



EN ISO 12100 and its relation to the Machinery Directive

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EN ISO 12100 – Overview

Safety of machinery – General principles for design Risk assessment & Risk reduction



EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 12100

November 2010

ICS 13.110

Supersedes EN ISO 12100-1:2003, EN ISO 12100-2:2003, EN ISO 14121-1:2007

English Version

Safety of machinery - General principles for design - Risk
assessment and risk reduction (ISO 12100:2010)

Sécurité des machines - Principes généraux de conception
- Appréciation du risque et réduction du risque (ISO
12100:2010)

Sicherheit von Maschinen - Allgemeine
Gestaltungsgrundsätze - Risikobeurteilung und
Risikominderung (ISO 12100:2010)

This European Standard was approved by CEN on 9 October 2010.

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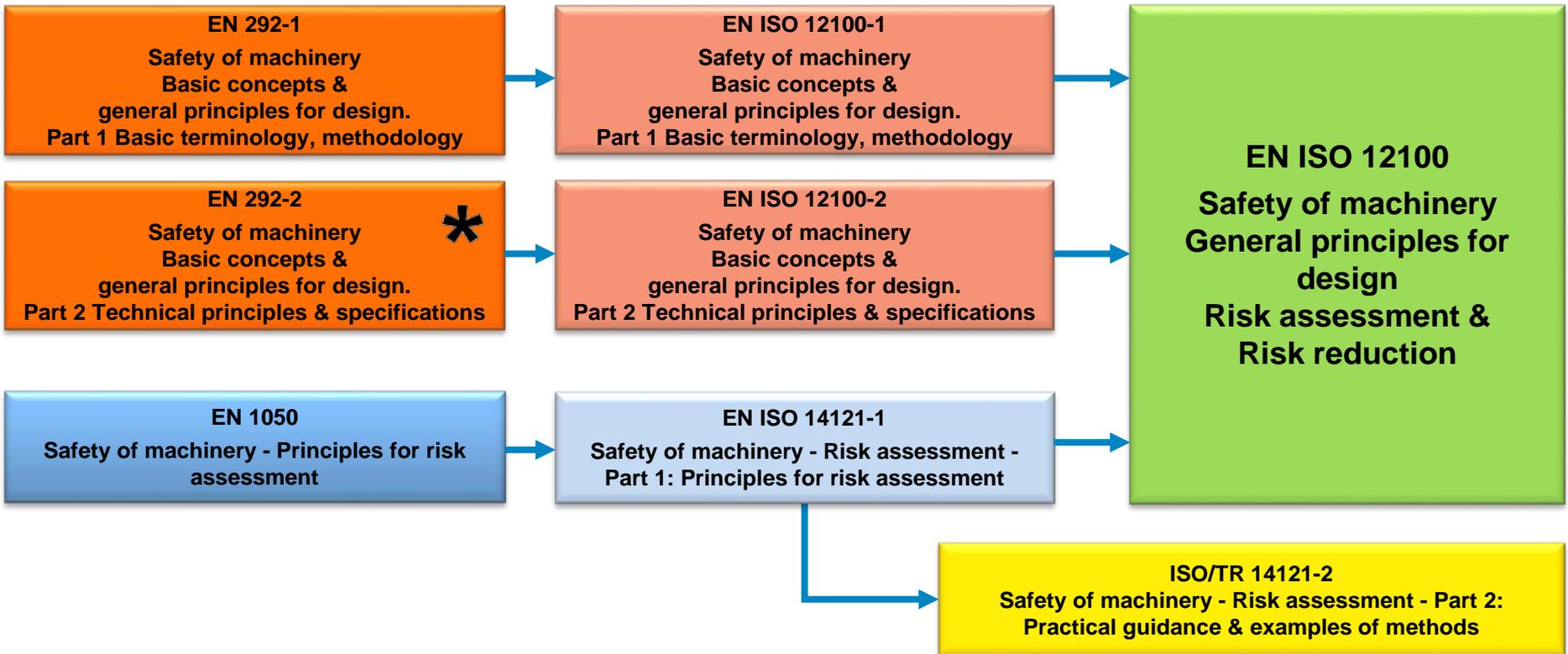
Ref. No. EN ISO 12100:2010: E

- EN ISO 12100 specifies
 - The methodology for design of safe machines
 - The application of risk assessment
 - The hierarchic use of risk reduction measures
- Content:
 - Foreword & Introduction
 - 1. Scope
 - 2. Normative references
 - 3. Terms & definitions
 - 4. Strategy for risk assessment and risk reduction
 - 5. Risk assessment
 - 6. Risk reduction
 - 7. Documentation of risk assessment & reduction
 - Annexes (ZA, A, B, C)
 - Bibliography



