Proceedings of the 35th European Safety and Reliability & the 33rd Society for Risk Analysis Europe Conference
Edited by Eirik Bjorheim Abrahamsen, Terje Aven, Frederic Bouder, Roger Flage, Marja Ylönen

doi: 10.3850/978-981-94-3281-3_ESREL-SRA-E2025-P3635-cd

New standards for industrial robots

Alessandra Ferraro

Dit, Inail, Italy. E-mail: ale.ferraro@inail.it

Daniela Freda

Dit, Inail, Italy. E-mail: d.freda@inail.it

Fabio Pera

Dit, Inail, Italy. E-mail: f.pera@inail.it

The new standards ISO 10218-1 Robotics — Safety requirements — Part 1: Industrial and robots, and ISO 10218-2 Robotics — Safety requirements — Part 2: Industrial robot applications and robot cells, have just been updated in February 2025. Main changes aim to give measures useful for the risk assessment developed by manufacturers and integrators. This activity results particularly heavy and it can be developed with safety functions embedded in the robot or adding external devices, integrating them into the safety control system.

Among the changes made, the standard ISO 10218-1 classifies robots in two classes named Class I or Class II. Classification as a Class I robot shall be determined by the maximum capability of the manipulator without being limited by robot or safety functions, but merely based on the following values: mass per manipulator (M) is 10 kg or less; maximum achievable speed of the tool center point is 250 mm/s or less; maximum achievable force per manipulator (*F*MPM) is 50 N or less. The latter must be verified in accordance with the test methodology proposed by the standard.

In this paper we analyse this change, focusing on the possible impact on the risk assessment of the manufacturers or system integrator as well as on any other activity of stakeholders of the machines safety. We highlight the consequences on safety measures referring to the current standards and new ones.

Keywords: industrial robot, safety, standardization.

Introduction

The standards ISO 10218 (part 1 and part 2) on industrial robots and robotic systems have just been updated by new documents in February 2025. The new standards aim at improving the previous one that left open many questions. In particular, the manufacturer or the system integrator had to develop a rigorous and hard risk assessment, for any type of industrial robot (among them also robots with collaborative application are included), many times without indications on the measures to be adopted. Indeed, they often referred to the risk assessment of the system integrator. This was not useful in a type C standard. In the old standards ISO 10218-1:2011 and ISO 10218-2:2012 there isn't difference between Robots not even according with their type. Collaborative robots often are very light and do not need to operate forces and pressures too high. The risk assessment and the safety function developed will be completely different from traditional industrial robots as they have specific capabilities to safely move and operate in a shared space with humans, while they refer to the same standards: ISO 10218. As analyzed in the Classification Criteria paragraph, the new standards provide a new classification to simplify the risk assessment, and the related measures adopted to reach an adequate risk reduction.

ISO 10218 are C-type standards. The part 1 refers to industrial robot (robot in the following) i.e. partly completed machinery robot. The Robots considered are automatically controlled, reprogrammable multipurpose manipulator(s), programmable in three or more axes, which can be either fixed in place or fixed to a mobile platform for use in automation applications in an industrial environment. The industrial robot includes the robot control and the means to teach or program the robot, including any communications interface (hardware and software), but it does not include the end-effector and related sensors and equipment.

The part 2 of the standard refers to the system realized with robot plus end-effector that gives a specific application i.e. the machine. A system integrator or a manufacturer of a robot system can use this part 2 to develop the risk assessment of the assembly.

This is an important premise regarding the field of application of the standards and related changes. In this paper we analyze the new robot classification introduced by the new ISO 10218-1, dividing the Robots in Class I and Class II, and the corresponding impact in the risk assessment. We'll analyze the pros introduced and the issues eventually to address in the risk assessment, especially focusing on the machine as a whole.

In the paragraph "Classification criteria" we investigate the chosen values for the classification comparing them with the impact force and pressure limit values for developing power and force limited applications.

