

# Safety design according to the EC

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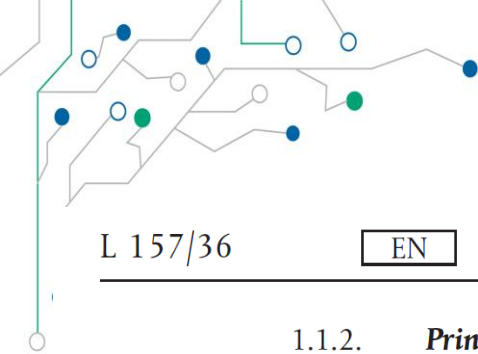


## Regulations

A "regulation" is a binding legislative act. It must be applied in its entirety across the EU.

## Directives

A "directive" is a legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals.



1.1.2. ***Principles of safety integration***

- (a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.

The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.

- (b) In selecting the most appropriate methods, the manufacturer or his authorised representative must apply the following principles, in the order given:

— eliminate or reduce risks as far as possible (inherently safe machinery design and construction),

— take the necessary protective measures in relation to risks that cannot be eliminated,

— inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.

- (c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorised representative must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.

The machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user's attention to ways — which experience has shown might occur — in which the machinery should not be used.

- (d) Machinery must be designed and constructed to take account of the constraints to which the operator is



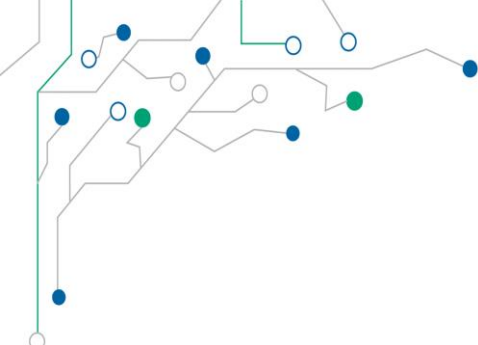
## Mandatory Documents

- CE marking
- Declaration of conformity
- Technical specifications
- User manual\*

**Guide to application of the Machinery Directive 2006/42/EC - Edition 2.1**

<https://ec.europa.eu/docsroom/documents/24722>

\* Several norms or technical documents exist about how to write a user manual






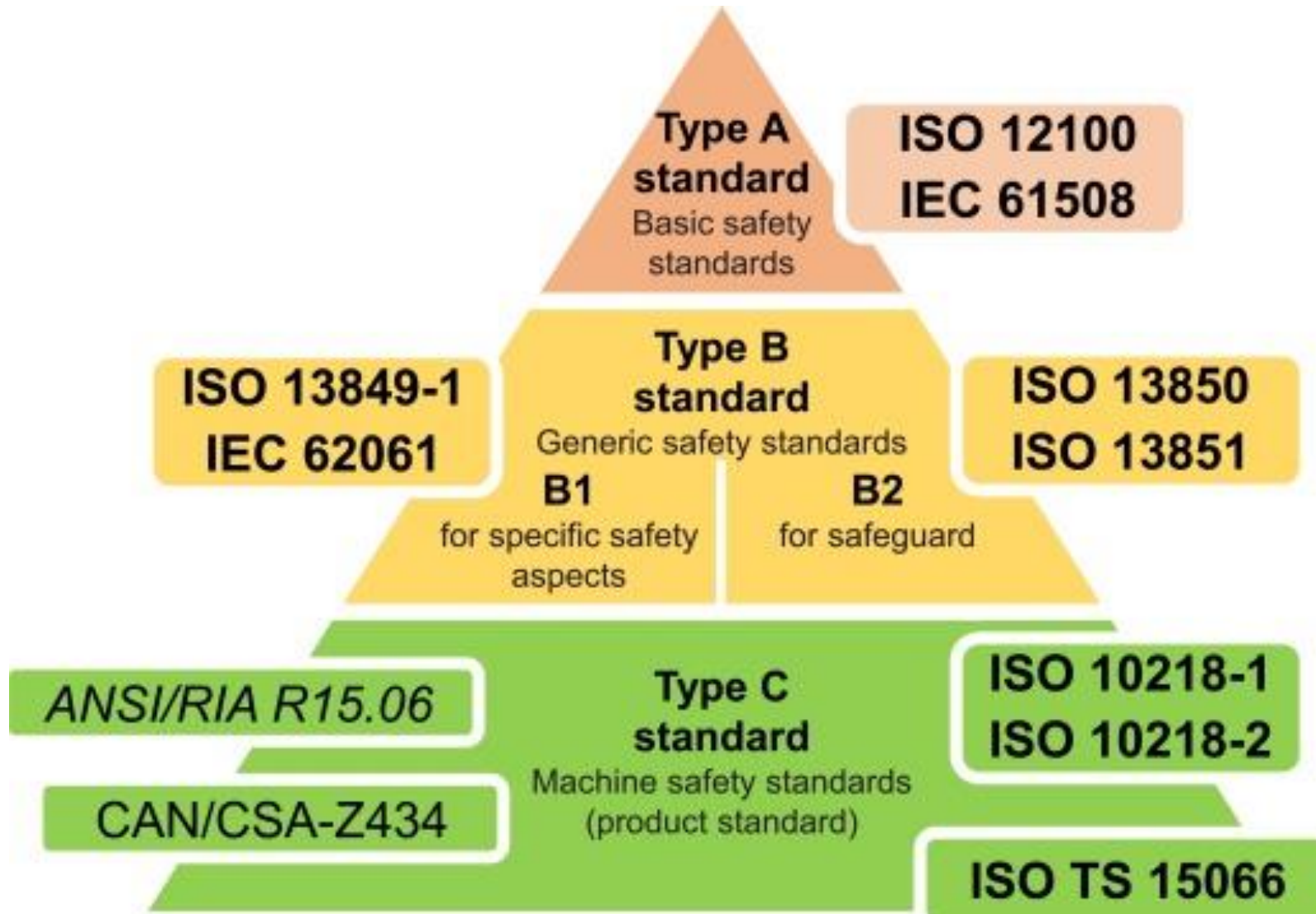
## INSTITUTES FOR VOLUNTARY TECHNICAL NORMS