EN ISO 12100 – The Story

Development to the actual version

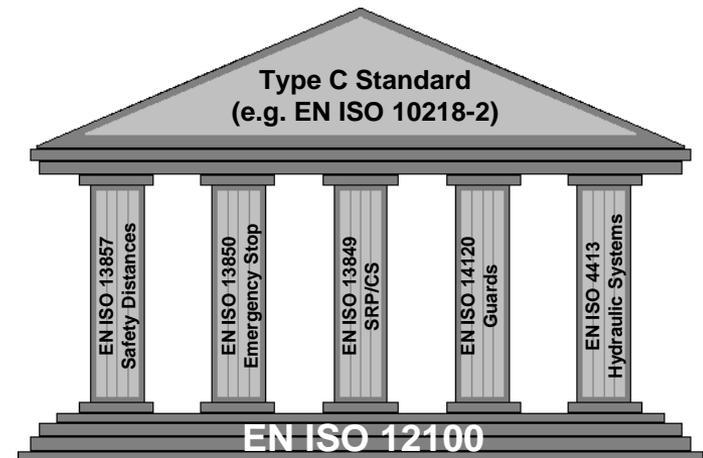


* Contains Annex I of the MD (89/392/EEC modified) as informative Annex A

EN ISO 12100 – The BASIS

Structure of Machinery Safety Standards

- Type-A standards (basic safety standards) giving basic concepts, principles for design and general aspects that can be applied to machinery;
- Type-B standards (generic safety standards) dealing with one safety aspect or one type of safeguard that can be used across a wide range of machinery:
 - Type-B1 standards on particular safety aspects (for example, safety distances, surface temperature, noise);
 - Type-B2 standards on safeguards (for example, two-hand controls, interlocking devices, pressure-sensitive devices, guards);
- Type-C standards (machine safety standards) dealing with detailed safety requirements for a particular machine or group of machines.



EN ISO 12100 – The Wording

Terms & Definitions



- Machine / Machinery
- Reliability
- Maintainability
- Usability

- Harm
- Hazard
- Relevant hazard
- Significant hazard
- Hazardous event
- Hazardous situation
- Hazard zone

- Risk
- Residual risk
- Risk estimation
- Risk analysis
- Risk evaluation
- Risk assessment
- Adequate risk reduction

- Safeguard
- Guard
- Fixed guard
- Movable guard
- Adjustable guard
- Interlocking guard
- Interlocking guard with guard locking
- Interlocking guard with start function
- Interlocking device
- Protective device
- Enabling device
- Hold to run device
- Two-hand control device
- Sensitive protective equipment
- Active optoelectronic protective device
- Mechanical restraint device
- Limiting device
- Limited movement control device
- Impeding device

- Protective measure
- Inherently safe design measure
- Safeguarding
- Information for use

- Safety function
- Unexpected start-up
- Fault
- Failure / Failure to danger
- Common cause failures
- Common mode failures
- Malfunction

- Emission value
- Comparative emission data

- **Emergency situation**
- **Emergency operation**
- **Emergency stop / function**

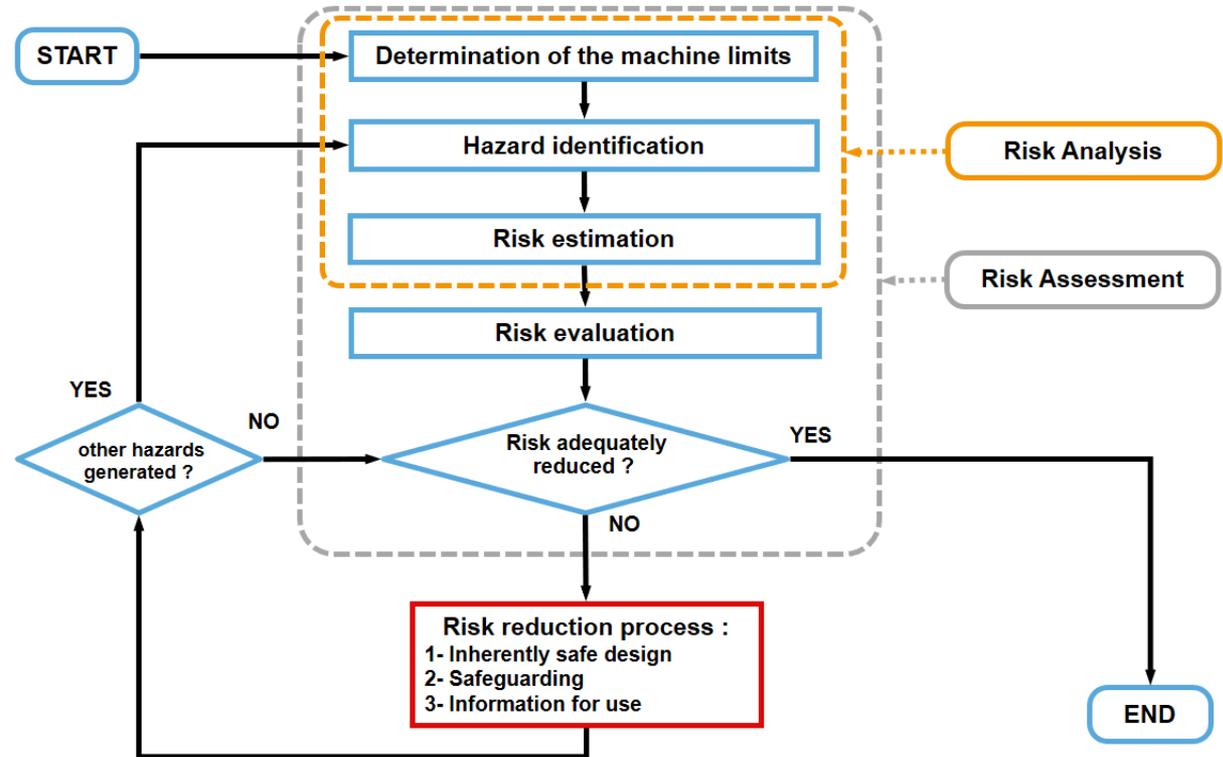
- Intended use
- Reasonably foreseeable misuse
- Task

