ISSA – Risk Assessment – ISO 12100:2010

SAFETSENSE
Machine Safety

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FSEoM # 2865/10

Safety at Workplace

We cannot change the human conditions

BUT

We can change the conditions in which humans work.

Safe-T-Sense

Introduction

Product & Services Divisions

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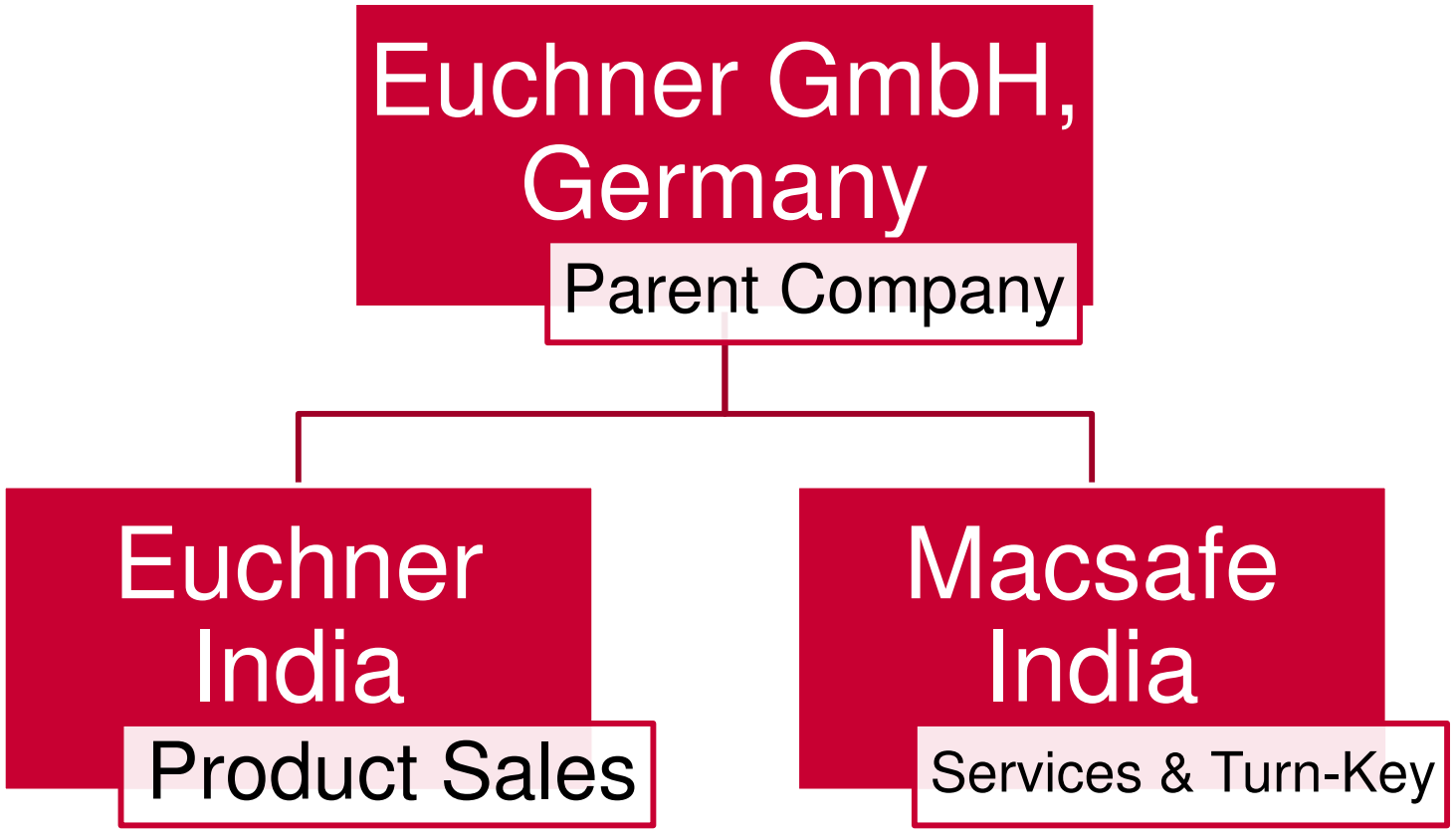

Products – EUCHNER More than safety. Brand name is used in India

Services – SAFETSENSE Machine Safety Brand name is used in India

Macsafe India Expertise

SAFETSENSE
Machine Safety

- **One Functional Safety Expert from TUV SUD – for Certification Training Program**
- **Five FSEoM (Functional Safety Engineer of Machines by TUV)**
- More than **14 years experience in Risk Assessment and providing safety solutions** as per international standard
- Expertise on **Safety Control System – Electrical and Pneumatic/Hydraulic Safety**
- Served – **Food – Pharma – FMCG, Automotive and Auto Ancillary, Machine Building**

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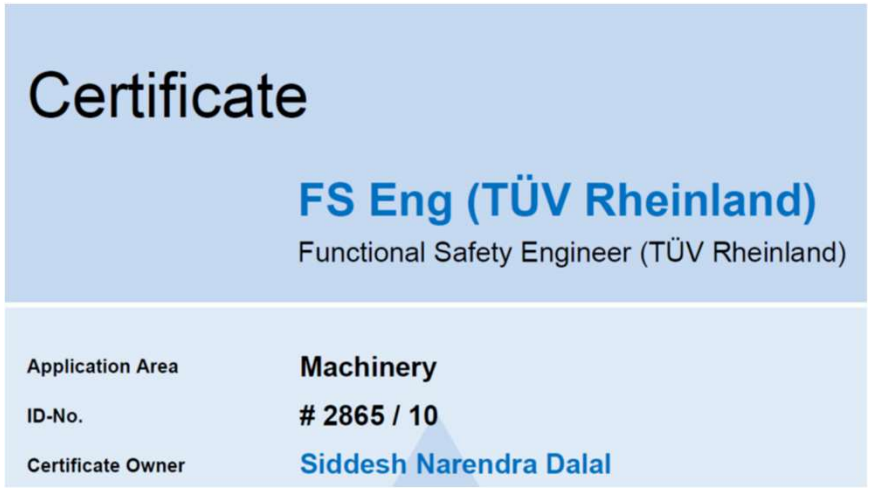

