Selecting Safeguards: Standards, Principles and Emerging Guidance

Webinar, 2014-05-28
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Agenda

1. Machines (definition, hazards, risks)
2. Regulations and standards
   - USA
   - EU
3. Risk assessment, risk reduction
4. Compliant safeguarding
5. Required functional safety integrity (Performance Level)
6. Summary
Machines (definition, hazards, risks)
Machines: Definition

EU Machinery Directive 2006/42/EC, Article 2(a):

“an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application"
Machines: known categories, special purpose, multi-purpose

Metal working lathe

Press brake

Special purpose (mfr of window frames)

"Multi-purpose": robot arm
Machine hazard types

Mechanical
Electrical
  Thermal
  Noise
  Vibration
  Radiation
  Substances
  Ergonomics
Environment of use

*Weighted representation by font-size applies to the average of machines investigated by UL, it does not necessarily apply to any particular machine.
## Machine hazards and consequences

<table>
<thead>
<tr>
<th>Hazard types</th>
<th>Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical</td>
<td>being run over; being thrown; crushing; cutting or severing;</td>
</tr>
<tr>
<td></td>
<td>drawing-in or trapping; entanglement; friction or abrasion;</td>
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<tr>
<td></td>
<td>impact; injection; shearing; slipping, tripping and falling;</td>
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<tr>
<td></td>
<td>stabbing or puncture; suffocation.</td>
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<tr>
<td>Electrical</td>
<td>burn; chemical effects; effects on medical implants;</td>
</tr>
<tr>
<td></td>
<td>electrocution; falling, being thrown; fire; projection of</td>
</tr>
<tr>
<td></td>
<td>molten particles; shock.</td>
</tr>
<tr>
<td>Thermal</td>
<td>burn; dehydration; discomfort; frostbite; injuries by the</td>
</tr>
<tr>
<td></td>
<td>radiation of heat sources; scald.</td>
</tr>
<tr>
<td>Noise</td>
<td>discomfort; loss of awareness; loss of balance; permanent</td>
</tr>
<tr>
<td></td>
<td>hearing loss; stress; tinnitus; tiredness; indirectly: any</td>
</tr>
<tr>
<td></td>
<td>other consequences.</td>
</tr>
<tr>
<td>Vibration</td>
<td>discomfort; low-back morbidity; neurological disorder;</td>
</tr>
<tr>
<td></td>
<td>osteo-articular disorder; trauma of the spine; vascular</td>
</tr>
<tr>
<td></td>
<td>disorder.</td>
</tr>
<tr>
<td>Radiation</td>
<td>burn; damage to eyes and skin; effects on reproductive</td>
</tr>
<tr>
<td></td>
<td>capability; mutation; headache, insomnia, etc.</td>
</tr>
<tr>
<td>Material/Substances</td>
<td>breathing difficulties, suffocation; cancer; corrosion;</td>
</tr>
<tr>
<td></td>
<td>effects on reproductive capability; explosion; fire; infection;</td>
</tr>
<tr>
<td></td>
<td>mutation; poisoning; sensitization.</td>
</tr>
<tr>
<td>Ergonomics</td>
<td>discomfort; fatigue; musculoskeletal disorder; stress;</td>
</tr>
<tr>
<td></td>
<td>indirectly: any other consequences.</td>
</tr>
<tr>
<td>Environment of use</td>
<td>burn; slight disease; slipping, falling; suffocation; any other</td>
</tr>
<tr>
<td></td>
<td>as a consequence of the effect caused by the sources of the</td>
</tr>
<tr>
<td></td>
<td>hazards on the machine or parts of the machine.</td>
</tr>
</tbody>
</table>
Machine risk

RISK
Related to a specific hazard

SEVERITY OF HARM
As a result of consequences of the hazard

PROBABILITY OF OCCURRENCE (of that harm)
- Exposure to hazard (hazardous situation)
- Occurrence of hazardous events
- Possibility to avoid or limit harm

