



Safety design according to the EU

Giovanni B. Lucido



SCHMERSAL

Safe solutions for your industry

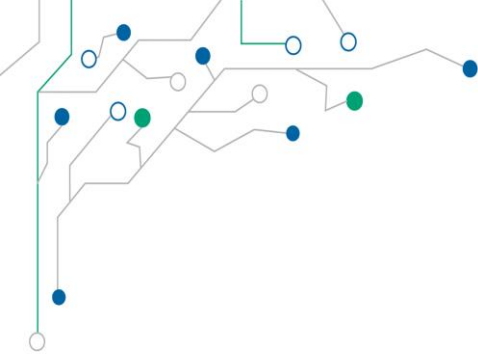


Regulations

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.



Machinery directive **2006/42/CE**

Essential health and safety requirements (EHSRs)
(compulsory – mandatory)

Reason: Free circulation of goods

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,

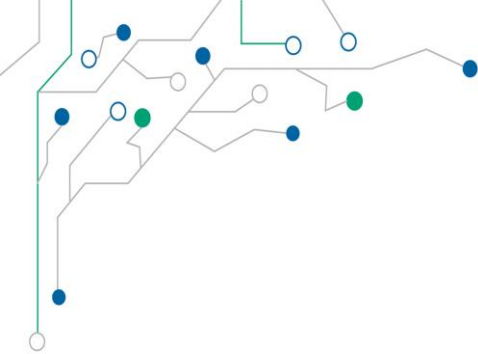
— inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.

- (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

the safety result during the use of work equipment depends on a combination of factors that are CLEARLY EXPRESSED ABOVE



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

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

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

Electromagnetic Compatibility Directive (EMC): 2014/30/EU

New guide foreseen for 2018

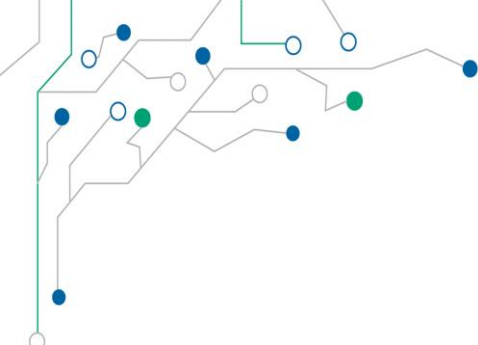
Radio Equipment Directive (RED): 2014/53/EU

Guide available @ <http://ec.europa.eu/docsroom/documents/23321>

Low voltage Directive (LVD) (2014/35/EU): ensures that electrical equipment within certain voltage limits provides a high level of protection for European citizens

ATEX Directive : 2014/34/EU: for explosive atmospheres

And more...






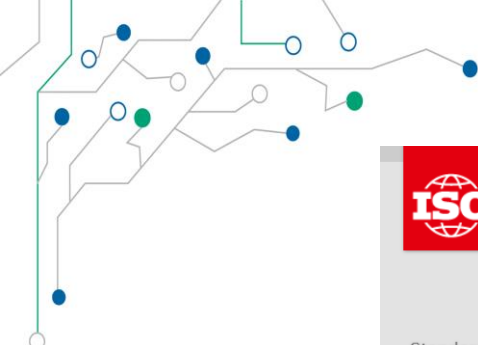

Institutes for VOLUNTARY TECHNICAL NORMS

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

Norm HIERARCHY

(most published on official EU gazette and therefore armonized)

- A  ALL MACHINERY (12100,...)
- B  SAFETY DEVICES/ASPECTS
B1 (13857, 60204,...)
B2 (14119, 13850,...)
- C  SPECIFIC MACHINERY

International Organization for Standardization

When the world agrees


Standards | All about ISO | Taking part | **Store**

Standards catalogue | Publications and products

Home > Store > Standards catalogue > Browse by ICS > 13 > 13.110 > ISO 12100:2010

ISO 12100:2010 [Preview](#)


Safety of machinery -- General principles for design -- Risk assessment and risk reduction


 **This standard was last reviewed and confirmed in 2015. Therefore this version remains current.**



ISO 12100:2010 specifies basic terminology, principles and a methodology for achieving safety in the design of machinery. It specifies principles of risk assessment and risk reduction to help designers in achieving this objective. These principles are based on knowledge and experience of the design, use, incidents, accidents and risks associated with machinery. Procedures are described for identifying hazards and estimating and evaluating risks during relevant phases of the machine life cycle, and for the elimination of hazards or sufficient risk reduction. Guidance is given on the documentation and verification of the risk assessment and risk reduction process.