Safety Services Overview

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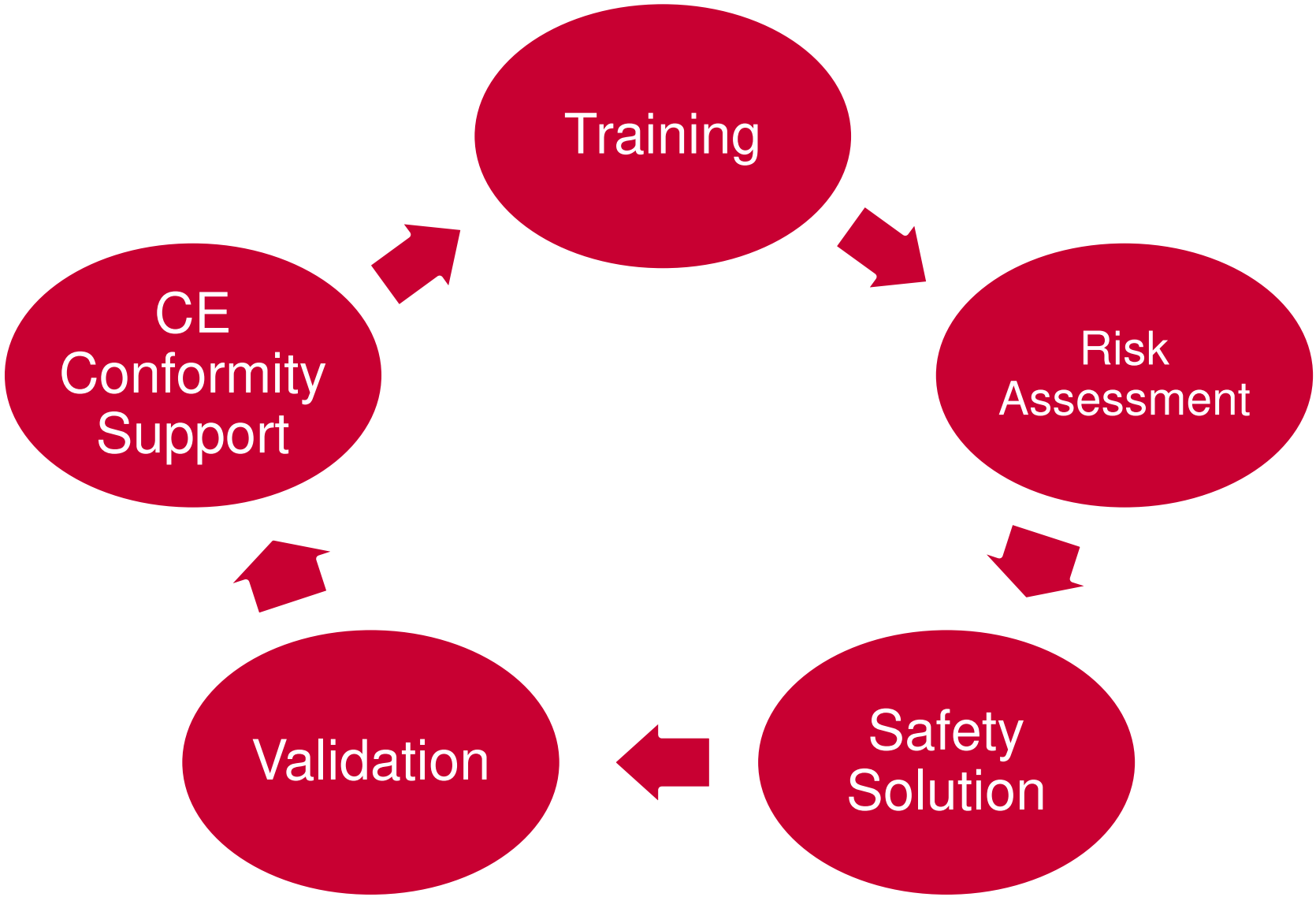

Stop Time Measurement

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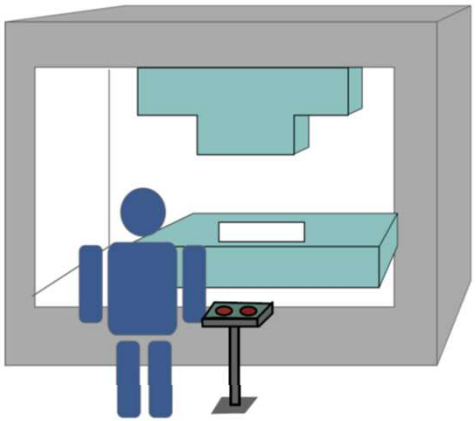
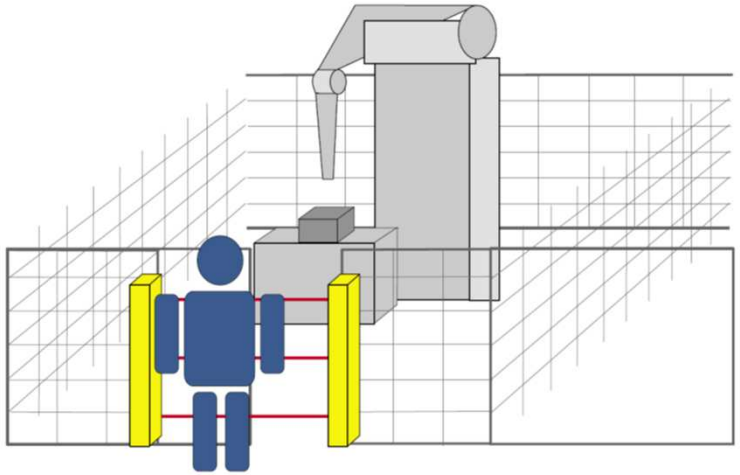
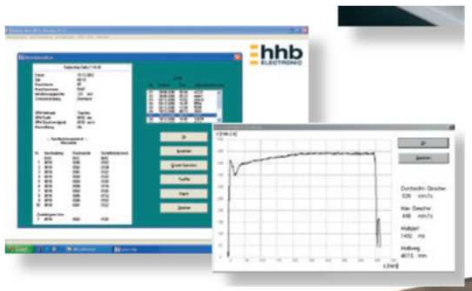


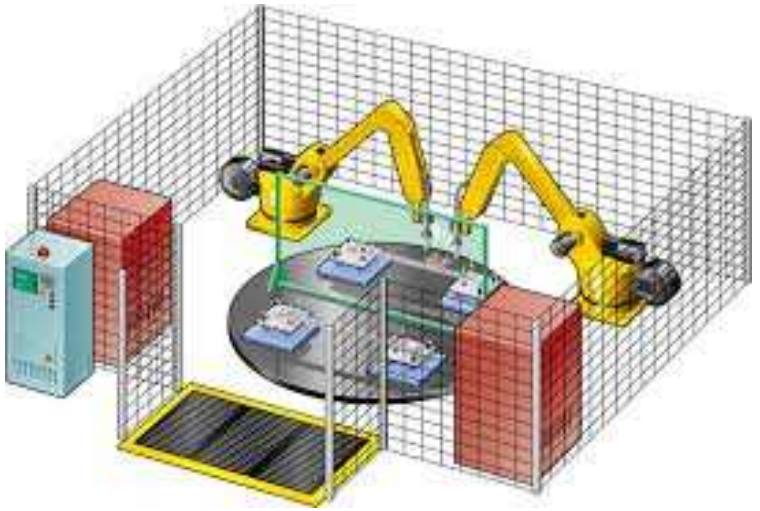
Safeguarding with a
Two Hand Control



Area Guarding with a AOPD



Stop Time Meter



Area Guarding with Safety Mat

Committee Work

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- *Actively Involved with BIS (Bureau of Indian Standards) – the national standard making organization for implementation of Machinery Safety in India*