EN ISO 12100 – The Strategy

Risk assessment and Risk reduction



- Determine the limits of the machinery, including intended use & reasonably foreseeable misuse
- Identify the hazards and associated hazardous situations
- Estimate the risk for each identified hazard and hazardous situation
- Evaluate the risk and take decisions about the need for risk reduction
- Eliminate the hazard or reduce the risk associated with the hazard



EN ISO 12100 – Considerations

Risk assessment information & limitation



- Information required
 - Machinery description
 - Regulations, Standards, Technical specifications
 - Experience of use
 - Relevant ergonomic principles
- Limits of the machinery
 - Use limits; operating modes, interventions, industrial / non-industrial , users, training, experience
 - Physical limits; range of movement, power supply, intended lifetime, environmental
 - Life Phases and related tasks; commissioning, operation, cleaning, start-up, feeding, stopping

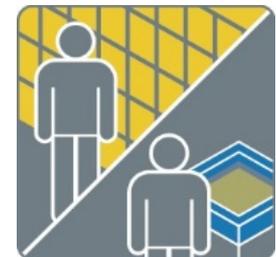
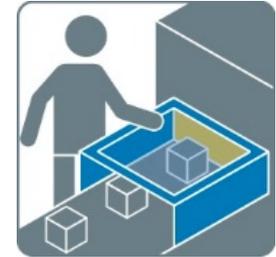


EN ISO 12100 – The use

Intended use & reasonably foreseeable misuse



- Intended use
 - The deemed usual use according to the design, construction & function of the machine
- Reasonably foreseeable misuse
 - Loss of control by the operator
 - Pressure to keep the machine running in all circumstances
 - Normal carelessness, human error, convenience
 - Reflex behavior and behavior of certain persons (children, disabled, elders)
- Other factors to be considered
 - Persons exposed
 - Exposure type and duration and relationship to effects
 - Human factors
 - Suitability of protective measures & possibility of circumventing
 - Ability to maintain the effectivity of protective measures



EN ISO 12100 – The Interaction

Life phases & tasks



■ Life phases

- Construction
- Transport
- Assembly and installation
- Commissioning
- Setting, teaching, programming
- Process changeover
- Operation
- Cleaning
- Fault finding
- Maintenance
- De-commissioning, dismantling
- Disposal (if applicable)

■ Tasks

- Setting
- Testing
- Start-up
- Feeding machine
- Teaching / programming
- Process / tool changeover
- Removal of product from machine
- Stopping the machine
- Stopping the machine in an emergency
- Recovery of operation from jam
- Re-start after unscheduled stop
- Faultfinding / trouble-shooting (operator)
- Cleaning and housekeeping
- Preventive maintenance
- Corrective maintenance