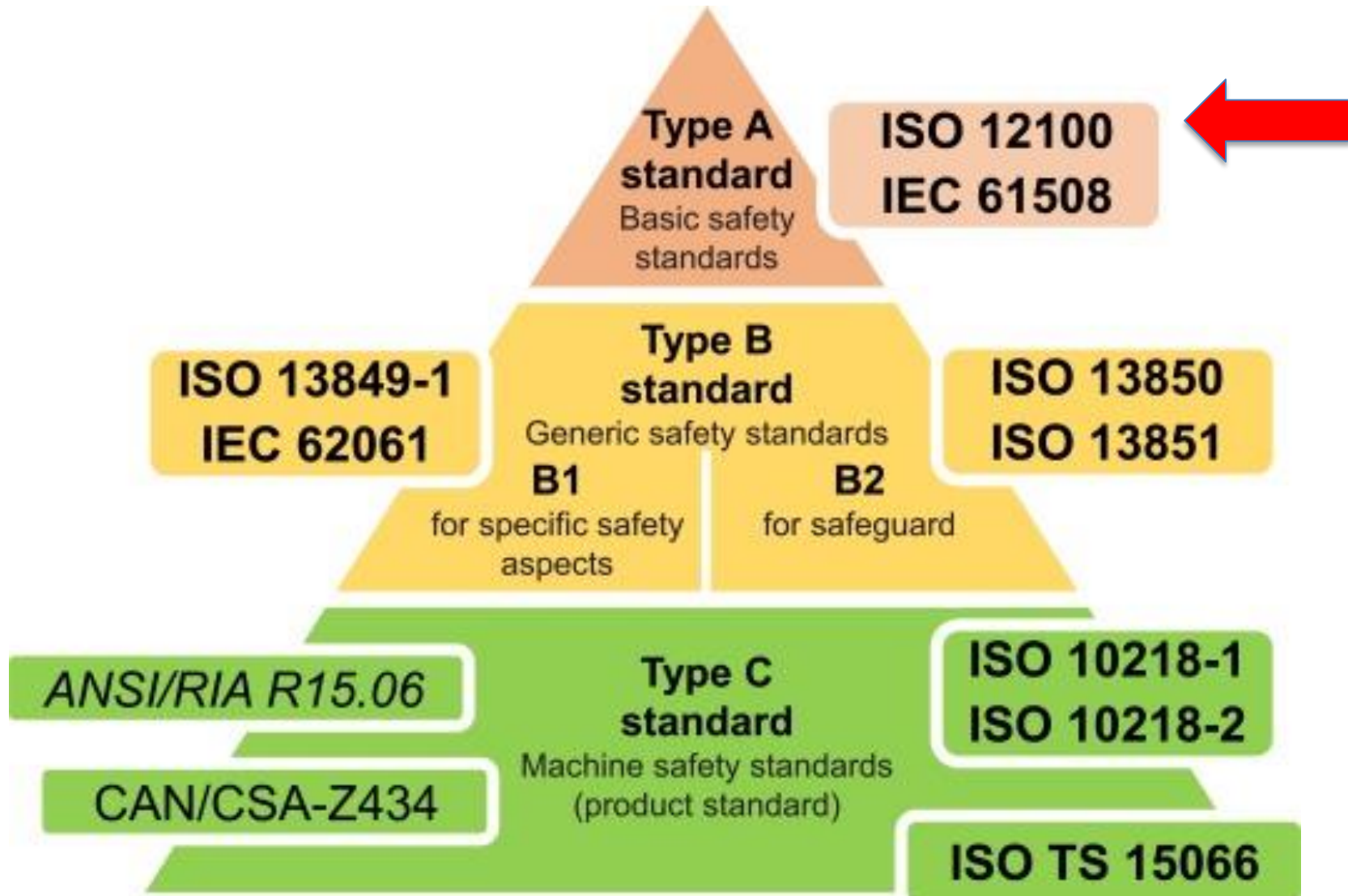
	<i>Electrical</i>	<i>All others</i>
<i>World</i>	IEC	ISO
<i>EU</i>	CENELEC	CEN
<i>Italy</i>	CEI	UNI

# Safety Norms Hierarchy

(most of which published on EU official gazette and therefore armonized)

- A  ALL THE MACHINE (design principles,...)
  
