ARE YOU STILL SAFE IN 2027?

New EU Machinery Regulation

Impacts on machines and mobile robots

New EU regulation forces manufacturers of mobile machinery to act

THE EU MACHINERY DIRECTIVE

The 2006 EU Machinery Directive (Directive 2006/42/EC) is part of national product safety legislation in the various EU countries. Compliance with the directive is thus a legal obligation for all machinery sold or brought to market in the European Union.

The requirements set out in the directive form the basis for the CE marking, which certifies to users that a machine is mechanically and electrically safe at the time of its placing on the market. The foundation of this certification is a declaration of conformity that must be prepared by the manufacturer; it is based among other things on a comprehensive risk analysis.

Various harmonized standards (standards explicitly referenced in the Machinery Directive) such as ISO 12100 on the safety of machinery and ISO 13849-1, which focuses on safety-related parts of control systems, are one source of assistance for machinery manufacturers preparing declarations of conformity. These standards are thus an important means of support for compliance with the Machinery Directive.

After discussions, negotiations and numerous changes over many months, the final version of the new EU Machinery Directive was published on June 29, 2023 (see figure 1). In the future it will be called the Machinery Regulation and bear the designation Regulation (EU) 2023/1230. Following a transition period of 42 months, this new document will – no later than January 14, 2027 – become required reading for anyone intending to build, sell or put into operation machinery in the EU.
It should be noted that after expiration of the transition period, the new Machinery Regulation will be a law that applies in identical terms in all EU member states, i.e., compliance with it is mandatory.

The term “machinery” is very broadly defined, ranging from an individual device or an assembly that performs a certain function on its own to entire installations consisting of combinations of machinery. The effort required for CE markings and the processes and institutions needed to ensure the safety of machinery thus vary greatly as well. While the risk assessment process for the declaration of conformity for an individual device is manageable, system integrators need to consider a much broader risk environment to qualify for a CE marking. In particular, new challenges in terms of both functional safety and IT security are posed by the interfaces between machine parts and also by the interfaces with the user; the Machinery Regulation now addresses these challenges explicitly.

In addition to a revised list of devices and installations, some of which (for example, mobile robots) are mentioned explicitly for the first time, the new document also takes into account new technologies and processes that reflect the state of the art in the machinery sector. Particularly worthy of mention are software-based safety features, self-learning safety systems, and a large number of functions for monitoring and recording machinery performance, such as built-in diagnostic and logging functionality.

At the time of writing, the list of harmonized standards and the cross-references to IT security standards were still open issues. The latter are currently still very much in a state of flux; the standards committee for the Machinery Regulation has not yet decided on a direct reference to and thus a harmonization of security standards such as IEC 62443, IEC 27100 or the EU Cyber Resilience Act.

Conversely, this means further changes to the Machinery Regulation are inevitable, so these gaps can still be closed by the time it enters into force.

The enormous increase in the number of pages (from 63 to 102) in the Machinery Regulation is by itself an indication of the technological progress in the past 17 years that made a revised version of the document necessary. A few examples of the challenges that can or will confront manufacturers, integrators or end users are highlighted below.

MOBILE MACHINES (AGVS AND AMRS) AS AN EXAMPLE OF CHANGED REQUIREMENTS

Significant change: unexpectedly becoming a manufacturer

A matter that is not clearly defined in the previous Machinery Directive, and thus often a cause for debate, is “significant change”. When is a change significant, and what effect does such a change have on the CE conformity of an overall system?