ISO 12100:2010 is also intended to be used as a basis for the preparation of type-B or type-C safety standards.

It does not deal with risk and/or damage to domestic animals, property or the environment.

General information 	
Current status : Published	Publication date : 2010-11
Edition : 1	Number of pages : 77

Buy this standard 

Format	Language
<input checked="" type="checkbox"/> PDF	English 
<input type="checkbox"/> Paper	English 

CHF 178 

Got a question?
Check out our [FAQs](#)

Customer care
+41 22 749 08 88
customerservice@iso.org

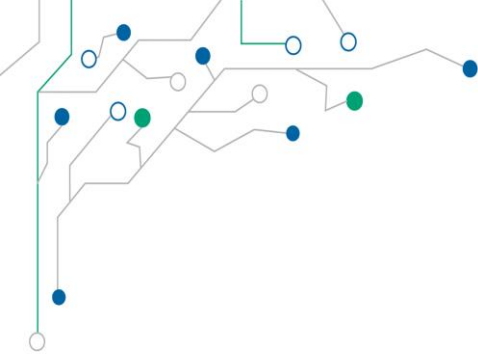
Opening hours:
Monday to Friday - 09:00-12:00, 14:00-17:00 (UTC+1)

ISO/TR 22100-1:2015(E)

Technical regulation related to ISO 12100:2010

provides assistance to the designer/manufacture of machinery and related components as to how the system of existing type-A, type-B and type-C machinery safety standards should be applied in order to design a machine to achieve a level of tolerable risk by adequate risk reduction

TR are important documents but no norms and no armonized, contains examples
No presumption of conformity



More on the topic “inform users”

UNI 10893:2000

Instructions for use - Articulation And Esposition Of The Content

UNI 10653:2003

Quality Of Product Technical Documentation

UNI/TS 11192:2006

Guidelines For Classification

UNI/TS 11083:2003

Guidelines To Prepare Useful Documents For Instruction And Training For The Use Of Goods

UNI ISO 15226:2007

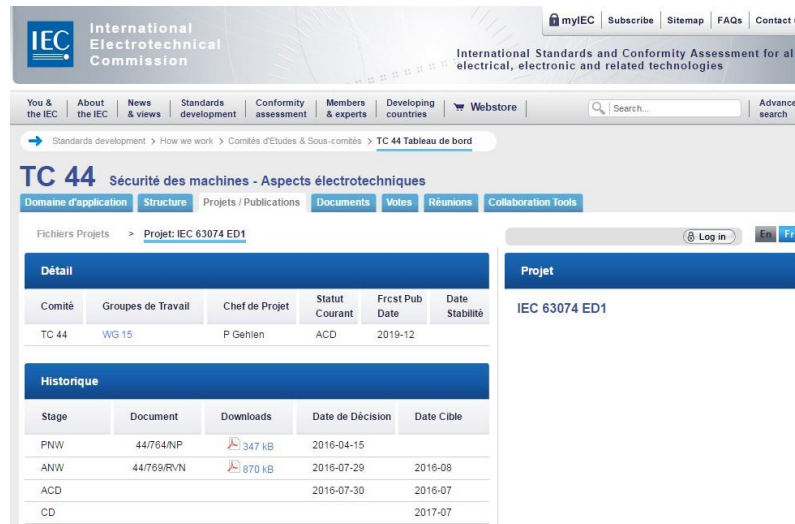
Life cycle model

SAFETY - SECURITY

IEC 63074

Primary aspect:
Human's Safety

**Machinery
Directive
2006/42/CE**



International Electrotechnical Commission
International Standards and Conformity Assessment for all electrical, electronic and related technologies

myIEC | Subscribe | Sitemap | FAQs | Contact us

You & the IEC | About the IEC | News & views | Standards development | Conformity assessment | Members & experts | Developing countries | Webstore | Search... | Advanced search