- B  B1: SPECIFIC SAFETY ASPECTS (es.: unexpected start up )  
B2: SAFEGUARDS (es.: emergency buttons,...)
  
- C  SPECIFIC MACHINES (if exsists, it supersedes A and B norms)







## RISK EVALUATION ACCORDING ISO 12100

**Example of numeric approach** according to UNI EN ISO 12100:2010 to calculate the HRN (Hazard Rating Number)

$$\text{HRN} = [\text{value PE}] \times [\text{value FE}] \times [\text{value MPL}] \times [\text{value NP}]$$

Where:

**PE** Possibility the exposure to the danger occurs  
(value between tra 0 = impossible and 15 = sure)

**FE** Frequency of exposure  
(value between tra 0,1 = rare and 5 = constant)

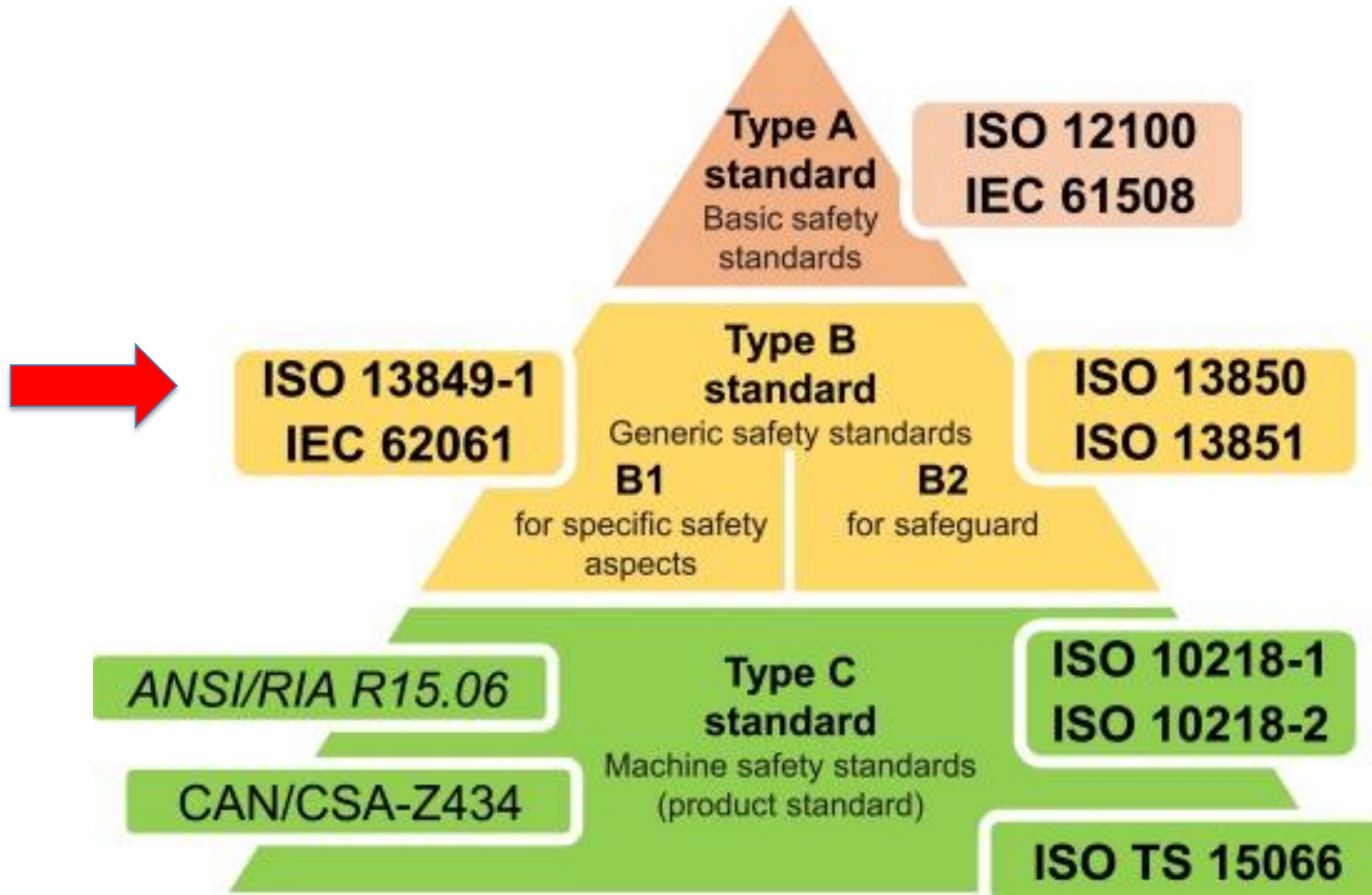
**MPL** Highest damage (value between tra 0,1 = scratches and 15 = death)