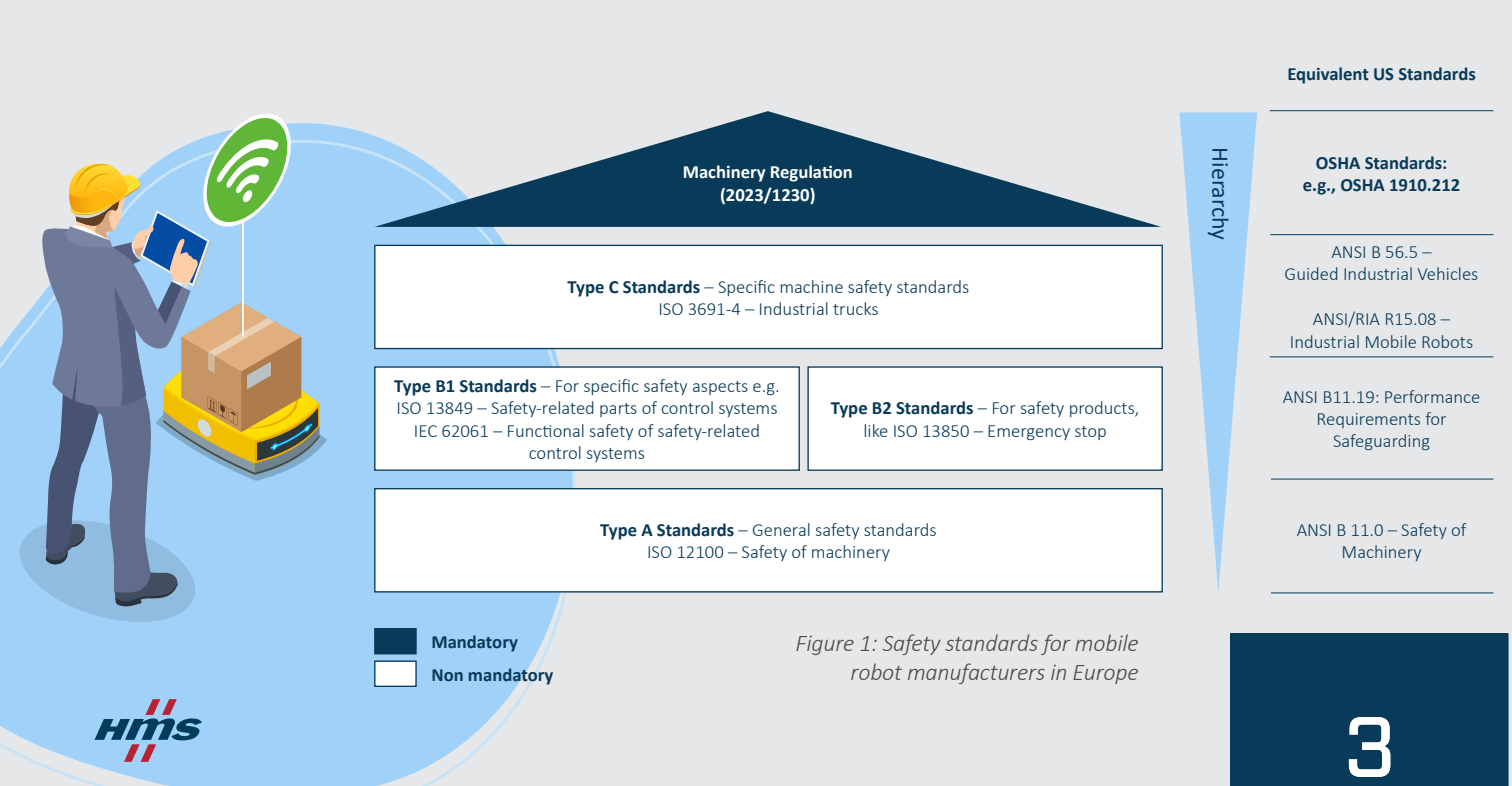

Figure 1: Safety standards for mobile robot manufacturers in Europe

The new Machinery Regulation provides a somewhat clearer definition of significant change, describing it as any change (whether electrical or mechanical) that can result in a new hazard situation or exacerbate an existing hazard.

Any such change can affect the CE conformity of an overall system. As a consequence, the entity changing the machine becomes legally the machine manufacturer; that entity would then have to fulfill the corresponding Machinery Regulation requirements for the changed machinery.

Mobile robot systems as an
illustrative example:

There is now a clear trend toward interoperability among mobile robot systems. The establishment of uniform communication standards like VDA 5050 in Europe and MassRobotics in the United States is a clear indicator of this.