In the paragraph "Collaborative application" we deepen into if the new classification can impact the design of collaborative application.

In the paragraph "Safety function" we analyse the new requirements for Class I Robot safety functions and the impact in the risk assessment of the machine manufacturer (Robot plus end-effector).

2. Classification Criteria

Classification as a Class I Robot shall be determined by the maximum capability of the manipulator without being limited by Robot or safety functions. This classification is based on the following three conditions which must all be satisfied, otherwise Robots may be classified as a Class II.

i. The mass per manipulator (M) shall be 10 kg or less. This value shall be determined by measurement of the weight of the moveable parts of the manipulator without its fixed base. When the manipulator is intended to be used in applications where the base moves, the mass per manipulator including the base and its fastenings shall be provided. Then the moving robots will mostly fall into Class II;
ii. The maximum achievable speed shall be 250 mm/s or less: this value corresponds to the reduced speed (required for Class II)
iii. The Maximum force per manipulator (*F*MPM) shall be 50 N or less and it must be evaluated in accordance with the test methodology proposed in Annex E (normative) - Test methodology for Class I robots – Maximum force per manipulator (*F*MPM).

With reference to the last bullet point, the standard refers to the studies conducted by the University of Mainz on the pain onset. According to this study (4), 50 N is below pain onset limit values for any area of the body studied. Anyway, if *F*MPM is less or equal to 50 N, then p= *F*MPM/A=50N/0,5 (the standard requires to apply the *F*MPM over a minimum contact area of 0,5 cm^2) =100 N/cm^2 max. This pressure value is below pain onset limit values as well.

The new standard requires that *F*MPM shall be measured to determine the maximum vertical (downward) and horizontal (sideways) clamping forces. Clamping force is not clearly defined but, considering that the whole approach refers to the studies conducted by the University of Mainz on pain onset levels, it reasonable to consider for it the force in the worst quasi-static contact. In this situation the Robot applies a pressure to the trapped body area for a long time.

The study of University of Mainz used a test apparatus with a flat 1,4 cm^2 of metal test surface with 2 mm radius on all four edges. The approach of the old standard ISO/TS 15066, to which the ISO 10218-1:2011 refers, was to give pressure limit value that can be used to estimate transient pressure and force limits using conservative estimates. Now the new standard requires in Annex E (normative) that the force *F*MPM is calculated applying the maximum pressure over a minimum contact area of 0,5 cm^2. In the table instead requires that the maximum force is measured with a minimum contact area of 1 cm^2. It could be useful a clarification in the published standards.

Collaborative application

The new standard ISO 10218-1 does not use the definition of “collaborative robot”, but it specifies that a collaborative application is developed in a robot system. This means that hypothetically it could be possible to develop collaborative application in every type of industrial robot. A collaborative application has a/some sequence/s where both the robot and the operator execute a task or a process within the same safeguarded space. The manufacturer must develop a very careful risk assessment for this space, safeguarding it through safety functions available on the Robot or protective devices external to the Robot, or a combination of both.

The standard suggests that Robot used for collaborative application should have the relevant capabilities and safety functions necessary to develop a collaborative application. The three capabilities considered are:

- Hand Guiding Control (HGC) and /or
- Power force limiting (PFL) and/or
- Speed and separation monitoring (SSM).

Note that the new standard does not consider Safety-rated monitored stop (SMS) as a collaborative capability.

The PFL means that if any contact occurs it does not injure the operator. The risk assessment will identify the contact scenarios then the force and pressure parameters will be set.

If a system integrator uses a Class I or a Class II robot to realize the robot system, he must develop the risk assessment in each case, but the limits of the Class I (speed, mass and *F*MPM) could be enough to reduce the risks of contact below the applicable threshold limits for contact events. Otherwise, the system integrator will set parameter limits, according to the instruction of Robot manufacturer, as for Class II robots.