- *A committee member for the MED (Mechanical Engg) and ETD (Electro-Technical) Committee responsible for adoption of ISO standards to BIS*

- *Also working very closely with the government departments for implementing Machinery Safety regulations in India*

मानकः पथप्रदर्शकः

सत्यमेव जयते
Department of Heavy Industry
Ministry of Heavy Industry & Public Enterprises
Government of India

Safety of Machinery

Introduction

FUNCTIONAL SAFETY (FS)

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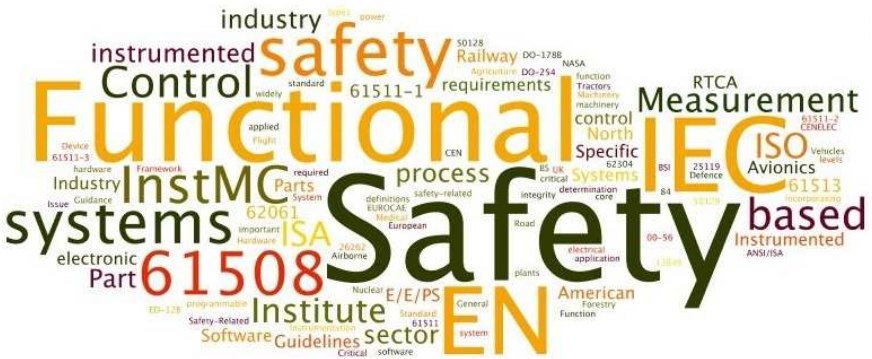
"Official" definition:

- **Functional safety** is the part of the overall safety of a system or piece of equipment that depends on automatic protection, operating correctly in response to its inputs or failure in a predictable manner (fail-safe) and which is designed to properly handle human errors, systematic errors, hardware failures and operational/environmental stress.

- The objective of functional safety is freedom from unacceptable risk of physical injury or of damage to the health of people either directly or indirectly



Hazard / Hazardous zone(s):

A situation in the workplace that has the potential to harm the health and safety of people or to damage plant and equipment. …

Hazardous situation: A circumstance in which a person is exposed to a hazard.

Risk: Exposure to the possibility of loss, injury or other adverse or unwelcome circumstances.

Machine Directive : MD 2006/42/EC

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1. This Directive applies to the following products:

(a) machinery;

(b) interchangeable equipment;

(c) safety components;

(d) lifting accessories;

(e) chains, ropes and webbing;

(f) removable mechanical transmission devices;

(g) partly completed machinery.

2. The following are excluded from the scope of this Directive:

(a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;

(b) specific equipment for use in fairgrounds and/or amusement parks;

(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;

(d) weapons, including firearms;

...

(a) 'machinery' means:

— 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,

— an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,

— an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,

— assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole,

— an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;

(g) 'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;

Risk Assessment
General

Doctors Approach to Human Safety

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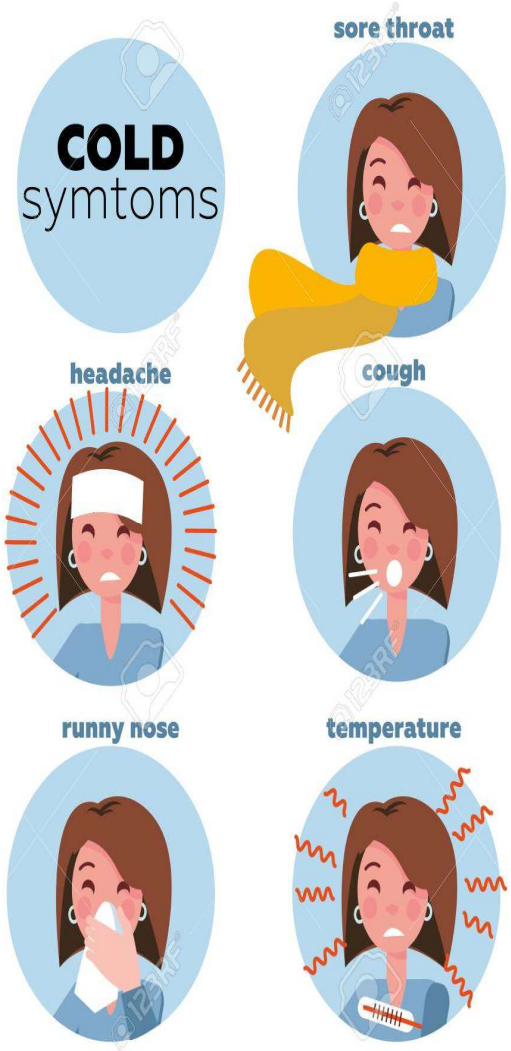
CASE A

- Fever, Cold & Cough
- No Doctor Consultation
- Medicine from neighborhood shop
- No cure or delayed Cure in most of the cases
- Chances of re-lapse of the ailment



CASE B

- Fever, Cold & Cough
- Doctor Consulted
- Tests if required done
- Medicine taken with Prescription
- Fast Cure and little chance of re-lapse

Blister Pack Machine – Pharma Company

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No Risk Assessment Done

Provided Safety Guards as per ISO 14120

Interlocks & E Stops as per relevant Standards

After 1 Month

Interlocks - Bypassed

Findings:

1. Ink had to be poured in the tray in running machine for better applicability
2. Blisters Packs had to be aligned for every new job between the rollers in running machine
3. **NO Risk Assessment** done to address these aspects

Dough Dividing Machine - Food

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One person was cleaning the blades → 2nd person operated the blades from the panel → Mis-communication between the two

1st Person lost 3 fingers of his right hand

Findings:

1. **No Risk Assessment** was done for cleaning / maintenance mode
2. There was no exclusive control with the 1st person

Press Machine – Safety

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A reputed Press Machine Manufacturer – in business for many decades now

Very recently Customers started asking for Safety Light Curtain in the Loading area

OEM installs safety compliant Type 3, PLe Safety Light Curtain in such machines

2-3 Incidences of severe hand injuries at a few End Users

Findings:

1. OEM installed Safety Light Curtain on the periphery of the machine
2. Safety Light Curtains were **NOT getting mounted at a Safe Distance** as per ISO 13855
3. **No Risk Assessment** was done to measure Stopping Time and Safe Distance

Need for Risk Assessment

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- A Safe Machine is Built.
- Human/Operator Safety is Ensured and given top priority.
- Safe Work Culture and environment.
- Increase in Productivity.
- Company Goodwill/Brand Image
- Avoid Overspending for safety.

- To Monitor & Track new risks due to changes.

Who should/can do Risk Assessment ?