For end users, it would appear very convenient at first glance to operate different robots and robot types in a single system. The users buy new robots, integrate them in their systems themselves using standardized communication interfaces, and are no longer dependent on individual manufacturers and integrators.

But a situation could quickly arise in which the addition of a new machinery type (e.g., automated forklifts where only unit load AGVs were previously used) or even the installation of a new software component for remote maintenance could lead to new hazard situations. While the individual machine is sold by its manufacturer as inherently safe and CE-compliant, that does not necessarily apply to the modified overall system in which the machine is integrated.

Before the integration of a new machinery type, at the very least a new risk analysis is needed. If this analysis reveals new or heightened hazards for the overall system, the end user would in this case become the manufacturer of the overall system and be obliged to fulfill the requirements of the Machinery Regulation. In this situation, it is useful to commission an independent expert (TÜV, VDI, etc.) for an initial assessment before any planned changes to an existing system.

Supervisory control function: safe remote stopping of mobile machinery

A specific requirement that will be relevant for the manufacturers of autonomous mobile machinery in the future is the supervisory control function described in section 3.2.4 of Annex III of the Machinery Regulation.

Mobile machinery must allow a supervisor to remotely receive information about the machinery. This information should enable the supervisor to have a complete and accurate view of the operation, movement and safe positioning of the machine in its travel and work areas.

At the same time, it should also enable the supervisor to safely stop and restart the machinery or move it to a safe position where it no longer poses a hazard (see figure 2).

A key problem in the implementation of this functionality is the transmission of safety-related signals over a wireless network since the mobile machinery generally has no direct, wired communication to avoid restricting its mobility. To transmit this safety-related data while complying with the requirements of the Machinery Regulation and the standards based on it (e.g., ISO 3691-4), the use of safe

fieldbus protocols such as PROFIsafe or CIP Safety is recommended. Although these protocols were not originally designed for wireless use, they can in principle also work without cables thanks to their underlying black channel principle. However, due to their different architectures some of the individual protocols differ significantly from one another in their performance in a wireless network. For a more detailed discussion of the individual protocols and their advantages and disadvantages when used in a wireless network, we refer you to our HMS white paper on the subject (***https://www.ixxat.com/safety-protocols-go-wireless***).

What all of the protocols have in common is that a stable wireless network is essential if an overall system is to function correctly. During the design phase of the network and of the data to be transmitted, consideration must be given to avoiding interference and keeping the amount of that data to a minimum – as much as needed and as little as possible. Otherwise problems can arise quickly with fleets of several hundred mobile machines if the individual safety messages no longer reach their intended recipients reliably. To react to unreliable communication, the system must be capable of switching to a safe mode on its own. In most cases, this means the system or at least parts of it can be safely shut down. In this context, unstable wireless connections can lead to significant downtime.

A further challenge for the manufacturers of mobile machinery and systems is splitting or merging two different safety circuits, a “slow” external one (e.g., for the aforementioned supervisor function) in which longer cycle times of up to several hundred milliseconds can be tolerated and a “fast” one on the vehicle itself (e.g., for pedestrian detection) in which a real-time reaction in an acutely hazardous