Considering SSM capability, the safety distances must be evaluated for every type of robot and the specific functions implemented. Certainly, starting from a robot that has a maximum speed of 250mm/s, the stopping time can be adequately designed.

Referring to HCG, the system integrator must address the same issues for the design of the collaborative application and, if not present and necessary for the risks assessed, he must provide a three-position (3P) enabling device external. Otherwise, this device is always present in Class II robots.

Safety functions

The standard ISO 10218-1:2011, in force, requires the following for the robot safety:

- a Performance level (PL) equal to d, cat.3 architecture or

- a Safety Integrity Level (SIL) equal to 2, Hardware Fault Tolerance (HFT) equal to 1 with a mission time not less than 20 years.

The new standard adds that the robot safety functions also could have SIL2 or PLd with Probability of Failure/Hour (PFH) less than $4{,}43x10^{-7}$/h. Then it will be possible to use a cat.2 architecture to reach PLd.

In the following we will refer to PL, considering the correlation between PL and SIL highlighted by EN ISO 13849-1:2023 Table 4 — Correlation between performance level (PL) and safety integrity level (SIL).

Moreover, the new standard ISO 10218-1, require for Class I robot safety functions, instead, at least PLb or SIL 1, different from Class II considered above. A PLb can be reached with single channel architectures without monitoring. Then the manufacturer of the partly completed machine could realize machines with these characteristics, then the whole robotic system will be assessed by the system integrator for the specific application. Some applications could require PLc or more.

So, if the system integrator wants to develop an high risk application, the related safety function must have PLc or more.

The system integrator will accurately have to focus these changes because he will have to realize a robotic system safety with an assessed PLr (Performance Level required).

This is an issue that could have some possible solutions to address. The first one, suggested by the part 1 of the standard, could be a safety function introduced externally added to the robot control system. For example, an end-effector load holding function realized in PLd and a Robot protective stop realized in PLb can exist independently in parallel as showed in the scheme of fig. 1.

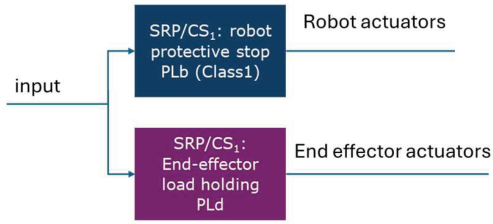

Fig. 1 – Scheme of two independent SRP/CS

Otherwise, if we consider a solely function "protective stop" subdivided in two subfunction, the first "Robot Protective Stop" in PLb, the second "End-effector Protective Stop" in PLc, it should be possible consider them as subsystems in series as in the scheme of Fig.2.

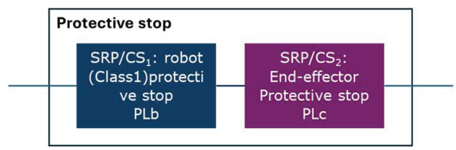

Fig. 2 – Scheme of a series alignment of two SRP/CS SRP/CS

In this case, if individual Probability of dangerous Failure per Hour (PFHDi) of the SRP/CSi are unknown, according to the table in fig 3, it will be possible to reach a PLb as maximum because:

- the lowest PL (PLlow) is PLb, and

- the number of SRP/CS with PLlow (Nlow) is 1.

PL_{low}	N_{low}	PL
a	>3	n.a.
	≤3	a
b	>2	a
	≤2	b
c	>2	b
	≤2	c

Fig. 3 – Calculation of PL for series alignment of SRP/CS (table 9 of EN ISO 13849-1:2022)

In this case, to move the PL of the robot system from b to c or d, it is necessary to increase the lowest PL, considering the possibility indicated in fig. 4 that gives the relationship between the category, the Average Diagnostic Coverage (DCavg) and Mean Time To Dangerous Failure (MTTFd) for each channel.

If the Class I robot is realized in cat B it will not be possible to arise this PL, while in cat 1 the maximum achievable is PLc.