EN ISO 12100 – The Hazards

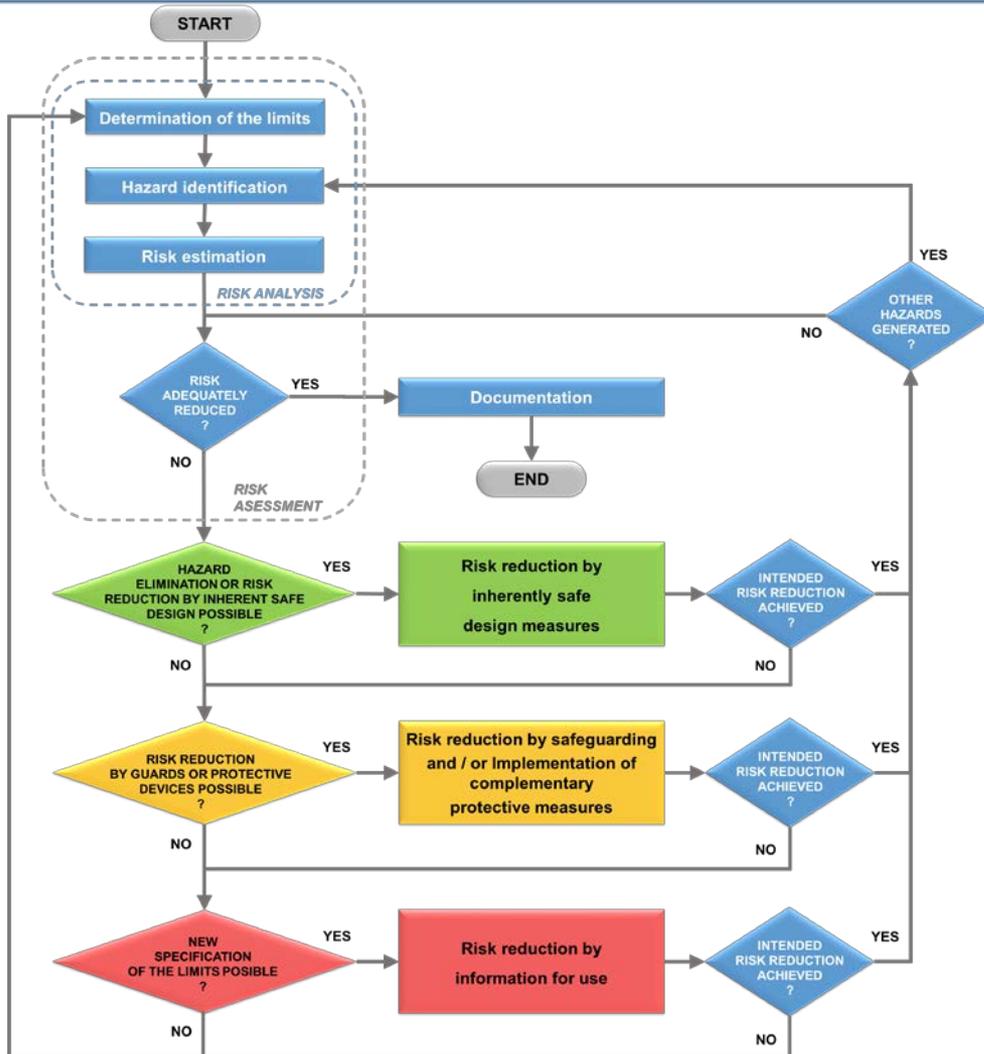
Hazard Identification – Resulting Harm



- Mechanical hazards
Crushing, shearing, cutting, drawing-in, trapping
entangling impact, stabbing, injection, abrasion
- Electrical hazards
Burns, electrocution, secondary chemical effects
- Thermal hazards
Burns, frostbite, scalds
- Noise hazards
Loss of hearing awareness or balance, stress
- Vibration hazards
Stress, low back morbidity, traumata....
- Radiation hazards
Skin, tissue or eye damage. Genetic mutation
- Material / substance hazards
Poisoning, infections, explosions, cancer
- Ergonomic hazards
Discomfort, fatigue, stress ...
- Environment related hazards
Slipping, falling, suffocation
- Combination of hazards
heat stroke, de-hydration, loss of awareness

EN ISO 12100 – Risk reduction

The 3-Step Method



Protective measures shall be applied in the following sequence (3-step method):

- Step 1: Inherently safe design measures;
Eliminate hazards or reduce the associated risks by a suitable choice of design
- Step 2: Safeguarding and/or application of complementary protective measures;
Apply appropriately selected safeguarding and complementary protective measures to reduce risk when it is not practicable to eliminate a hazard, or reduce its sufficiently associated risk with Step 1
- Step 3: Information for use;
Identify in the information for use the risks which remain despite application Step 1 & Step 2

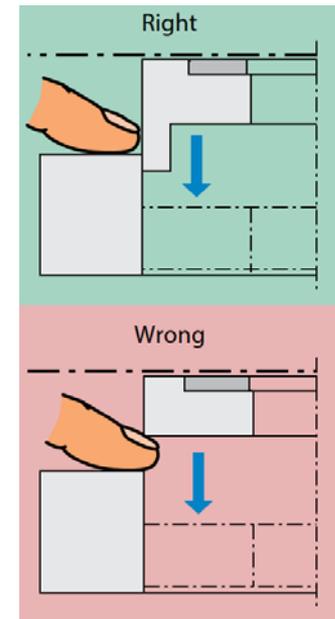


EN ISO 12100 – Step 1

Inherently safe design principles



- Consideration of geometric factors and physical aspects
- Consideration of common technical knowledge on construction of machines
- Application of the principle of positive mode actuation between mechanical parts
- Selection of suitable technologies
- Provisions for the stability
- Provisions for maintainability
- Consideration of ergonomic principles
- Prevention of electrical hazards
- Avoidance of hazards from pneumatic or hydraulic equipment
- Application of measures for inherent safe design of control systems
- Minimizing the failure of safety functions
- Limitation of hazard exposure by reliability of equipment
- Limitation of hazard exposure by mechanisation or automation of loading and unloading tasks
- Limitation of hazard exposure by localisation of areas for system setting and maintenance outside of hazardous areas