Standards development > How we work > Comités d'Etudes & Sous-comités > TC 44 Tableau de bord

TC 44 Sécurité des machines - Aspects électrotechniques

Domaine d'application | Structure | Projets / Publications | Documents | Votes | Réunions | Collaboration Tools

Fichiers Projets > Projet: IEC 63074 ED1 | Log in | En | Fr

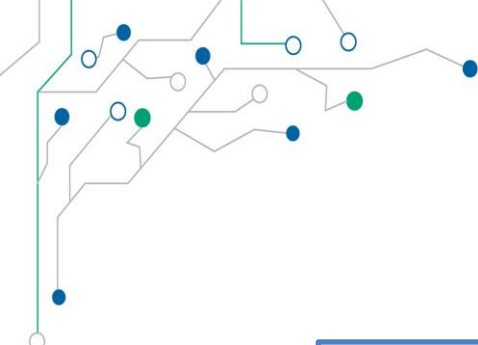
Détail					
Comité	Groupes de Travail	Chef de Projet	Statut Courant	Frcst Pub Date	Date Stabilité
TC 44	WG 15	P Gehlen	ACD	2019-12	

Historique				
Stage	Document	Downloads	Date de Décision	Date Cible
PNW	44/764/NP	347 kB	2016-04-15	
ANW	44/769/RVN	870 kB	2016-07-29	2016-08
ACD			2016-07-30	2016-07
CD				2017-07

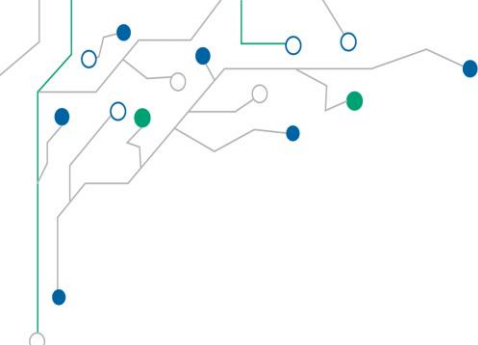
Secondary aspect:
Data's Security

WARNING:
a compromised
parameter could
become a **SAFETY**
related problem

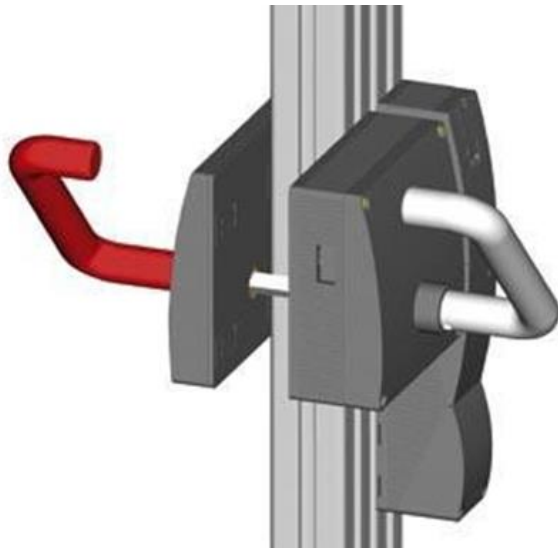
IEC 62443-2-4:2015 (IEC/TC65)
“Security for industrial automation and control systems - Part 2-4: Security program requirements for IACS (industrial automation and control systems) service providers”.



- Regulation on materials and articles intended to come into contact with food **1935/2004**
- Regulation on plastic materials and articles intended to come into contact with food **10/2011**
- Regulation of GMP on good manufacturing practice for materials and articles intended to come into contact with food **2023/2006**



For operation see also D.lgs. 81/2008
if you are operating in this country



EN ISO 14119 = type B2-Standard

Interlocking devices associated with guards -- Principles for design and selection

Successor of EN 1088

Focus on measures required to **minimize defeat possibilities**

It is addressed to device and machinery manufacturers

[Home](#) > [Comunicazione](#) > [Pubblicazioni](#) > [Catalogo Generale](#)