Instead, adding diagnostic coverage, i.e realizing a Class I robot with a cat 2 or 3 architecture, and changing some component with a higher MTTFd, it will be possible to reach respectively PLd or even Ple.

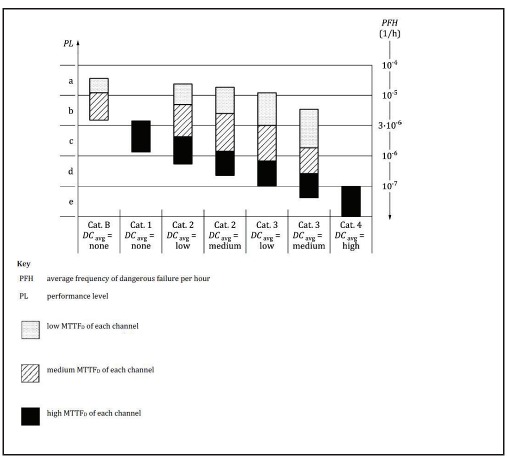

Fig. 4 – Relationship between categories, DCavg, MTTFd, of each channel and PL (figure 12 of EN ISO 13849-1:2022)

In the new standard ISO 10218 there isn't any requirement on the category that a Class I Robot must fulfill, but there is a very important measure among the information that a partly completed machinery manufacturer must give to the integrator: "instructions shall be provided of any tests or examinations necessary after change of component parts or addition of optional equipment (both hardware and software) to the robot that can affect the safety-related functions".

Conclusion

Referring to the new classification for Robot (Class I and Class II), in order to calculate the *F*MPM, it's necessary to measure the force applied on a small test apparatus (0,5 cm^2) and this choice is conservative for safety (surface smaller than the Maiz test device of 1,4 cm^2).

The Class I Robot manufacturer can produce and put into the market his partly completed machine, developing safety functions with PLb, providing all information needed to implement other protective measures.

In this paper we highlighted that, for high-risk applications, the system integrator of Class I Robot must develop safety function with a PL higher than the PLb. The specific application influences the chosen end-effector and, as a result, the PLr. For example, there will be a strong difference between a Robot for welding or inspection, gluing, etc…

Then, now the effort of the system integrator to reach the goal of PLr must be accurately evaluated, considering the whole performance of the machine and the PL of the Robot safety functions, especially if it is a Class I (according with ISO 10218-1:1 classification criteria). The standards provide different possibilities to arise the PL of the Robotic System, but they do not provide which characteristics of Class I robot are useful to be safely and easily adopted for high-risk application.

It could be useful, to ease the risk assessment of low-risk application, to identify some scenarios that are safe "by design", probably adding other parameters to the classification criteria. On the other hand, it would be very interesting to develop studies to identify the criteria for which it is safer to use a Class I Robot than a Class II.

References

EN ISO 10218-1:2012 Robots and robotic devices - Safety requirements for industrial robots - Part 1: Robots

UNI EN ISO 10218-2:2011 Robot e attrezzature per robot - Requisiti di sicurezza per robot industriali - Parte 2: Sistemi ed integrazione di robot

ISO/FDIS 10218-1.2:2025 Robotics — Safety requirements — Part 1: Industrial robots

ISO/FDIS 10218-2.2:2025 Robotics — Safety requirements — Part 2: Industrial robot applications and robot cells

EN ISO 13849-1 Safety-related parts of control system. Part 1: General principles for design

EN ISO 13849-2 Safety-related parts of control system. Part 2: Validation

EN ISO 13849-1:2023 Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design

Pera, F. and G.L., Amicucci (2017). I sistemi di comando delle macchine secondo le norme EN ISO 13849-1 e EN ISO 13849-2. ISBN 978-7484-548-4

Research project No. FP-0317: Collaborative robots – Investigation of pain sensibility at the Man-Machine-Interface. Institution for Occupational, Social and Environmental Medicine at the Johannes Gutenberg University of Mainz, Germany. Final Report December 2014.