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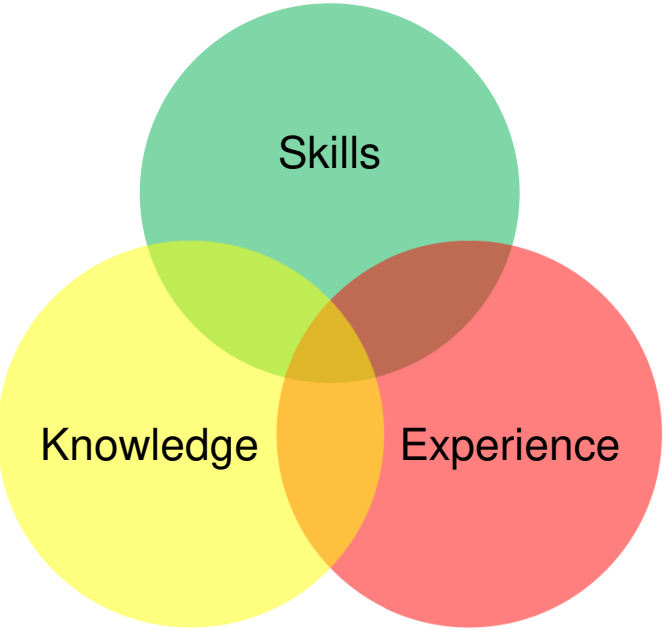
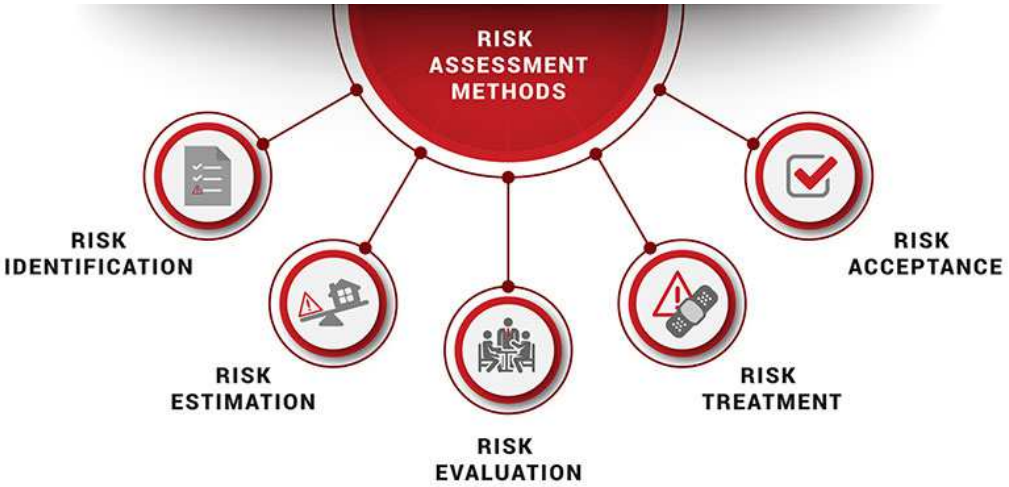
- A group of people from different backgrounds
- May not necessarily need specific training or qualifications.
- Someone competent in terms of necessary skills, knowledge & experience.





Risk Assessment
ISO 12100:2010

ISO 12100

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CONTENT

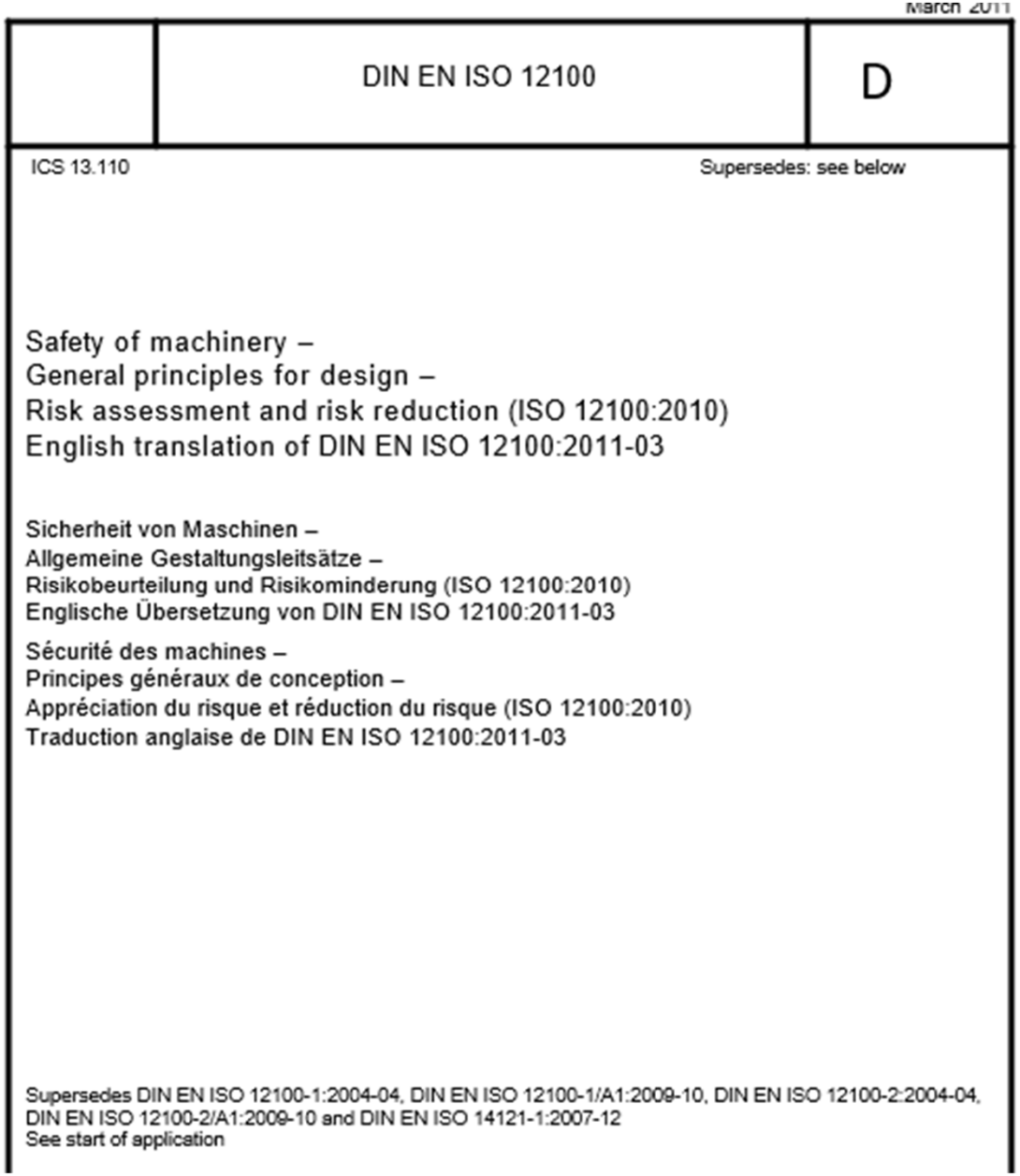
Section 1 : Scope

Section 4 : Strategy for Risk Assessment and Risk Reduction.