RISK = SEVERITY OF HARM × PROBABILITY OF OCCURRENCE
Regulations and standards

One or more methods of machine guarding shall be provided to protect the operator and other employees in the machine area from hazards such as those created by point of operation, ingoing nip points, rotating parts, flying chips and sparks. Examples of guarding methods are-barrier guards, two-hand tripping devices, electronic safety devices, etc.
Drivers and Influencers in Workplace Safety

- Governmental:
  - **OSHA**: Occupational Safety and Health Administration
  - **AHJ’s**: Authorities Having Jurisdiction

- Industrial associations:
  - **NFPA** National Fire Protection Association
  - **RIA** Robotics Industries Association
  - **AMT** Association of Manufacturing Technology
  - ...

- Private corporations:
  - Equipment manufacturers -> OEMs -> Employers
  - Test houses, certification organisations

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**ANSI** Facilitates & adopts

- OSHA Standards
- NFPA Standards
- RIA Standards
- B11.xx
- ...
- UL Standards
- FM Standards
- ...

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[Image of ANSI logo]
OSHA recommended ("appropriate", "industry consensus") standards

ANSI B11.1-1982 Mechanical Power Presses
ANSI B11.2-1982 Hydraulic Power Presses
ANSI B11.3-1982 Power Press Brakes
ANSI B11.4-1983 Shears
ANSI B11.5-1988 Iron Workers
ANSI B11.6-1984 Lathes
ANSI B11.7-1985 Cold Headers and Cold Formers
ANSI B11.8-1983 Drilling, Milling, and Boring Machines
ANSI B11.9-1975 Grinding Machines
ANSI B11.10-1983 Metal Sawing Machines
ANSI B11.11-1985 Gear Cutting Machines
ANSI B11.12-1983 Roll Forming and Roll Bending Machines
ANSI B11.13-1983 Single- and Multiple-Spindle Automatic Screw/Bar and Chucking Machines
ANSI B11.14-1983 Coil Slitting Machines/Equipment
ANSI B11.15-1984 Pipe, Tube, and Shape Bending Machines
ANSI B11.17-1982 Horizontal Hydraulic Extrusion Presses
ANSI B11.18-1985 Machinery and Machine Systems for the Processing of Coiled Strip, Sheet, and Plate
ANSI B11.19-1990 Machine Tools, Safeguarding
ANSI B11.20-1991 Manufacturing Systems/Cells
(ANSI B15.1-1994/6) Power Transmission Apparatus
ANSI B19.1-1990 Air Compressor Systems
ANSI B19.3-1986/90 Compressors for Process Industries
ANSI B20.1-1990 Conveyors and Related Equipment
ANSI B24.1-1985 Forging Machinery
ANSI B28.6-1983 Rubber Machinery, Hose
ANSI B28.7-1983 Rubber Machinery, Hose
ANSI B28.8-1983 Rubber Machinery, Hose
ANSI B28.9-1983 Rubber Machinery, Hose
ANSI B28.10-1986 Rubber Machinery, Endless Belt
ANSI B30.16-1987 Overhead Hoists
ANSI B151.1-1990 Plastics Injection Molding Machinery, Horizontal

