corresponding output signals to the machinery actuators, causing the machine to perform in an intended manner.

Therefore, machines equipped with machine learning must not be able to carry out tasks or assessments that go beyond those defined by the manufacturer for the purpose of the machine. Moreover, when AI is replacing conventional systems that perform a safety function, whether they are safety components independently placed on the market or homemade by the machinery manufacturer, the level of performance required must be tested and validated taking account both of the hardware and software aspects of such systems. To date, specifications for the design of safety-related parts of control systems are given in standards ISO 13849-1 [20], and in EN 62061 standard [21] but the applicability of this standard to AI algorithms has not been demonstrated, so it makes necessary to adapt the recommended test methods and Performance Levels (PLs) to AI.

When safety functions are performed by an AI algorithm, other problems are generated related to connectivity as it feeds on data from different devices and sensors. This, in turn, implies exposure to cybersecurity risks that must be treated appropriately in the reviewed framework of the risk assessment process for intelligent machines.

The following Tab. 1 shows the implications that the AI incorporated in the machines could have on EHSRs based on the experience of the authors in the field of risk assessment on machines and the Machinery Directive.

5. Conclusion

The implementation of artificial intelligence and machine learning will lead to the intelligent machines. The in-depth analysis conducted in this paper has highlighted the potential impact of new technologies on the EHSRs of the Machinery Directive and, consequently, on the related harmonized standards. In particular, the analysis identified the EHSRs of the Machinery Directive which will be most influenced by the incorporation of AI/ML applications in the design of the machines, highlighting the changes needed for the Machinery Directive to guarantee safety levels for innovative products at least equivalent to the current ones.

This update has also to be applied to all machinery standards in order to offer manufacturers above all useful references for the product design and construction phase. All these imply a new standard of risk and safety management in the new industrial era [22].

In future, a Risk Assessment 4.0 will be developed by considering the new technologies and the continuous monitoring and data acquisition.

Essential Health and Safety Requirement (EHSR)	Implications of AI embedded application
EHSR 1.1.2 - Principles of safety integration	Machinery should be also supplied with test procedures for updating and checking the embedded AI system.
EHSR 1.1.6 – Ergonomics	Machinery design should guarantee an adequate human- robot interfaces.
EHSR 1.3.7 Risks related to moving parts	It should be taken into account that man and automatic mobile robot share the same space without barriers and with the possibility of contact.
EHSR 1.2.1- Safety and reliability of control systems	It should be necessary developing new standard to test AI algorithm reliability when it replaces conventional systems that perform a safety function.
New EHSR related to cybersecurity risks	A new EHSR should be developed in order to take into account the emerging risks related to cybersecurity due to the connectivity between machines and others smart devices.

Tab. 1. Implications of AI embedded applications on Machinery Directive in terms of EHSRs.

References

- [1] Ustundag Alp, Cevikcan Emre. (2017) “Industry 4.0: managing the digital transformation” *Springer book*.
- [2] Turing Alan. (1950) “Computing machinery and intelligence”. *Mind* **59**: 433-460.
- [3] ISO/IEC 2382:2015. Information technology — Vocabulary.
- [4] Das Sumit, Dey Aritra, Pal Akash, Roy Nabamita. (2015) “Applications of Artificial Intelligence in Machine Learning: Review and Prospect” *International Journal of Computer Applications* **115**: 31-41.
- [5] ISO/IEC 38505-1:2017 Information technology — Governance of IT — Governance of data — Part 1: Application of ISO/IEC 38500 to the governance of data.
- [6] Anastasi Sara, Monica Luigi. (2018) “Evolution of European product directives in perspective of industry 4.0” *WIT Transactions on Built Environment* **174**: 163-168.
- [7] Madonna Marianna, Monica Luigi, Anastasi Sara, Di Nardo Mario. (2019) “Evolution of cognitive demand in the human–machine interaction integrated with industry 4.0 technologies.” *WIT Transactions on the Built Environment* **189**:13-19.
- [8] Di Nardo Mario; Gallo Mosè; Madonna Marianna; Santillo Liberatina C. (2015) “A conceptual model of human behaviour in socio-technical systems”. *Communication in Computer and Information Science* **532**: 598-609.
- [9] Lee Jay, Davari Hossein, Singh Jaskaran, Pandhare Vibhor (2018) “Industrial Artificial Intelligence for Industry 4.0 – based manufacturing systems”. *Manufacturing Letters* **18**: 20-23.
- [10] Al-Garadi Mohammed Ali, Mohamed Amr, Al-Ali Abdulla Khalid, Du Xiaojiang; Ali Ihsan, Guizani Mohsen. (2020) “A Survey of Machine and Deep Learning Methods for Internet of Things (IoT)” *IEEE Communications Surveys & Tutorials* **22** (3): 1646-1685.
- [11] ISO 3691-4:2020 Industrial trucks — Safety requirements and verification — Part 4: Driverless industrial trucks and their systems.
- [12] Markis Alexandra, Papa Maximilian, Kaselautzke David, Rathmair Michael, Sattinger Vinzenz, Brandst Mathias. (2019) “Safety of Mobile Robot Systems in Industrial Applications.” *Proceedings of the ARW & OAGM Workshop*: 26–31.
- [13] ISO 18497:2018 - Agricultural machinery and tractors - Safety of highly automated agricultural machines - Principles for design.
- [14] ISO/TS 15066:2016 - Robots and robotic devices - Collaborative robots.
- [15] Bozhinoski Darko, Di Ruscio Davide, Malavolta Ivano, Pelliccione Patrizio, Crnkovic Ivica. (2019) “Safety for Mobile Robotic System: A Systematic Mapping Study from a Software Engineering Perspective” *Journal of Systems and Software* **51**:150–179.
- [16] ISO 13849-1:2015 - Safety of machinery - Safety-related parts of control systems - General principles for design.
- [17] Tancredi Giovanni Paolo, Tebaldi Letizia, Bottani Eleonora, Longo Francesco, Vignali Giuseppe. (2020) “Analysis and testing of an online solution to monitor and solve safety issues for industrial systems.” *Procedia Manufacturing* **42**: 542–547.
- [18] European Commission. White Paper on Artificial Intelligence: a European approach to excellence and trust. COM (2020) 65 Final.
- [19] European Commission. Technical Report on Robustness and Explainability of Artificial Intelligence. 2020.
- [20] ISO 13849-1:2015 - Safety of machinery - Safety-related parts of control systems - General principles for design.
- [21] EN 62061:2005 - Safety of machinery - Functional safety of safety-related electrical, electronic and programmable electronic control systems.
- [22] Di Nardo Mario, Madonna Marianna, Santillo Liberatina C. (2016) “A system dynamics approach to manage risks in a process plant”. *International Review on Modelling and Simulations* **9** (4):256-264.