Section 5 : Risk Assessment
- Machine Limits
- Hazard Identification
- Risk Estimation
- Risk Evaluation

Section 6 : Risk Reduction

Section 7 : Documentation of Risk Assessment and Risk Reduction



March 2011

	DIN EN ISO 12100	D

ICS 13.110 Supersedes: see below

Safety of machinery –
General principles for design –
Risk assessment and risk reduction (ISO 12100:2010)
English translation of DIN EN ISO 12100:2011-03

Sicherheit von Maschinen –
Allgemeine Gestaltungsleitsätze –
Risikobeurteilung und Risikominderung (ISO 12100:2010)
Englische Übersetzung von DIN EN ISO 12100:2011-03

Sécurité des machines –
Principes généraux de conception –
Appréciation du risque et réduction du risque (ISO 12100:2010)
Traduction anglaise de DIN EN ISO 12100:2011-03

Supersedes DIN EN ISO 12100-1:2004-04, DIN EN ISO 12100-1/A1:2009-10, DIN EN ISO 12100-2:2004-04, DIN EN ISO 12100-2/A1:2009-10 and DIN EN ISO 14121-1:2007-12
See start of application

Scope

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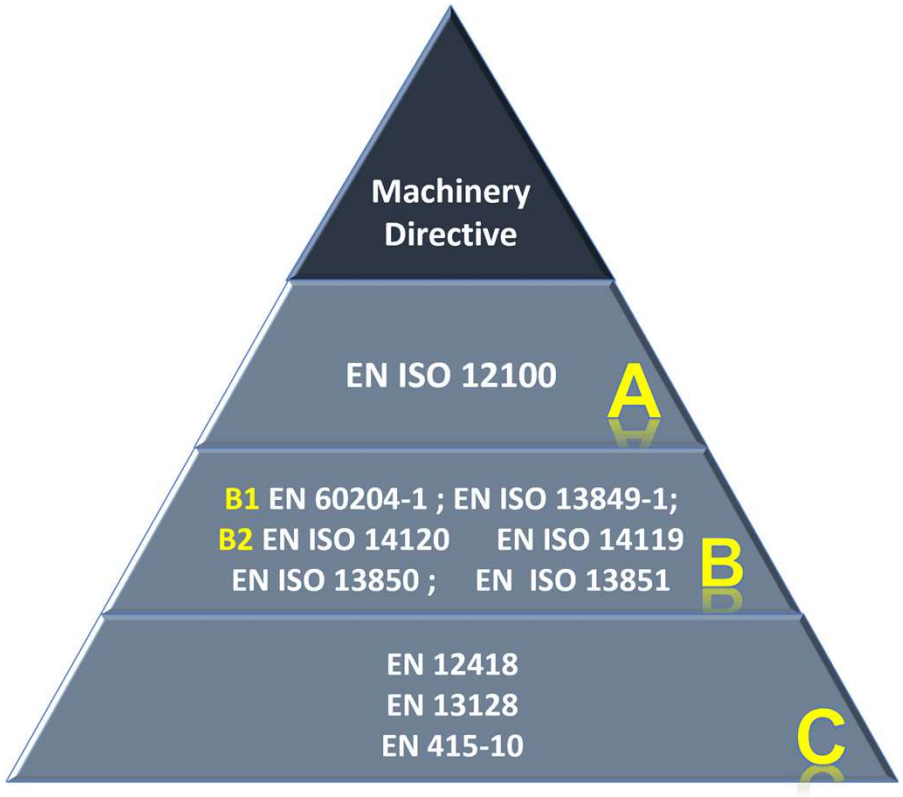
- Document prepared by Technical Committee ISO/TC 199 in collaboration with Technical Committee CEN/TC 114.
- This International Standard is a type-A standard
- Intended to be used as a basis for the preparation of type-B or type-C safety standards.
- It does not deal with risk and/or damage to domestic animals, property or the environment.
- Specifies basic terminology, principles and methodology for achieving safety in the design of machinery.
- Specifies principles of risk assessment and risk reduction to help designers.
- Principles are based on knowledge and experience of the design, use, incidents, accidents and risks associated with machinery.



Definition : Risk assessment is a series of logical steps to enable, in a systematic way, the analysis and evaluation of the risks associated with machinery.

Information Evaluated for Risk Assessment:

- *Related to Machinery Description*
- *Related to Regulations, Standards and Other Applicable documents*
- *Related to Experience of Use*
- *Relevant Ergonomic Principles*

. Four factors to be considered, ***in the following order of preference:***

1. the safety of the machine during all the phases of its life cycle;

2. the ability of the machine to perform its function;

3. the usability of the machine;

4. the manufacturing, operational and dismantling costs of the machine.