**NP** Number of people exposed to the danger  
(value between 1 = 1 o 2 people and 12 = 50 people or more)

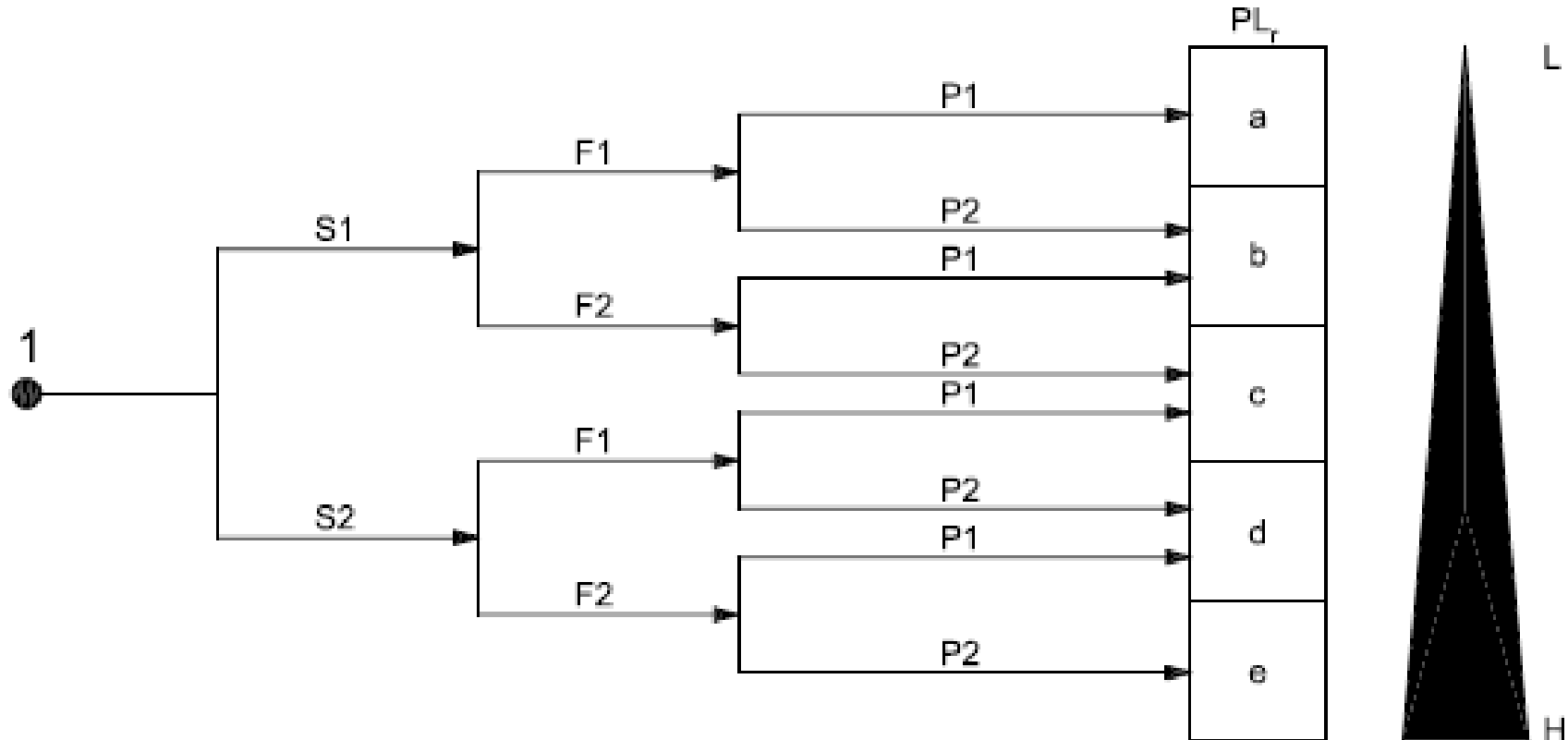
**HRN** is a number between 0 and 10000 and ranks the level of risk.

## RISK EVALUATION ACCORDING ISO 12100

- **Admissible  $HRN \leq 10$ :** Very low, just give the information to end users about the residual risk.
- **Low but significant  $10 < HRN \leq 50$ :** Low but some measures have to be taken to reduce the risk and information to end users about the level of risk must be addressed.
- **High  $50 < HRN \leq 500$  :** A considerable risk is present and strong actions must be done to increase the safety level. sono necessarie misure di sicurezza.
- **Extreme  $500 < HRN$  :** Inacceptable, the machine must not work until strong countermeasures are taken.