source: A. Neudörfer ©

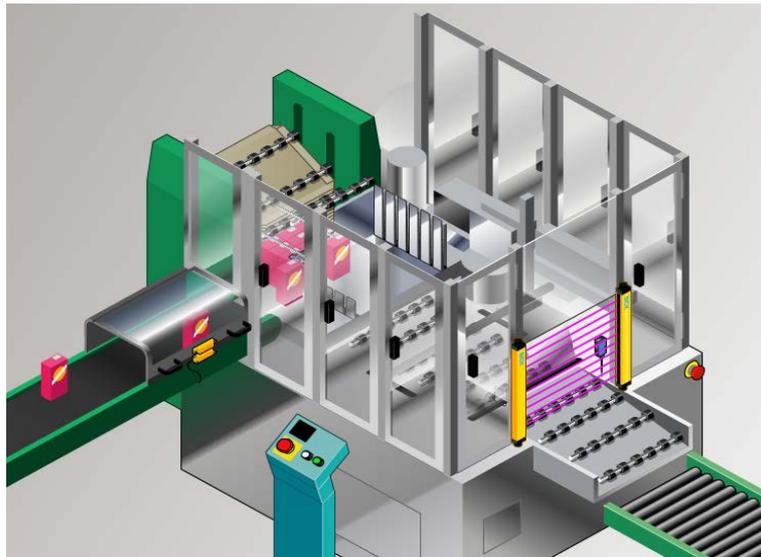
EN ISO 12100 – Step 2

Safeguarding



▪ Guards

- fences
- covers
- casings
- shields
- screens
- tunnels . . .



▪ Protective devices

- light curtains
- single beam photo cells
- laser scanners
- vision based protective equipment
- enabling devices
- two hand controls . . .

EN ISO 12100 – Step 2

Complementary Protective Measures

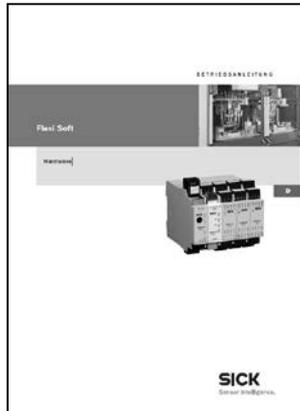


- Emergency stop function
- Measures for escape and rescue of trapped persons
- Measures for isolation and energy dissipation
- Provisions for easy and safe handling of machines and their heavy component parts
- Measures for safe access to machinery
- Devices for limiting
- Devices to prevent machine collision / interference
- Devices for monitoring emissions
- Devices to ensure presence of persons or elements



EN ISO 12100 – Step 3

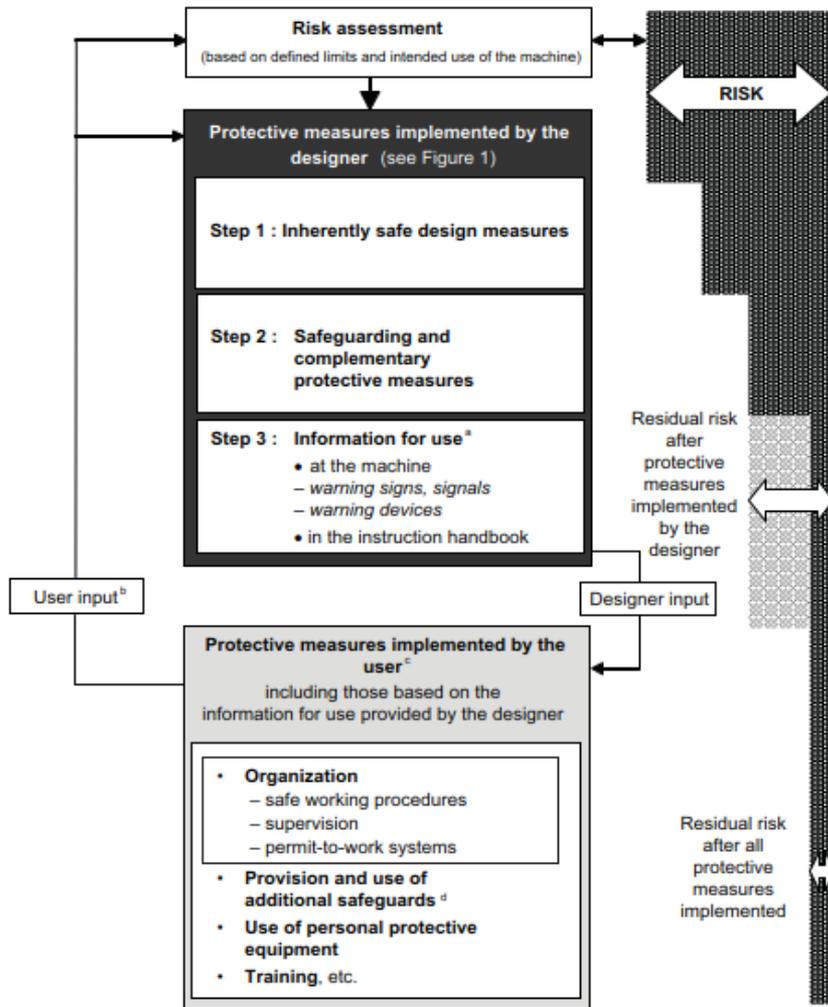
Information (for use) about residual risks



- If the safe design or technical protective measures are not completely effective, the user shall also be warned about residual risks and informed about necessary measures.
- Information of use includes :
 - Signaling and warning devices
 - Signs, pictograms, markings, warnings
 - Operating instructions, training requirements
- User information shall not be a replacement for other risk reduction measures !