- > Avvisi e scadenze
- > News ed eventi
- > Sala Stampa
- > Campagne
- > Pubblicazioni
 - > **Catalogo Generale**
 - > Come acquisire una pubblicazione
 - > Rapporti e relazioni Inail
 - > Quaderni di ricerca
 - > Quaderni del CIV
 - > Dati Inail
 - > Rivista Infortuni
 - > Bollettino trimestrale
 - > Superabile
 - > Multimedia

Il defeating di un dispositivo di interblocco associato ai ripari

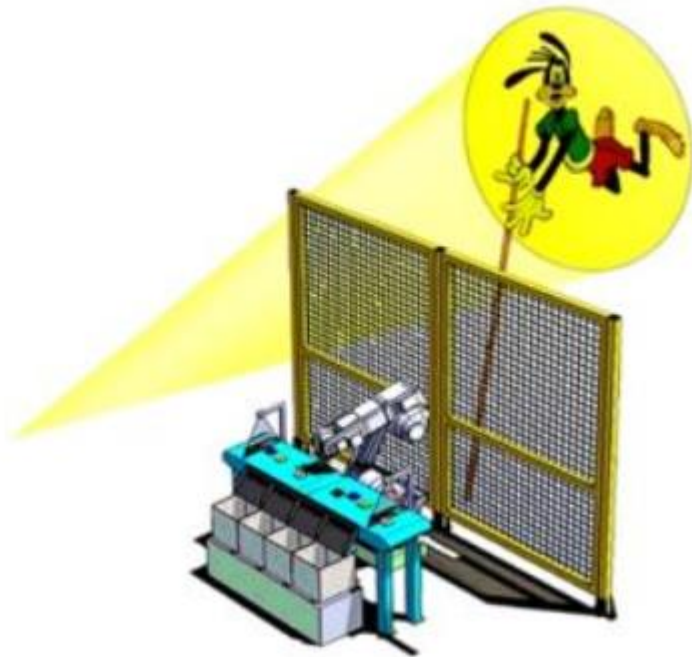
Le linee di indirizzo contenute nella pubblicazione, edita nelle due lingue italiano e tedesco, sono state elaborate - dal gruppo di lavoro formato dal Laboratorio macchine ed attrezzature di lavoro del Dit dell'Inail insieme a Ministero del Lavoro, Gruppo Interregionale macchine e impianti, Federmacchine, UNI, UCIMA, Schmersal Italia S.p.A. - con l'intento di approfondire un argomento di grande rilevanza sociale e prevenzionale quale il defeating ovvero la neutralizzazione di un dispositivo con funzioni di sicurezza per macchine ed attrezzature di lavoro.

Si configurano quindi come valido aiuto ai fabbricanti, datori di lavoro e progettisti che si confrontano con la necessità di utilizzare le prescrizioni contenute nella nuova edizione della norma entrata in vigore dal 1 maggio 2015.

Prodotto: Volume
Edizioni: Inail - 2016
Disponibilità: Sì – Consultabile anche in rete
Info: dcpianificazione-comunicazione@inail.it



[Il defeating di un dispositivo di interblocco associato ai ripari](#)
(.pdf - 14,4 mb)



ISO/DIS 14120 type-B2 standard
(General requirements for the design and
construction of fixed and movable guards)

Successor of EN 953

Machine must be designed, built and
positioned with safety distances to prevent
hazard zones being reached by upper and
lower limbs as indicated in ISO 13857



- > Prevenzione e sicurezza
- > Assicurazione
- > Prestazioni
- > Ricerca e Tecnologia
 - > Finanziamenti per la ricerca
 - > Borse di studio per la ricerca
 - > Formazione in collaborazione con le Università
 - > Area salute sul lavoro
 - > Area sicurezza sul lavoro
 - > Certificazione, verifica e innovazione
 - > Cultura della salute e della sicurezza
 - > Progetti a finanziamento esterno
 - > Pubblicazioni Scientifiche
 - > Applicativi per la salute e la sicurezza sul lavoro
 - > Mappe esposizione a vari inquinanti area di Roma
 - > **Software per la sicurezza del macchinario**
 - > AGILE-G - gestione sicurezza in impianti a rischio
 - > Formazione specialistica
 - > Partnership - Network
 - > BibliOnWeb - La Biblioteca online
- > Dati e statistiche