# HOW TO MAKE SAFETY FUNCTIONS ACCORDING TO ISO 13849



**PL = Performance Level**  
**S = Severity**  
**F = Frequency**  
**P = Possibility**



## HOW TO MAKE SAFETY FUNCTIONS ACCORDING TO ISO 13849

**MTTF<sub>d</sub>**

**Mean Time To Failure dangerous**

It's a measure of the reliability of components

# HOW TO MAKE SAFETY FUNCTIONS ACCORDING TO ISO 13849

DC

## Diagnostic Coverage

It measures the capability of the function to detect a dangerous failure

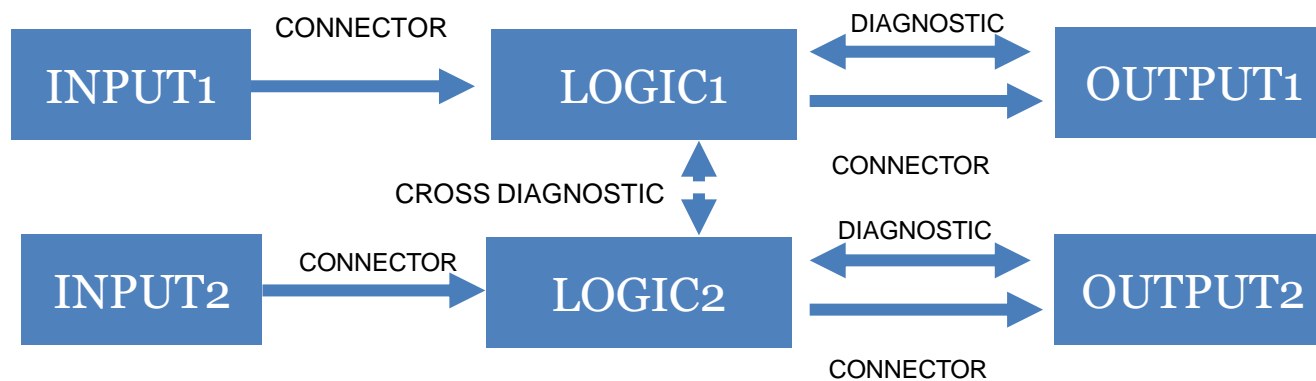
# HOW TO MAKE SAFETY FUNCTIONS ACCORDING TO ISO 13849

## Category B



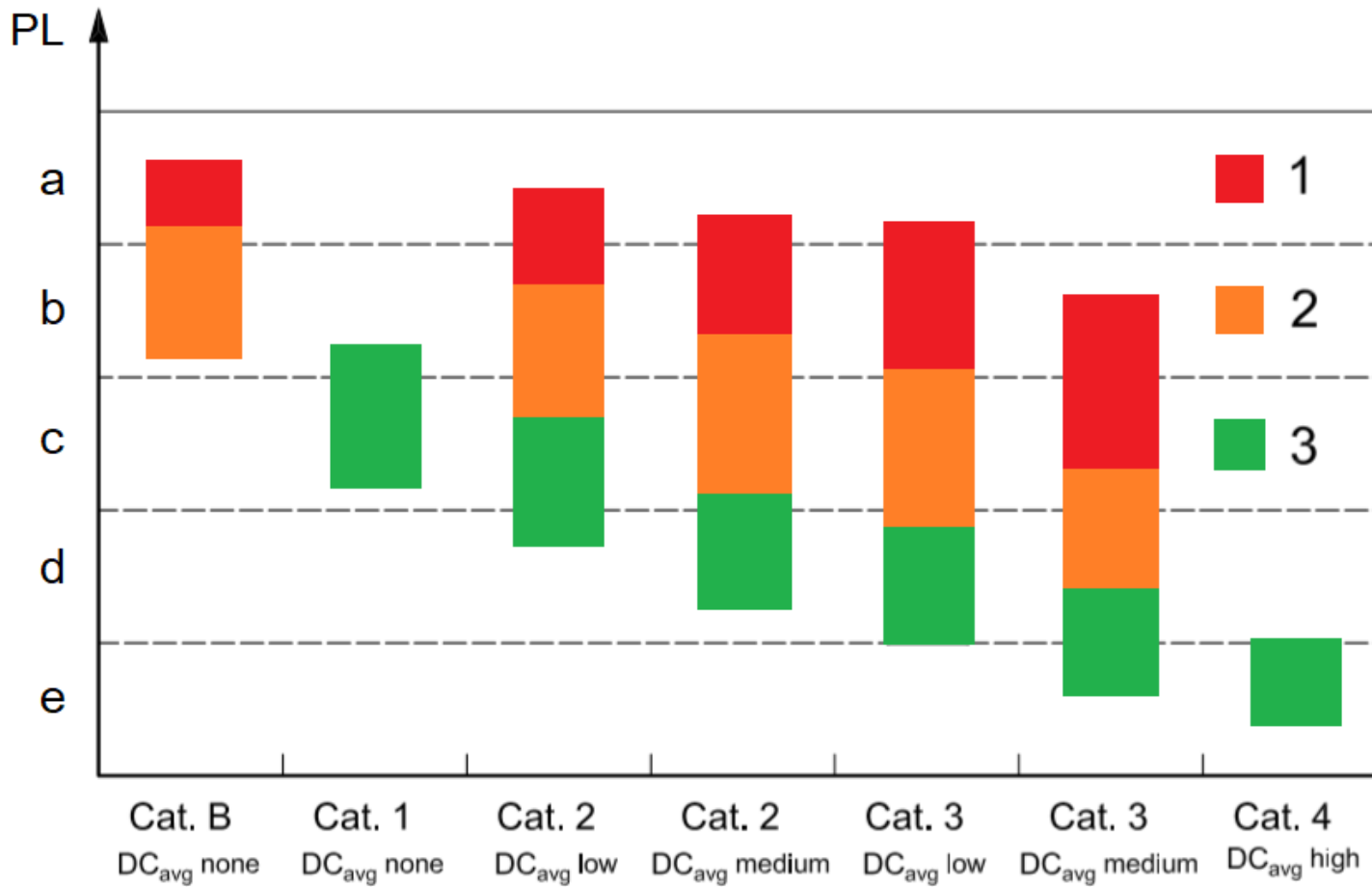
# HOW TO MAKE SAFETY FUNCTIONS ACCORDING TO ISO 13849