EN ISO 12100 – The USER

Relationship with user dependent risk reduction



- The information for use provided by the machinery designer is the basis for the design & selection of the protective measures to be implemented by the user.
- For protective measures to be implemented by the user ISO/TR 22100-1 does not specify any hierarchy since these are outside of the scope.
- Available user input may be an important (and useful) part of the information required for the risk assessment !
- Use of additional safeguarding provided by the user may be required at specific uses or installation situations which are not foreseeable for the designer

EN ISO 12100 – The ESHR's Relationship with Annex I of the MD

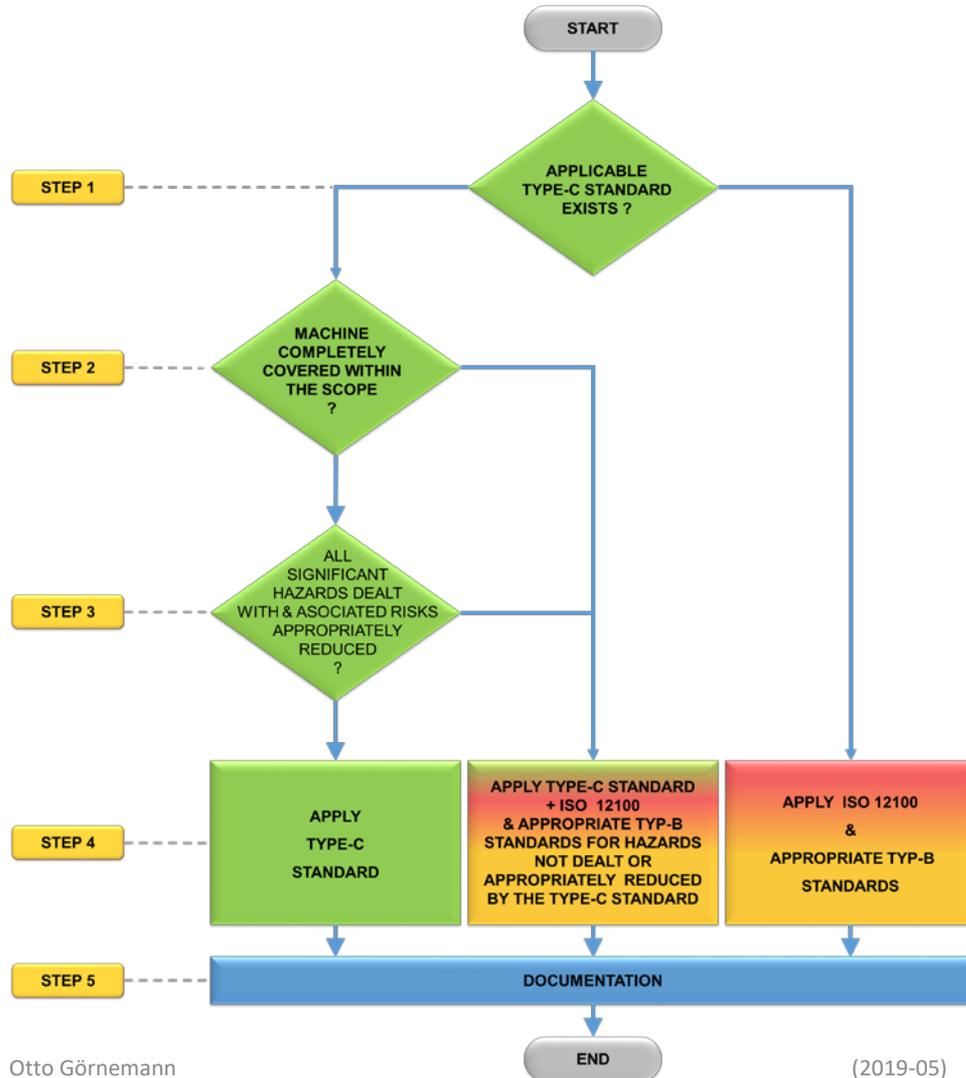


Nr.	Chapter or Subclause of EN ISO 12100	Requirement Annex I	Nr.	Chapter or Subclause of EN ISO 12100	Requirement Annex I
	Foreword / Introduction	n.a.	6.2.3	Taking into account general technical knowledge of machine design	1.1.5, 1.3.2, 1.3.5, 1.3.7
1	Scope	n.a.	6.2.4	Choice of appropriate technology	1.2.6, 1.3.9
2	Normative references	n.a.	6.2.5	Applying principle of positive mechanical action	1.2.1
3	Terms and definitions	1.1.1	6.2.6	Provisions for stability	1.3.1
4	Strategy for risk assessment and risk reduction	GP 1, 1.1.2	6.2.7	Provisions for maintainability	1.6
5	Risk assessment	GP 1, 1.1.2	6.2.8	Observing ergonomic principles	1.1.6, 1.1.8
5.1	General	GP 1, 1.1.2	6.2.9	Electrical hazards	1.5.1, 1.5.2
5.2	Information for risk assessment	n.a.	6.2.10	Pneumatic and hydraulic hazards	1.3.2, 1.5.3
5.3	Determination of limits of machinery	n.a.	6.2.11	Applying inherently safe design measures to control systems	1.2.1
5.3.1	General	n.a.	6.2.12	Minimizing probability of failure of safety functions	1.2.1
5.3.2	Use limits	1.1.2 c)	6.2.13	Limiting exposure to hazards through reliability of equipment	1.2.1
5.3.3	Space limits	n.a.	6.2.14	Limiting exposure to hazards through mechanization or automation of loading (feeding)/ unloading (removal) operations	1.1.2, 1.6.4
5.3.4	Time limits	n.a.	6.2.15	Limiting exposure to hazards through location of setting and maintenance points outside danger zones	1.1.2, 1.1.7, 1.2.2
5.3.5	Other limits	n.a.	6.3	Safeguarding and complementary protective measures	1.4
5.4	Hazard identification	n.a.	6.3.1	General	1.4.1
5.5	Risk estimation	n.a.	6.3.2	Selection and implementation of guards and protective devices	1.4.1
5.5.1	General	n.a.	6.3.3	Requirements for design of guards and protective devices	1.4.2, 1.4.3
5.5.2	Elements of risk	n.a.	6.3.4	Safeguarding to reduce emissions	1.4.1
5.5.3	Aspects to be considered during risk estimation	1.1.2	6.3.5	Complementary protective measures	1.2.4.3
5.6	Risk evaluation	n.a.	6.4	Information for use	1.7
5.6.1	General	n.a.	6.4.1	General requirements	1.7
5.6.2	Adequate risk reduction	n.a.	6.4.2	Location and nature of information for use	1.7, 1.7.1
5.6.3	Comparison of risks	n.a.	6.4.3	Signals and warning devices	1.2.2, 1.7.1.2
6	Risk reduction	1.1.2	6.4.4	Markings, signs (pictograms) and written warnings	1.7.3
6.1	General	1.1.2	6.4.5	Accompanying documents (in particular — instruction handbook)	1.7.4
6.2	Inherently safe design measures	1.1.3	7	Documentation of risk assessment and risk reduction	Annex VII - A
6.2.1	General	n.a.			
6.2.2	Consideration of geometrical factors and physical aspects	1.1.4, 1.3.3, 1.3.4			

GP = General principles in Annex I of the Machinery Directive (MD)