ANSI B151.2-1982/88 Plastics Machinery, Film Casting
ANSI B151.3-1982/88 Plastics Machinery, Screen Changers
ANSI B151.4-1982/88 Plastics Machinery, Blown Film Takeoff & Auxiliary Equipment
ANSI B151.5-1982/88 Plastics Machinery, Film & Sheet Winding
ANSI B151.6-1982/88 Plastics Machinery, Slit Tape & Monofilament Postextrusion Equipment
ANSI B151.7-1982/88 Plastics & Rubber Extrusion Machinery
ANSI B151.11-1982 Plastics Machinery, Granulators, Pelletizers, & Dicers
ANSI B151.15-1985 Plastics Machinery, Extrusion Blow Molding
ANSI B151.21-1986 Plastics Machinery, Injection Blow Molding
ANSI B151.25-1988 Plastics Machinery, Injection Molding
ANSI B152.2-1982 Permanent-Mold Casting Machines (Other than Gray Iron)
ANSI B153.1-1990 Automotive Lifts
ANSI B155.1-1986 Packaging Machinery
ANSI B169.1-1990 Envelope Manufacturing Machinery
ANSI B176-1985 Copper-Alloy Diecasting
ANSI B177.2-1977/82 Printing Ink Vertical Post Mixers
ANSI/NEMA ICS2:225.95-1983 Interlocking Control Circuits for Personnel Protection
ANSI/NFPA 79-1991 Electrical Standard for Industrial Machinery
ANSI/RIA R15.06-1986 Industrial Robots and Robot Systems
ANSI Z8.1-1972 Commercial Laundry & Dry-Cleaning Equipment
ANSI Z241.2-1989 Foundry, Melting & Pouring of Metals
ANSI Z241.3-1989 Foundry, Cleaning & Finishing of Castings
ANSI Z245.1-1984 Refuse Collecting & Compacting Equipment
ANSI Z245.3-1977/83 Stability of Refuse Bins
ANSI Z245.5-1982 Bailing Equipment
ANSI Z268.1-1082 Metal Scrap Processing Equipment
US Regulations & Standards (Robotics Perspective)

National Electrical Code (NEC) NFPA 70

Machinery and Machine Guarding
OSHA 1910 - O

OSHA (org)

Safeguarding Functional and performance requirements for safety-related control systems

Safety reqmts on electrical machinery eqpmt
NFPA 79

Emergency stop

Risk Assessment, Risk Reduction

Hazard Identification, Risk Assessment
ANSI B11-TR3

Safeguarding

Safety-related aspects of control functions, Risk reduction,
Safety-related SW/HW control systems

Product standard
ANSI/UL 1740

Product standard
ANSI/RIA R15.06

Product standard
ISO 10218-1

Safeguarding

ANSI B11.19, ANSI B11.1, ANSI B11.2,
OSHA 1910 .147 (lockout/tagout) ...

Functional Safety

ISO 13849, IEC 62061, IEC61800-5-2,
UL 1998/UL991, IEC 61496, ...

Recognized Test Standard

Compliance with

Replaces clause 4

Hazard Identification, Risk Assessment

Article 670

Safety reqmts on electrical machinery eqpmt
NFPA 79

Safety-related control system performance

Functional Safety

ANSI B11-TR3

OSHA 1910 - O

Compliance with

Emergency stop

Safeguarding

ANSI/UL 1740

Product standard
ANSI/RIA R15.06

Product standard
ISO 10218-1

Safeguarding

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Functional Safety

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UL 1998/UL991, IEC 61496, ...

Encourages
EU Machinery Directive 2006/42/EC, Annex I

Essential health and safety requirements relating to the design and construction of machinery

GENERAL PRINCIPLES

1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.

By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:

— determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,
— identify the hazards that can be generated by the machinery and the associated hazardous situations,
— estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,
— evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Directive,
— eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).
Machinery Directive and Standards

Basic Safety Requirements (EC Treaties)
Machinery Directive 2006/42/EC
Harmonized Standards, Presumption of Conformity

Hazard Identification, Risk Assessment ("Type A" stds)
- EN ISO 12100: Safety of Machinery – Basic concepts, general principles of design

Particular machines ("Type C" stds)
- EN ISO 10218: Robots for Industrial Environments –
- EN 693: Mechanical presses
- EN 1870: Circular saws
- EN 474: Earth moving machines

Safeguards ("Type B1")
- EN ISO 13850: Emergency stop
- EN ISO 13851: Two-hand controls
- EN IEC 60204-1: Electrical equipment
- EN 61496-1: ESPE
- EN 14119: Interlocking