## Category 4

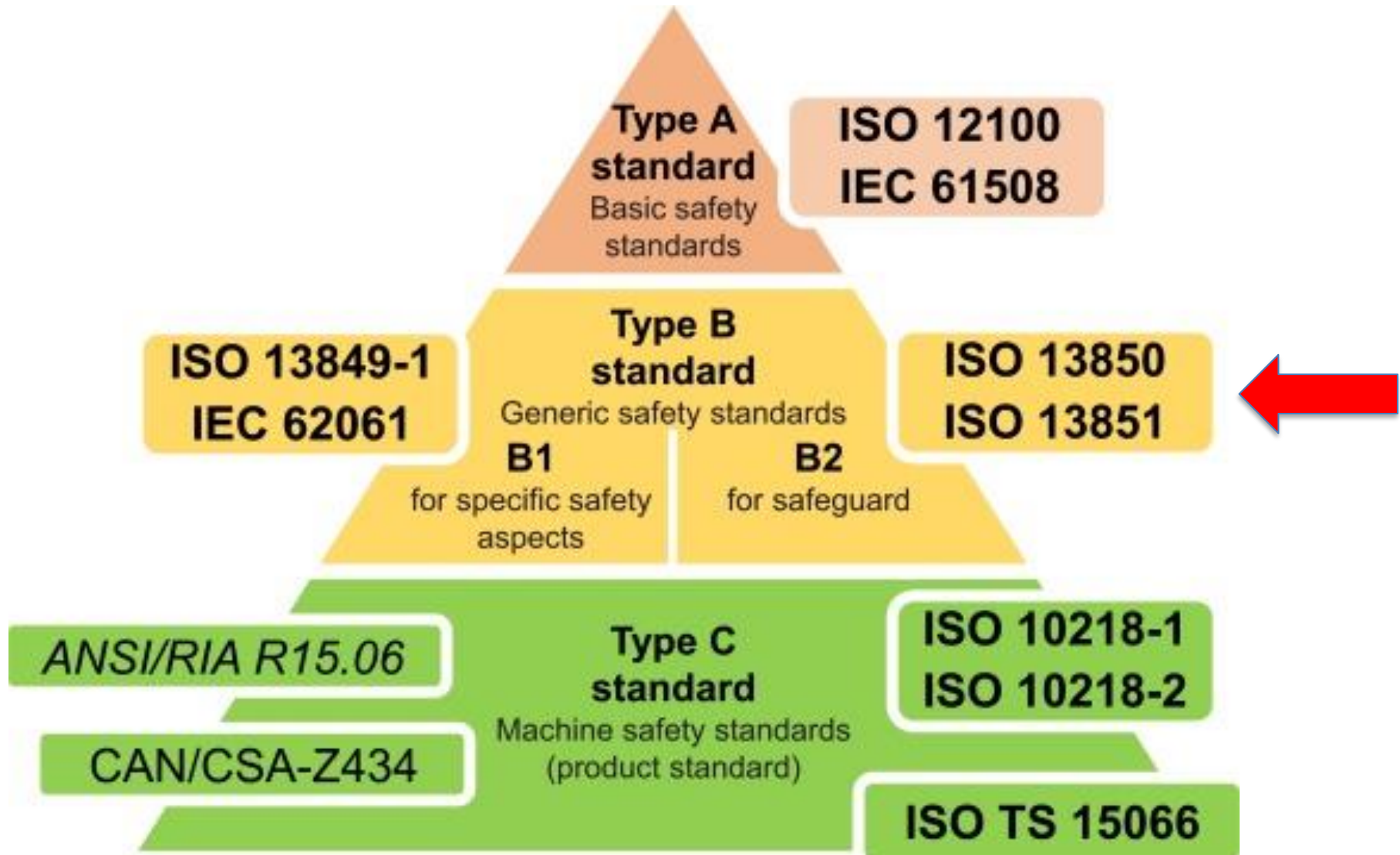




## HOW TO MAKE SAFETY FUNCTIONS ACCORDING TO