ISO/TR 22100-1 – Relationship

How ISO 12100 relates to type-B/-C standards

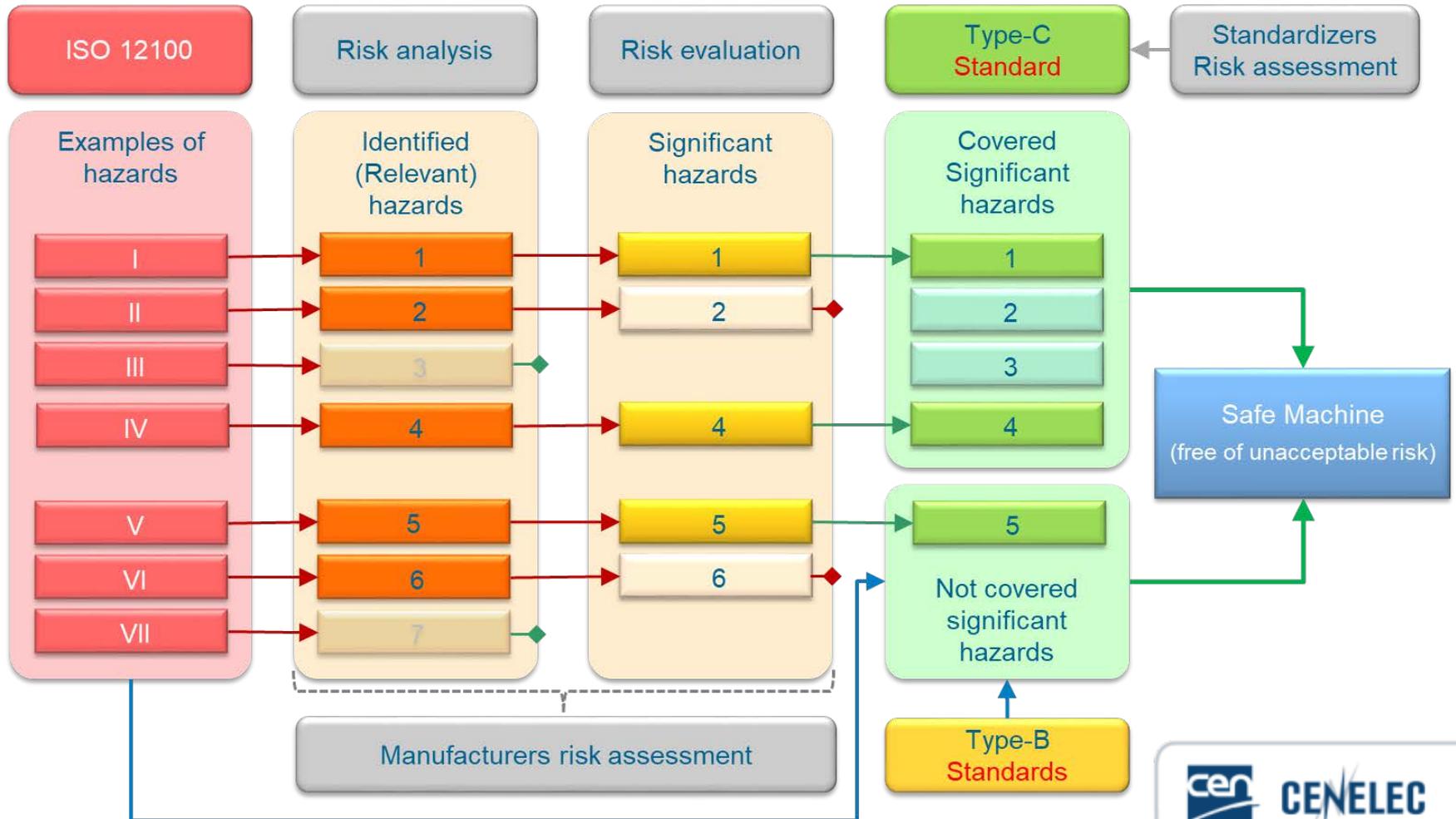


- Explains the general structure and the system of Type-A –B –C standards
- Gives guidance for practical application of ISO 12100, type-B and type-C standards in order to design a machine which achieves a level of tolerable risk by adequate risk reduction
- Supports the user in the selection of appropriate Type-B machinery standards



ISO/TR 22100-1 – Relationship

Methodology application



ISO/TR 22100-1 – Navigation

Selection of applicable Type-B standards

GENERAL PRINCIPLES FOR DESIGN – RISK ASSESSMENT & RISK REDUCTION – EN ISO 12100 (TYPE A STANDARD)

STANDARDS RELATED TO SAFETY ASPECTS (HAZARDS / TYPE B-1 STANDARDS)

NOISE

Determination of emission sound pressure levels at a workstation
EN ISO 11200
EN ISO 11201 to 11205

Determination of sound power & energy levels
EN ISO 3741, EN ISO 3743-1
EN ISO 3744, EN ISO 3745,
EN ISO 3746, EN ISO 3747

Determination of sound power levels by sound intensity
EN ISO 9614-1, -2, -3

Insulation performance of enclosures
EN ISO 11546-1, -2

Insulation performances of cabins
EN ISO 11957

Declaration & verification of noise emission
EN ISO 4871

SUBSTANCES

Evaluation of emission of airborne hazardous substances ISO 29042-x
(≈ EN 1093-x)

Reduction of risks to health from hazardous substances EN ISO 14123-x

Hygiene requirements
EN ISO 14159

TERMAL HAZARDS

Human responses to contact surfaces
EN ISO 13732-1, -3

FIRE HAZARDS

Fire prevention and protection
EN ISO 19353

ELECTRIC HAZARDS

(Protection against electric shock)
EN 60204-1 (≈ IEC)

VIBRATION & SCHOCK

Whole body vibration
ISO 2631

Hand-arm vibration
EN ISO 13753

Hand-held & hand-guided machinery
EN ISO 20643

ERGONOMICS

Access openings
ISO 15534-x (≈ EN 547-x)

Anthropometric requirements for workstations