Software per la sicurezza del macchinario

Nati dalla collaborazione del Dipartimento Innovazioni tecnologiche e sicurezza degli impianti, prodotti e insediamenti antropici, con il Ministero del Lavoro e delle politiche sociali, Federmacchine, Gruppo interregionale macchine e impianti, Cei CT44X - Equipaggiamenti elettrici delle macchine industriali, Uni, i Software per la sicurezza del macchinario hanno l'obiettivo di rendere disponibile in modo immediato ed intuitivo ai fabbricanti, ai progettisti, ai fornitori ed anche ai datori di lavoro, uno strumento di applicazione delle principali norme di riferimento per impedire il raggiungimento delle parti pericolose delle macchine e delle attrezzature di lavoro, proteggendo in tal modo gli operatori da un contatto anche accidentale con tali parti.

I software sono stati elaborati con un linguaggio comprensibile a tutti e sono dotati di immagini ed help. In particolare questi prodotti risultano utili ai datori di lavoro, tenuti a mettere a disposizione propria e dei propri lavoratori macchine ed attrezzature di lavoro che siano sicure.

I due applicativi, consultabili anche in lingua inglese, sono particolarmente risolutivi nel caso in cui dispositivi di protezione materiali e/o immateriali siano:

- forniti e installati successivamente alla fabbricazione del macchinario o della attrezzatura di lavoro;
- installati al fine di ottemperare alle prescrizioni contenute nell'allegato V del d.lgs. 81/2008 (macchine non marcate CE).

Va sottolineato, comunque, che questo lavoro non può e non deve sostituirsi all'analisi ed alla valutazione dei rischi che devono predisporre i soggetti di volta in volta coinvolti nelle varie fasi della vita della macchina. Questo significa che fabbricanti, progettisti, fornitori ed anche datori di lavoro dovranno tener conto non solo della legislazione applicabile, ovvero d.lgs. 81/08 e direttive di prodotto (direttiva macchine 98/37/CE e 2006/42/CE), ma anche delle norme armonizzate che, ancorché a carattere volontario, rappresentano un mezzo per soddisfare lo stato dell'arte e il rispetto dei requisiti essenziali di sicurezza e salute. Si ricorda inoltre che, in funzione della tipologia di macchina e del dispositivo di sicurezza applicato, possono riscontrarsi delle differenze nei valori prescritti da norme di Tipo C1 rispetto a norme di Tipo A (norme fondamentali di sicurezza) o B (norme di sicurezza generiche) prese in esame per il presente lavoro.

Le due norme oggetto del software sono la EN 13857:2008 "Distanze di sicurezza per impedire il raggiungimento di zone pericolose con gli arti superiori e inferiori" e la EN 13855:2010 "Sicurezza del macchinario - posizionamento dei dispositivi di protezione in funzione delle velocità di avvicinamento di parti del corpo".

Prima autenticazione tramite form di registrazione, gli utenti che abbiano necessità di calcolare e/o verificare le distanze di sicurezza dalle parti pericolose delle attrezzature di lavoro, possono utilizzare gli applicativi direttamente online.

L'Inail garantisce, ai sensi della legge 196/2003, l'assoluta riservatezza dei dati comunicati e la possibilità di richiederne la modifica o la cancellazione. I dati forniti saranno utilizzati dall'Inail esclusivamente per eventuali comunicazioni inerenti i software applicativi in questione nonché per i fini statistici delle attività di ricerca.