ISO 13849



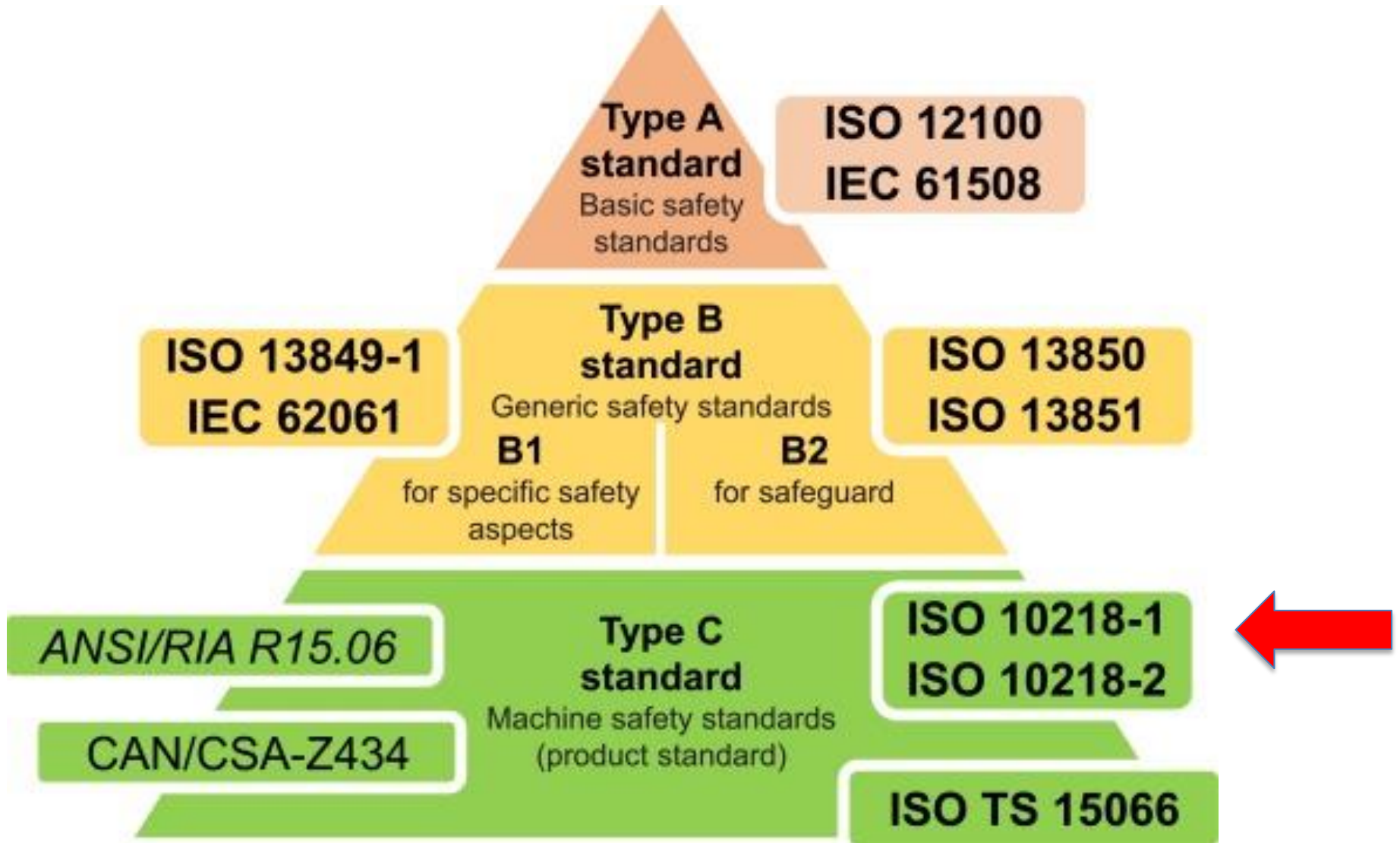
1 MTTFd = LOW  
 2 MTTFd = MEDIUM  
 3 MTTFd = HIGH