Safety aspects and principles ("Type B1")
- EN 547, EN 13855, EN 13857: Dimensions and speeds
- EN 374x, EN 1120x: Noise
- EN ISO 13849, EN 62061, EN 61800-5-2: Functional safety
Machinery Directive, 100's of Type B-and C standards…


EN ISO 11200:2009 Acoustics - Noise emitted by machinery and equipment - Guidelines for the use of basic standards for the determination of emission sound pressure levels at a work station and at other specified positions (ISO 11200:1995, including Cor.1:1997)
EN ISO 11201:2010 Acoustics - Noise emitted by machinery and equipment - Determination of emission sound pressure levels at a work station and at other specified positions in an essentially free field over a reflecting plane with negligible environmental corrections (ISO 11201:2010)
EN ISO 11202:2010 Acoustics - Noise emitted by machinery and equipment - Determination of emission sound pressure levels at a work station and at other specified positions applying approximate environmental corrections (ISO 11202:2010)
EN ISO 11203:2009 Acoustics - Noise emitted by machinery and equipment - Determination of emission sound pressure levels at a work station and at other specified positions from the sound power level (ISO 11203:1995)
EN ISO 11204:2010 Acoustics - Noise emitted by machinery and equipment - Determination of emission sound pressure levels at a work station and at other specified positions applying accurate environmental corrections (ISO 11204:2010)
EN ISO 11205:2009 Acoustics - Noise emitted by machinery and equipment - Engineering method for the determination of emission sound pressure levels in situ at the work station and at other specified positions using sound intensity (ISO 11205:2003)
EN 12254:2010 Screens for laser working places - Safety requirements and testing
EN 12254:2010/AC:2011
Risk assessment, risk reduction
Hazard Identification and Risk Assessment as of ISO 12100

START

Determination of the limits of the machinery (see 5.3)

Hazard identification (see 5.4 and Annex B)

Risk estimation (see 5.5)

Risk evaluation (see 5.6)

Has the risk been adequately reduced? (adequate risk reduction: see Clause 6)

RISK ASSESSMENT according to Clause 5

This iterative risk reduction process shall be carried out separately for each hazard, hazardous situation, under each condition of use.

Risk analysis

Are other hazards generated?

YES

NO

Documentation (see Clause 7)

END
Risk Reduction Process as of ISO 12100

At each step of the iterative process: risk estimation, risk evaluation and, if applicable, risk comparison.

Step 1
Risk reduction by inherently safe design measures
(see 6.2)

Step 2
Risk reduction by safeguarding
Implementation of complementary protective measures
(see 6.3)

Step 3
Risk reduction by information for use
(see 6.4)

Reference to ISO 13849, IEC 62061
Strategy or Risk Reduction (ISO 12100)

Hazards are eliminated or reduced through a hierarchy of measures

1. By design
2. Safeguarding
3. Information for use

Safeguarding will usually translate to safety functions and implies safety-related control

Required performance level to be determined
Selecting safeguards in compliance with essential health and safety requirements
ISO/TR 22100-1: "Bridge" between risk assessment/reduction and Type B standards (1/3)


Figure 1 — General structure of the system of machinery safety standards
Recommended steps for practical use of ISO 12100, Type B and Type C standards:

1. Start
2. Machine completely covered by Type C std?
   - Yes: Apply Type C std
   - No: Proceed to next step
3. All significant hazards dealt with?
   - Yes: Proceed to next step
   - No: Apply ISO 12100 in conjunction with appropriate type-B stds
4. Applicable Type C std?
   - Yes: Apply type-C std and ISO 12100 in conjunction with appropriate type-B stds
   - No: Apply ISO 12100 in conjunction with appropriate type-B stds
ISO/TR 22100-1: "Bridge" between risk assessment/reduction and Type B standards (2/3)

Recommended steps for practical use of ISO 12100, Type B and Type C standards:

1. Start
2. Machine completely covered by Type C std?
   - YES: Go to next step
   - NO: Proceed to next step
3. All significant hazards dealt with?
   - YES: Proceed to next step
   - NO: Review and adjust the risk assessment/reduction process
4. Applicable Type C std?
   - YES: Complete the process
   - NO: Proceed to next step

Ensure that all steps are followed to achieve a thorough risk assessment and reduction.
Support for navigating between Type B standards in dependence of hazard types:
Required Performance Level
ISO/TR 22100-2, the "bridge" between ISO 12100 and ISO 13849

ISO/TR 22100-2:2014

"Safety of machinery — Relationship with ISO 12100 — Part 2: How ISO 12100 relates to ISO 13849-1"

Figure 3 — Interrelation between ISO 12100 and ISO 13849-1
new slides 75-77 introducing new "bridge" document ISO/TR22100-2

Thomas Maier; 01-04-2014
ISO/TR 22100-2, the "bridge" between ISO 12100 and ISO 13849

Information from ISO 12100 to ISO 13849-1:

- Machine limits regarding use, space, time, environment, …

- Risks for machine hazards in terms of Severity, and probability of occurrence (exposure & occurrence & avoidance)

- Specification of risk reduction measure
  Functionality (nominal, failure, operating and non-operating modes, …)
  Performance (response time, accuracy, …)
  Environmental conditions
  Implementation proposals and constraints (e.g. safety components, interfaces)
ISO/TR 22100-2, the "bridge" between ISO 12100 and ISO 13849

Information from ISO 13849-1 to ISO 12100:
• Confirmation that intended risk reduction is achieved
  Based on verification and validation of
  Intended functionality
  User friendliness
  Residual risk (=> PERFORMANCE LEVEL)
• Instructions for assembly and integration
• Instructions for use
Risk Graph for Determining Required PL_r Safety Function (Figure A.1)

Key

1 starting point for evaluation of safety function's contribution to risk reduction
L low contribution to risk reduction
H high contribution to risk reduction
PL_r required performance level

Risk parameters:
S severity of injury
S1 slight (normally reversible injury)
S2 serious (normally irreversible injury or death)
F frequency and/or exposure to hazard
F1 seldom-to-less-often and/or exposure time is short
F2 frequent-to-continuous and/or exposure time is long
P possibility of avoiding hazard or limiting harm
P1 possible under specific conditions
P2 scarcely possible

Per Draft Amendment 1 (2013):
P combines possibility of occurrence AND avoidance
As opposed to other standards (IEC 61508, IEC 62061), ISO 13849-1 does not explicitly consider the probability of occurrence of the hazardous event. New A.2.3:

"A.2.3 Probability of Occurrence & Possibility of avoiding the Hazardous Event P1 and P2

The probability of avoiding the hazard and the probability of occurrence of a hazardous event are both combined in the parameter P. When a hazardous situation occurs, P1 should only be selected if there is a realistic chance of avoiding a hazard or of significantly reducing its effect; otherwise P2 should be selected. Where the probability of occurrence of a hazardous event can be reasonably estimated, the PLr may be reduced by one level."

Comment UL: no indication of probability limits in this Draft. If failure of the "normal" control system is the hazardous event, guidance should be used based on IEC 61508-1 clause 7.5.2.5: minimally $10^{-5}/h$ failure rate may be claimed for normal control system.
new slide on amendment draft.
Thomas Maier; 01-04-2014
Summary
Summary

Amount of information to be considered, in order to achieve compliance with regulations, can be overwhelming

• Number of OSHA recognized testing standards, and industry consensus standards
• Number of EU Machinery Directive Type B standards and Type C standards

New documents are (being) provided, to support consistent selection of safeguarding and functional safety integrity (Performance Levels)

Latest amendment of ISO 13849-1 in order to better align determination of required PL
• with ISO 12100 risk assessment and reduction
• with other functional safety standards (IEC 62061, IEC 61508)
Thanks!

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