ISO 12100 – Schematic Representation

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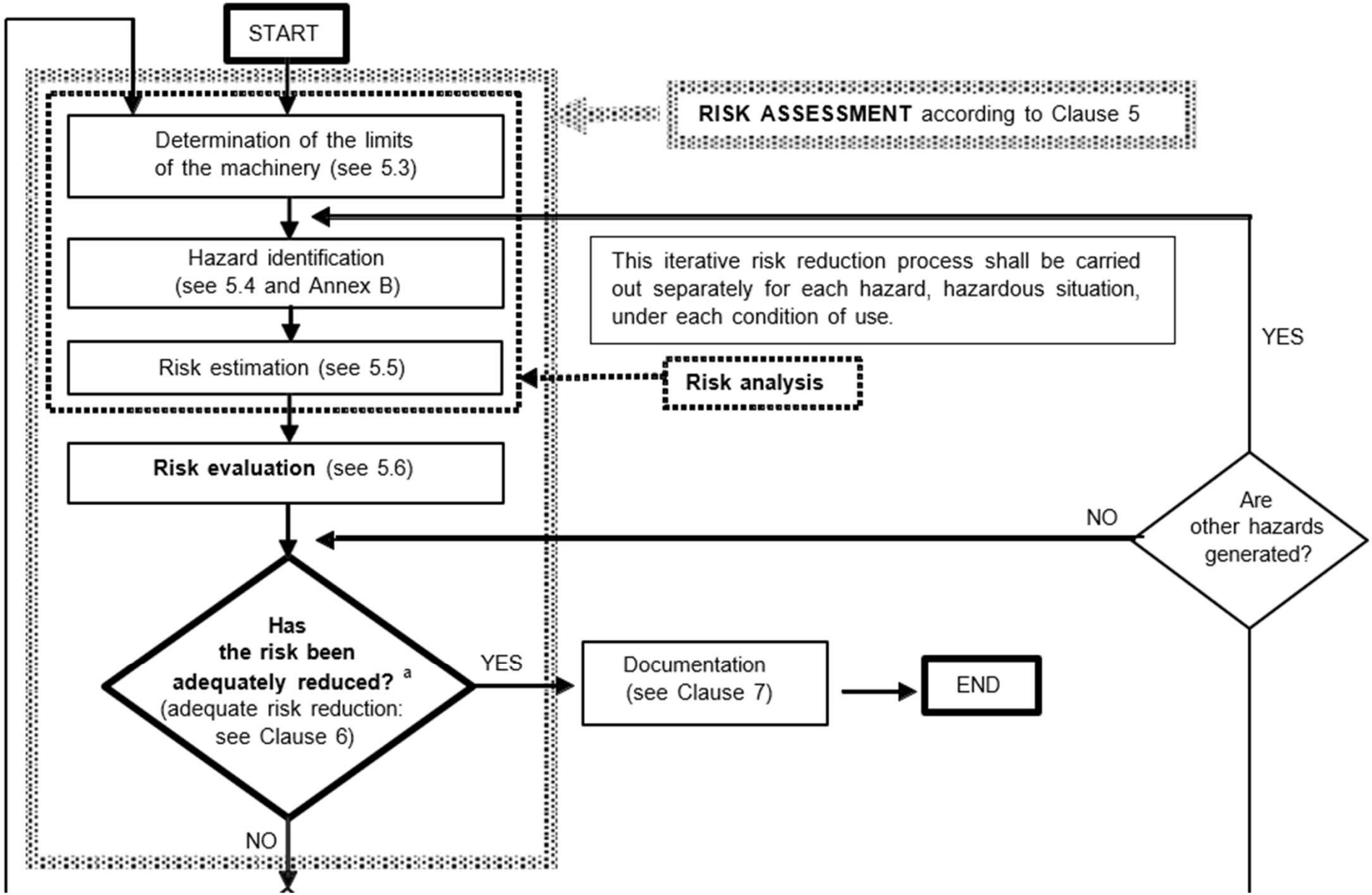
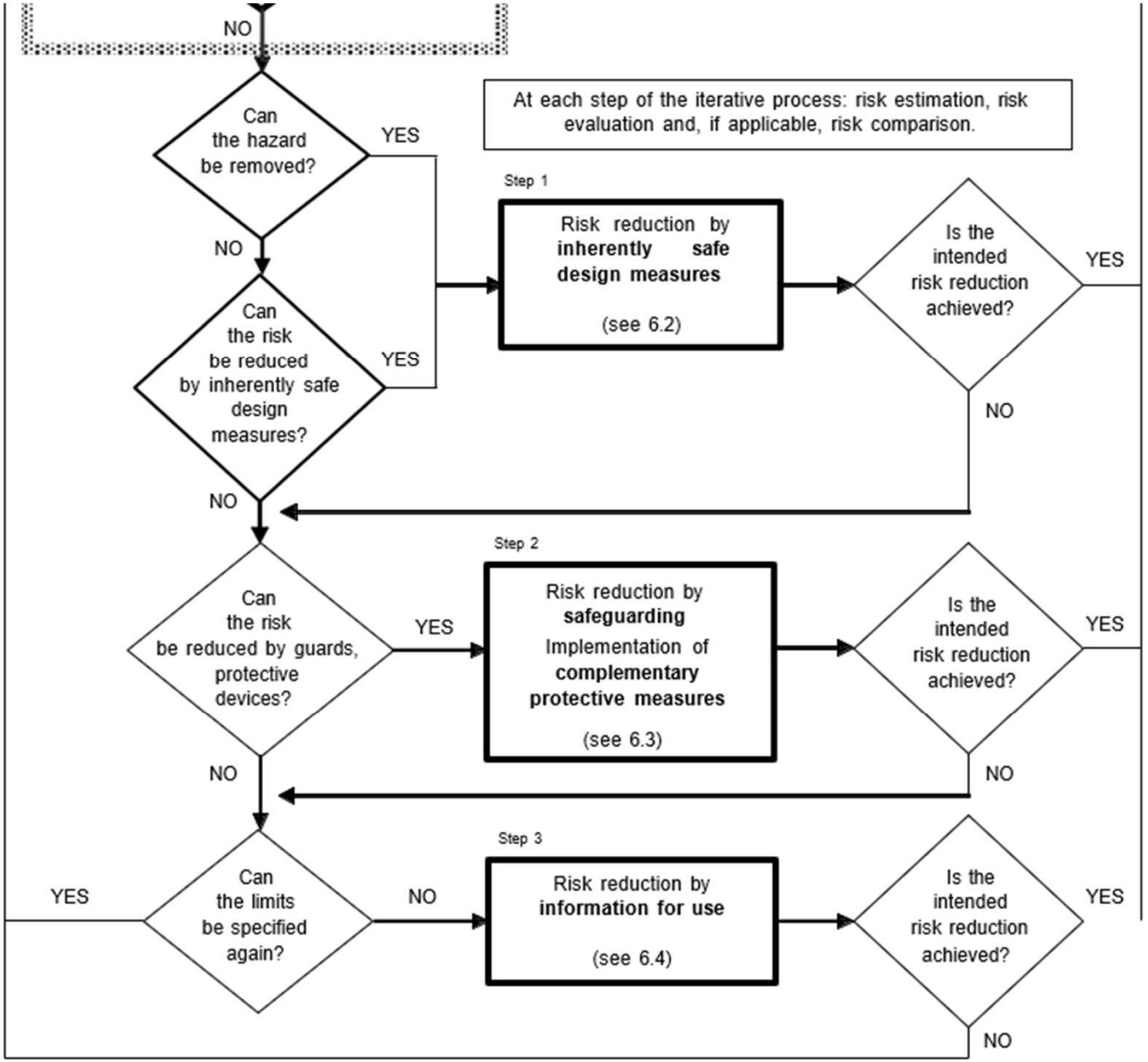


ISO 12100 – Schematic Representation

SAFETSENSE
Machine Safety



Machine Limits

RISK ASSESSMENT – Machine Limits

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Use Limits

- Operating Modes + Interventions
- Training and Experience
- Intended Operators

Space Limits

- Range of Movement
- Space of Operators
- Human Interactions
- Machine Power Supply Interface

Time Limits

- Life Limit – Machine and Components
- Service Intervals

Others

- Material being Processed
- Housekeeping
- Environmental

Hazard Identifications

Overview

RISK ASSESSMENT – Hazard Identification

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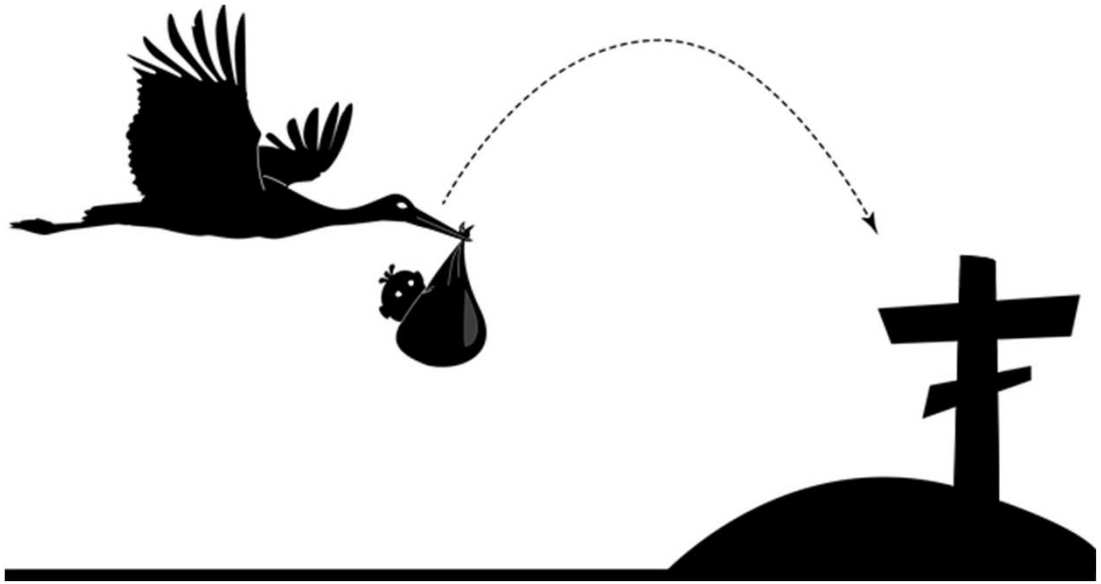
- Transport,
- assembly
- installation
- Commissioning
- Use
- De-commissioning and disposal