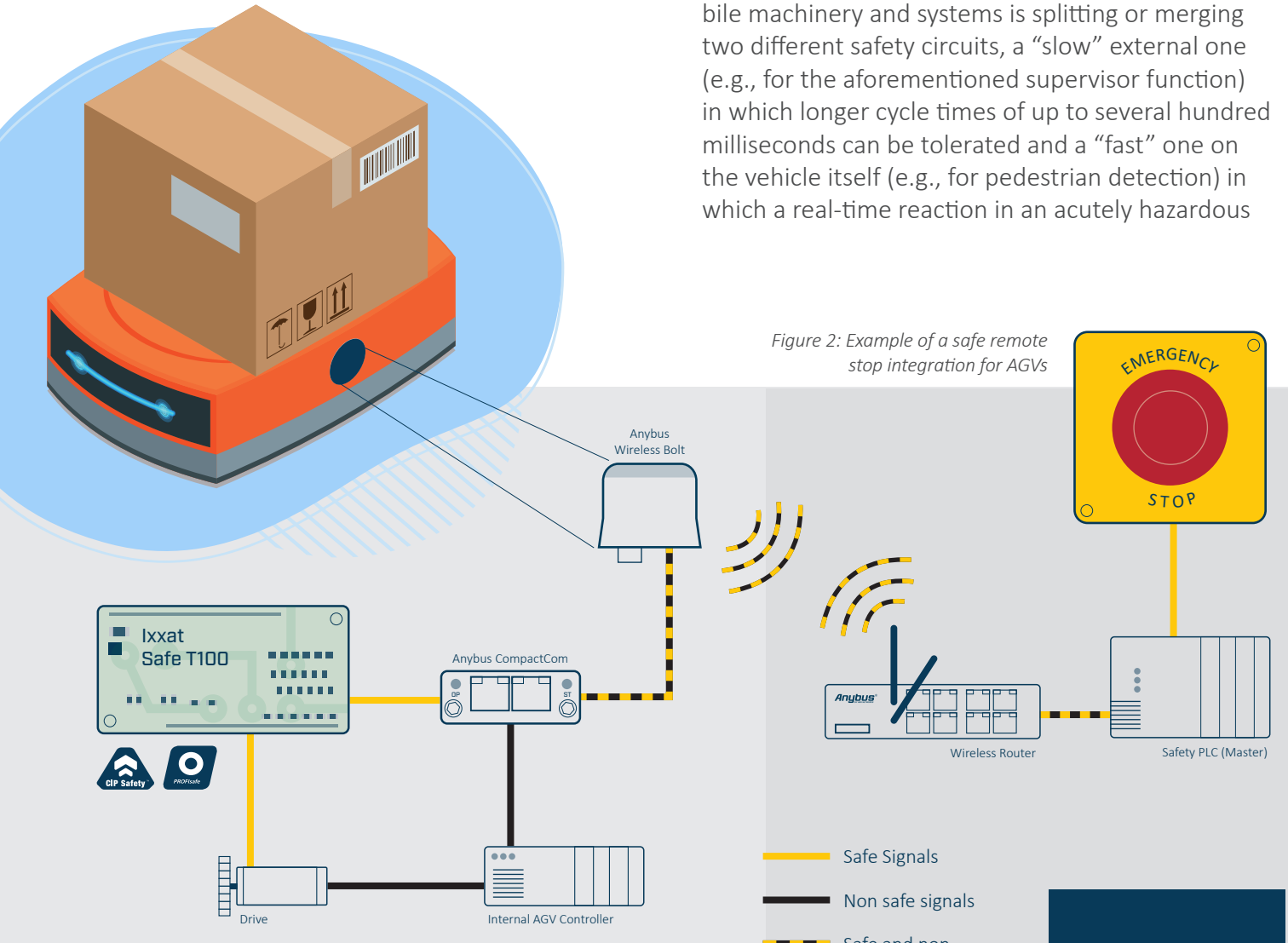

Figure 2: Example of a safe remote stop integration for AGVs

situation is called for. This example shows how important cooperation between machinery manufacturers and system integrators is in order to properly implement in practice the functionality required by the Machinery regulation.

Protection against tampering: system security and logging requirements

An important reason for the need to revise the current Machinery Directive was and is the issue of IT security.

Whereas (functional) safety and IT security were usually considered separately in the past, the two fields are now converging more and more as machines become increasingly interconnected with each other and with global networks (see figure 3). In the broadest sense, safety is about protecting people from machinery and security is about protecting machinery from people.

As long ago as 2010, Stuxnet drew the world's attention to the dangers that can result from malicious tampering with industrial installations. And nearly every day brings new reports about companies and installations that have become victims of cyberattacks.

Thus it was urgently necessary to consider this aspect in the new Machinery Regulation. In the future, it will no longer be enough to put up firewalls between machinery and the internet.