EN ISO 14738

Computer manikins and body templates
EN ISO 15536-1, -2

RADIATION HAZARDS

Lasers and laser-related equipment - Vocabulary & symbols
EN ISO 11145

Lasers and laser-related equipment - Test methods for laser beam power
EN ISO 11554

STANDARDS RELATED TO TECHNOLOGY (SAFEGUARDING / TYPE B2 STANDARDS)

DIMENSIONS & DISTANCES

Gaps to avoid crushing
ISO 13854 (▶ EN)

Safety distances
EN ISO 13857 (▶)

Permanent means of access
EN ISO 14122-x

ALARMS & WARNINGS

Design principles for safety signs
ISO 3864-1

Registered safety signs
ISO 7010

Auditory danger signals
EN ISO 7731

Visual, acoustic and tactile signals
EN 61310-1 (=IEC)

POWER SOURCE

Pneumatic equipment
EN ISO 4414

Hydraulic equipment
EN ISO 4413

Electric equipment of machines - Part 1 General
IEC 60204-1 (≈ EN)

CONTROL SYSTEMS

Avoidance of unexpected start-up
EN ISO 14118

Design of safety related parts of control systems
EN ISO 13849-1 (▶)

Validation of safety related parts of control systems
EN ISO 13849-2

Emergency Stop
EN ISO 13850

SAFETY DEVICES

Guards
EN ISO 14120

Interlocking devices
EN ISO 14119 (▶)

Minimum distances
EN ISO 13855

Two hand controls
EN ISO 13851

Pressure-sensitive Protective Equipment
EN ISO 13856-x

Electro-sensitive Protective Equipment
IEC 61496-x (=EN)

Application of SPE
EN IEC 62046

ASSEMBLY OF MACHINES

Integrated manufacturing systems
EN ISO 11161 (▶)

- Type A- Standards
- Type B- Standards
- IEC Standards (not aligned to ISO Types)
- ▶ Revision under ISO/IEC lead (also EN)
- > Revision planned (also EN)
- = EN version identical to ISO/IEC
- = EN version modified from ISO/IEC

EN ISO 12100

and its relation with the Machinery Directive



**Thank you
for your attention!**

**Otto Görnemann, SICK AG, Waldkirch - Germany
Chairman CEN/TC114 & ISO/TC199 Safety of Machinery**