Hazard identification
Reasonably foreseeable hazards during all phases of the life cycle:

RISK ASSESSMENT – Hazard Identification

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a) Human interaction during the whole life cycle of the machine

- setting;
- testing;
- teaching/programming;
- process/tool changeover;
- start-up;
- all modes of operation;
- feeding the machine;
- removal of product from machine;
- stopping the machine;
- stopping the machine in case of emergency;
- recovery of operation from jam or blockage;
- restart after unscheduled stop;
- fault-finding/trouble-shooting (operator intervention);
- cleaning and housekeeping;
- preventive maintenance;
- corrective maintenance.

b) Possible states of the machine

c) Unintended behavior of the operator or reasonably foreseeable misuse of the machine

ISO 12100 – Hazard Identification

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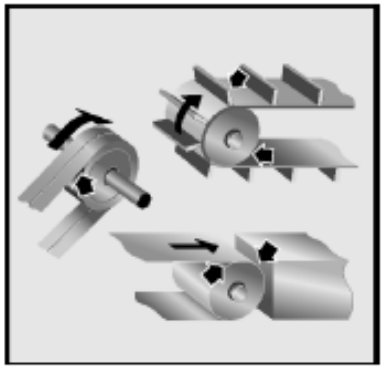


Origin

moving elements
(three examples)

Potential consequences

— drawing-in

— friction, abrasion

— impact

Origin

live electrical parts

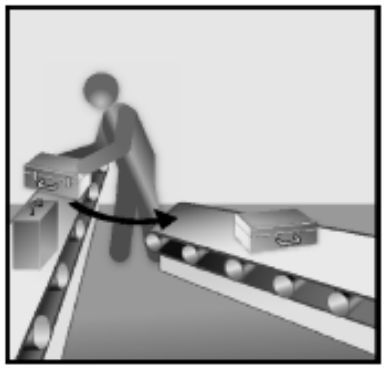
Potential consequences

— electric shock

— burn

— puncture

— scald



Origin

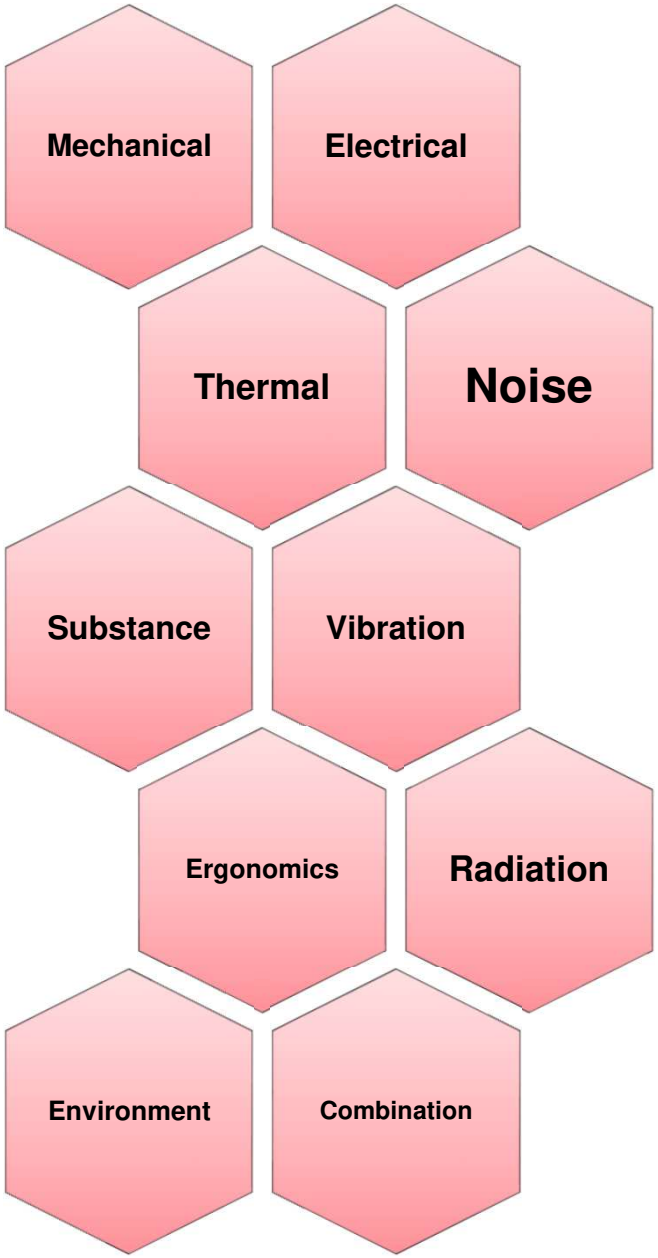
posture

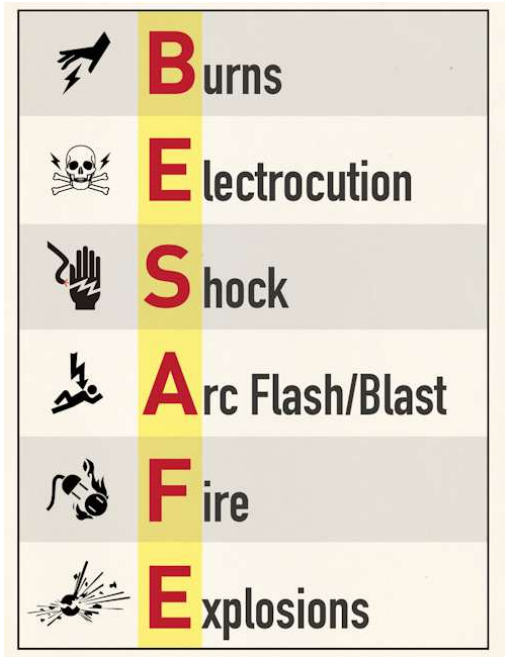
Potential consequences

— discomfort

— fatigue

— musculoskeletal disorder





ISO 12100 – Hazard Identification

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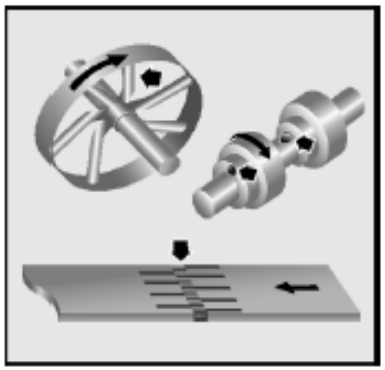


