EN ISO 12100
and its relation to the Machinery Directive

Otto Görnemann, SICK AG – Waldkirch
Chairman CEN/TC114 – ISO/TC199  Safety of Machinery
EN ISO 12100 – Overview
Safety of machinery – General principles for design
Risk assessment & Risk reduction

- 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

EN 292-1
Safety of machinery
Basic concepts &
general principles for design.
Part 1 Basic terminology, methodology

EN ISO 12100-1
Safety of machinery
Basic concepts &
general principles for design.
Part 1 Basic terminology, methodology

EN ISO 12100
Safety of machinery
General principles for
design
Risk assessment &
Risk reduction

EN ISO 12100-2
Safety of machinery
Basic concepts &
general principles for design.
Part 2 Technical principles & specifications

EN 292-2
Safety of machinery
Basic concepts &
general principles for design.
Part 2 Technical principles & specifications

EN 1050
Safety of machinery - Principles for risk
assessment

EN ISO 14121-1
Safety of machinery - Risk assessment -
Part 1: Principles for risk assessment

EN ISO 14121-2
Safety of machinery - Risk assessment - Part 2:
Practical guidance & examples of methods

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

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(2019-05)
**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.

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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

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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

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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...
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
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.
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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 12100

Examples of hazards
I
II
III
IV
V
VI
VII

Risk analysis
Identified (Relevant) hazards
1
2
3
4
5
6
7

Risk evaluation
Significant hazards
1
2
3
4
5
6

Type-C Standard
Covered Significant hazards
1
2
3
4
5

Safe Machine (free of unacceptable risk)
Not covered significant hazards

Manufacturers risk assessment

Standardizers Risk assessment

Type-B Standards

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ISO/TR 22100-1 – Navigation
Lost in the safety standards universe?
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

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

- VIBRATION & SCHOCK
  - Whole body vibration
    EN ISO 2631
  - Hand-arm vibration
    EN ISO 13353
  - Hand-held & hand-guided machinery
    EN ISO 20643

- DIMENSIONS & DISTANCES
  - Gaps to avoid crushing
    ISO 13854 (EN)

- POWER SOURCE
  - Pneumatic equipment
    EN ISO 4414

- SAFETY DEVICES
  - Guards
    EN ISO 14120

- ERGONOMICS
  - Human responses to contact surfaces
    EN ISO 13732-1

- TERMSHAZARDS
  - Access openings
    ISO 15534-x (~ EN 547-x)

- ALARMS & WARNINGS
  - Design principles for safety signs
    ISO 3864-1

- CONTROL SYSTEMS
  - Avoidance of unexpected start-up
    EN ISO 14118

- FIRE HAZARDS
  - Fire prevention and protection
    EN ISO 19353

- DIMENSIONS & DISTANCES
  - Permanent means of access
    EN ISO 14122-x

- ELECTRIC HAZARDS
  - (Protection against electric shock)
    EN 60204-1 (~ IEC)

- RADIATION HAZARDS
  - Lasers and laser-related equipment
    EN ISO 11145

- LASER HAZARDS
  - Lasers and laser-related equipment – Test methods for laser beam power
    EN ISO 11154

- ASSEMBLY OF MACHINES
  - Integrated manufacturing systems
    EN ISO 11161 (EN)

- 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

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Thank you for your attention!

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Chairman CEN/TC114 & ISO/TC199 Safety of Machinery