Annex III of the coming Machinery Regulation will address this topic in more detail in its section entitled "Protection against corruption." The manufacturer of a system must ensure that connecting a third-party device such as a laptop cannot lead to a hazardous situation. Furthermore, machinery must be capable in the future of identifying and collecting information about legitimate and illegitimate interventions in safety-related components (including software components).

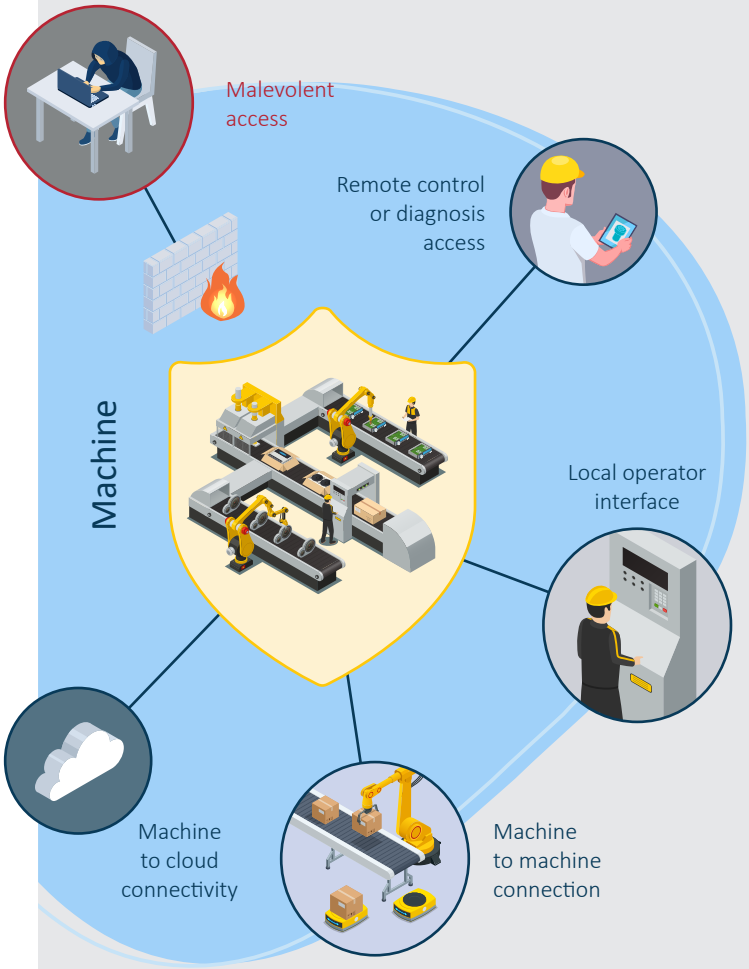

Figure 3: Functional security and IT safety are particularly required at the machine interfaces

SUMMARY: WHAT IS IN STORE FOR MACHINERY MANUFACTURERS?

The topics addressed above are examples of the challenges that will confront machinery manufacturers in their efforts to comply with legal requirements within the EU. Protecting people, property and the environment from the hazards that can originate from machinery remains the paramount objective.

Significant changes are being made to the current Machinery Directive, particularly in the field of security, where much stricter legal requirements will apply. In the future, machinery will need to be capable of identifying and logging attacks, and of preventing them as far as possible. Manufacturers should give thought to these matters at an early stage and work with experienced partners to find solutions for the coming requirements.

Explicitly including mobile machinery in the new regulation will establish clear requirements to be met by machinery, bringing it out of the current "gray zone" that can provide latitude for interpretation and misunderstandings.

By the time the Machinery Regulation enters into force in 2027, references to harmonized standards will inevitably be added to close current gaps in standardization. This means all manufacturers need to exercise foresight today in the development of new products if those products are to be successfully brought to market in the EU after 2027.

Standards will continue to provide important support for manufacturers in their efforts to comply with the Machinery Regulation, and using pre-certified components will help them simplify their system designs.