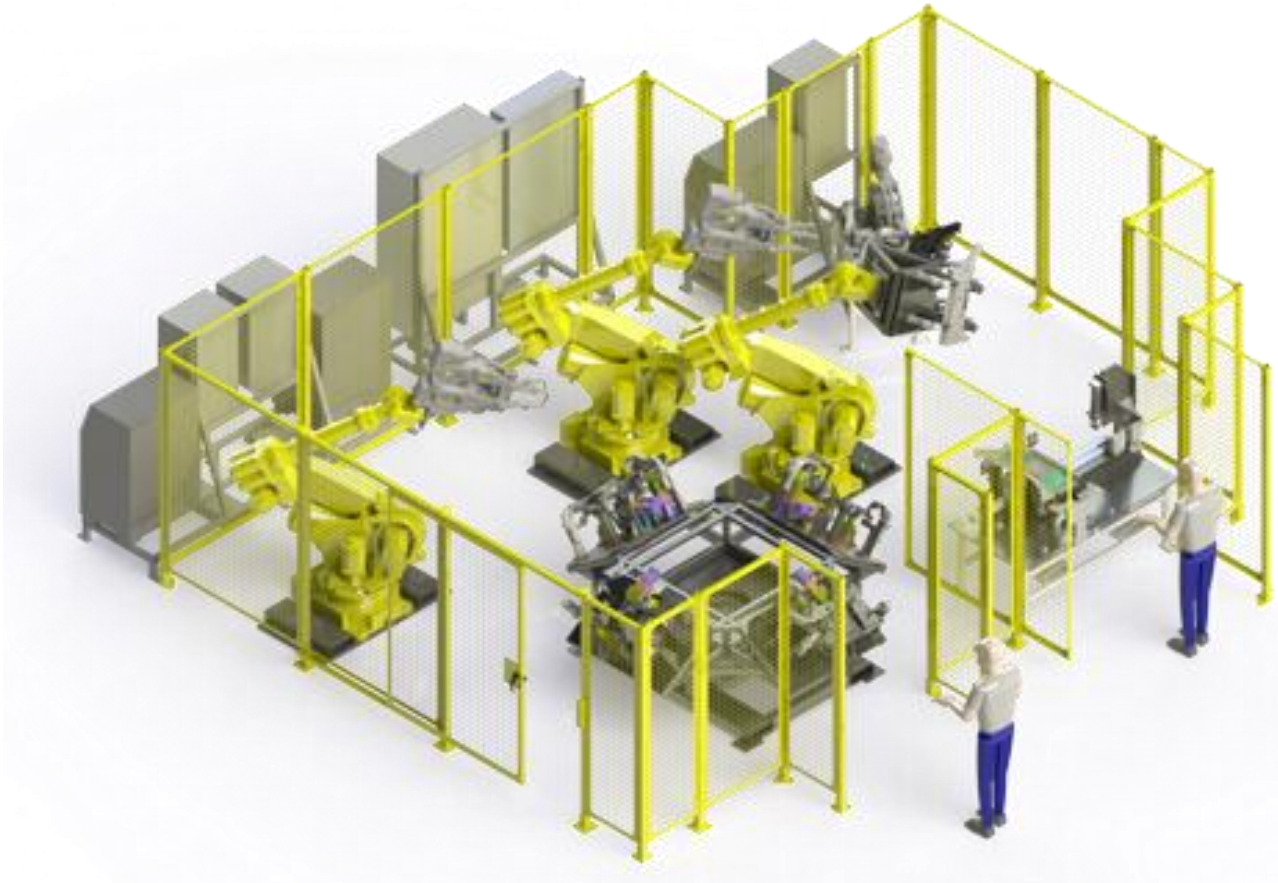
# SAFETY OF MACHINERY – EMERGENCY STOP – PRINCIPLES FOR DESIGN ISO 13850

EN ISO 13850: 2015 and E-Stop zoning



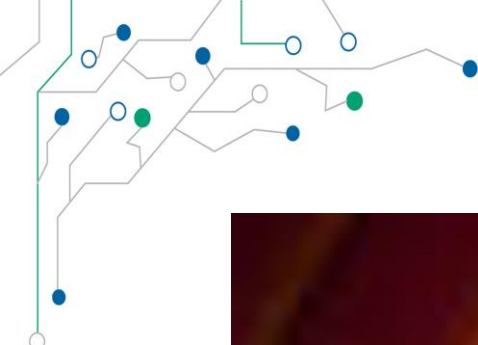


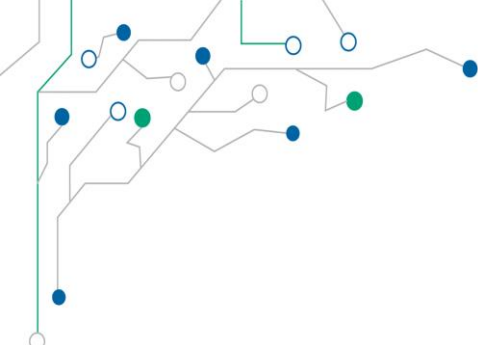
# SAFETY REQUIREMENTS FOR INDUSTRIAL ROBOTS - ISO 10218-1 AND ISO 10218-2



# SAFETY REQUIREMENTS FOR PACKAGING MACHINES – EN 415







# THANKS FOR YOUR ATTENTION!

Massimo Eritale

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Safe solutions for your industry