Contatti: sicurezzaamacchinario.dit@inail.it



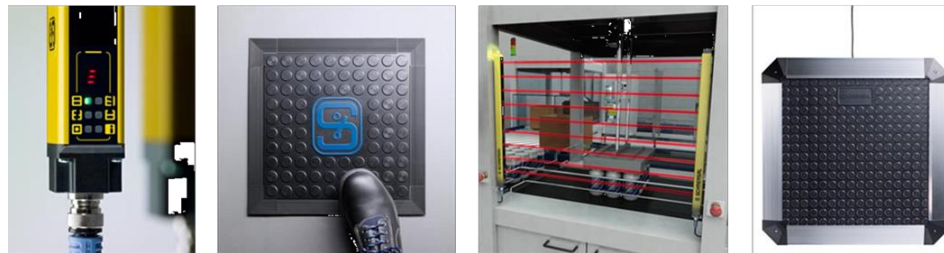
> **Software per la sicurezza del macchinario**

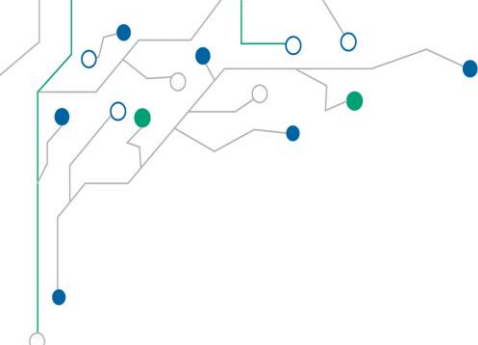
IEC 62046:2018

Application of protective equipment to detect the presence of persons

Usable in absence of inertia

This technical specification covers the application of electro-sensitive protective equipment (ESPE) and pressure sensitive mats and floors (PSPD)





- **IEC 60204-1** Safety of machinery - Electrical equipment of machines - Part 1: General requirements.”
applies to electrical, electronic and programmable electronic equipment and systems to machines not portable by hand while working, including a group of machines working together in a co-ordinated manner.
- **IEC 61439-2** “Low-voltage switchgear and controlgear assemblies (LV panels) - Part 2: Power switchgear and controlgear assemblies” that establish requirements for electrical panels, including machine electrical panels.
- **ATTENTION – PARTIAL OVERLAP**

N O R M A I T A L I A N A C E I

Norma Italiana
CEI EN 60204-1

La seguente Norma è identica a: EN 60204-1:2006-06.

Data Pubblicazione	Edizione
2006-09	Quarta
Classificazione	Parcoodi
44-5	8422

TITOLO
Sicurezza del macchinario - Equipaggiamento elettrico delle macchine
Parte 1: Regole generali

TITOLO
Safety of machinery - Electrical equipment of machines
Part 1: General requirements



More upcoming (abstract)

- published 2017:

IEC 62745 (ED1) Safety of machinery - Requirements for cableless control systems of machinery.

ISO/IEC 17305 (ED1) Safety of machinery - Safety functions of control systems.

IEC 61511-1:2016+AMD1:2017 CSV Consolidated version Functional safety - Safety instrumented systems for the process industry

- maintenance/development:

IEC 60204-11 (ED2) Safety of machinery - Electrical equipment of machines - Part 11: Requirements for HV equipment for voltages above 1000 V A.C. or 1500 V DC and not exceeding 36 kV.

IEC 61496-3 (ED3) Safety of machinery - Electro-sensitive protective equipment –

Part 3: Particular requirements for Active Opto-electronic Protective Devices responsive to Diffuse Reflection (AOPDDR).

IEC 62046 (ED3) Safety of machinery – Application of protective equipment to detect the presence of persons.

IEC 62061 (ED2) Safety of machinery - Functional safety of safety-related electrical, electronic and programmable control systems.

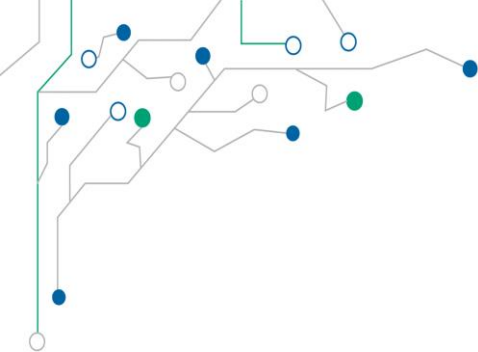
IEC 62998-721 (ED1) Safety of machinery - Electro-sensitive protective equipment - Safety-related sensors for protection of person.

IEC TR 63161 (ED1) Assignment of a safety integrity requirements - Basic Rationale.

- New Projects:

IEC 62046 (ED1) Safety of machinery - Application of presence sensing protective equipment to machinery.

.....



THANKS !