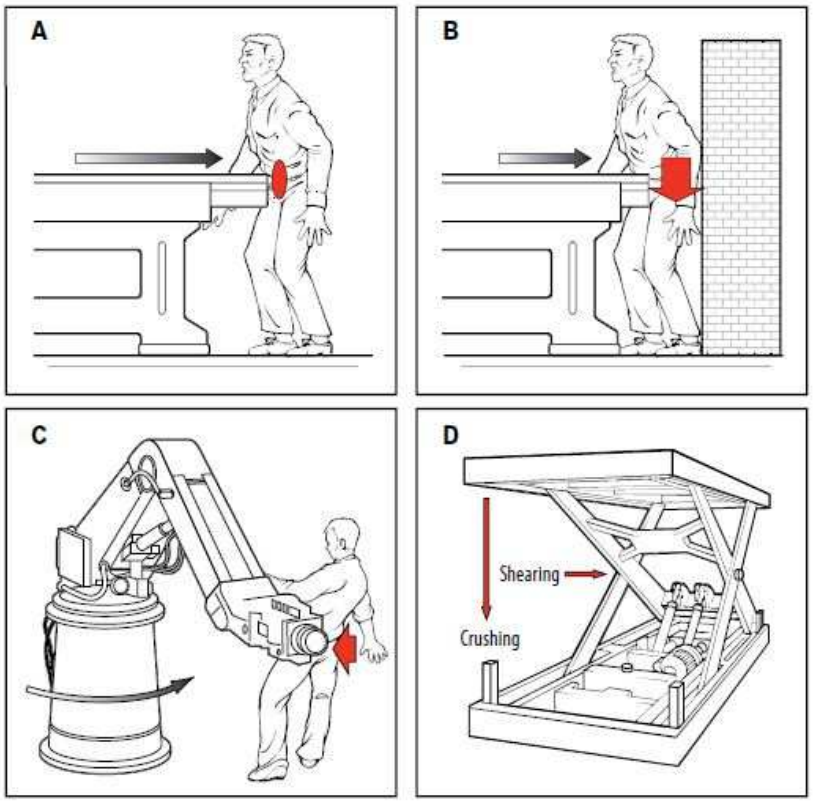
Origin

rotating or moving elements (three examples)

Potential consequences

— severing

— entanglement



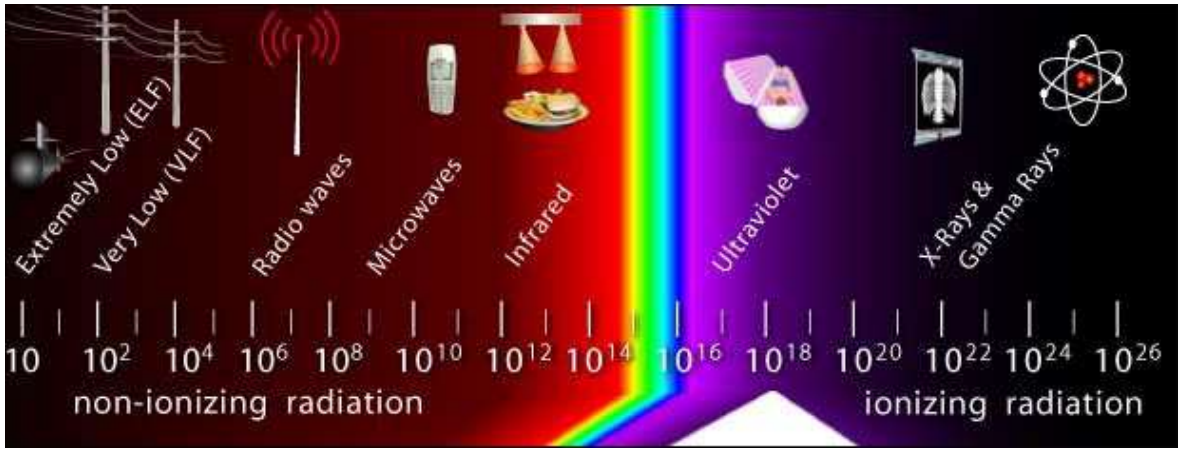
Chemical Warning Signs (Figure 1)

Ignitable chemicals generally are liquids with flash points below 60°C or 140°F.

Reactive chemicals ignite or create poisonous vapors when mixed with other products or can explode when exposed to heat, air, water, or shock.

Corrosive chemicals are generally aqueous wastes with a pH less than or equal to 2.0 or greater than or equal to 12.5.

Toxic chemicals may cause long-term illness (such as cancer). Pesticides, paint thinners, many auto products, and some cleaners are toxic.



Risk Estimation

Overview

Risk Estimation –Section 5.5.2

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RISK

related to the considered hazard

is a function of

SEVERITY OF HARM

that can result from the considered hazard

and

PROBABILITY OF OCCURRENCE of that harm

- Exposure of person(s) to the hazard
- the occurrence of a hazardous event
- the possibility to avoid or limit the harm

RISK ASSESSMENT CHART

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LO (Likelihood of Occurrence)		
0.0		Only in extreme circumstances
33	Almost impossible	
1	Highly unlikely	Though conceivable
1.5	Unlikely	But could occur
2	Possible	But unusual
5	Even chance	Could happen
8	Probable	Not surprising
10	Likely	To be expected
15	Certain	No doubt

FE (Frequency of Exposure)	
0.5	Annually
1	Monthly
1.5	Weekly
2.5	Daily
4	Hourly
5	Constantly

HRN	Risk
0-5	Negligible
5-50	Low, significant
50-500	High
Over 500	Unacceptable

HRN = LO x FE x DPH x NP

DPH (Degree of Possible Harm)	
0.1	Scratch or bruise
0.5	Laceration or mild ill-effect
2	Break of minor bone or minor illness (temporary)
4	Break of major bone or major illness (temporary)
6	Loss of one limb, eye, hearing (permanent)
10	Loss of two limbs or eyes (permanent)
15	Fatality

NP (Number of Persons at risk)	
1	1-2 persons
2	3-7 persons
4	8-15 persons
8	16-50 persons
12	50+ persons

Risk Evaluation

Overview

5.6.2 Adequate risk reduction

Following the application of the three-step method,

adequate risk reduction is achieved when

— all operating conditions and all intervention procedures have been considered,

— the hazards have been eliminated or risks reduced to the lowest practicable level,

— any new hazards introduced by the protective measures have been properly addressed,

— users are sufficiently informed and warned about the residual risks (see 6.1, step 3),

— protective measures are compatible with one another,

— sufficient consideration has been given to the consequences that can arise from the use in a non-professional/non-industrial context

— the protective measures do not adversely affect the operator's working conditions or the usability of the machine.

5.6.3 Comparison of risks

As part of the process of risk evaluation, the risks associated with the machinery can be compared with those of similar machinery, provided the following criteria apply:

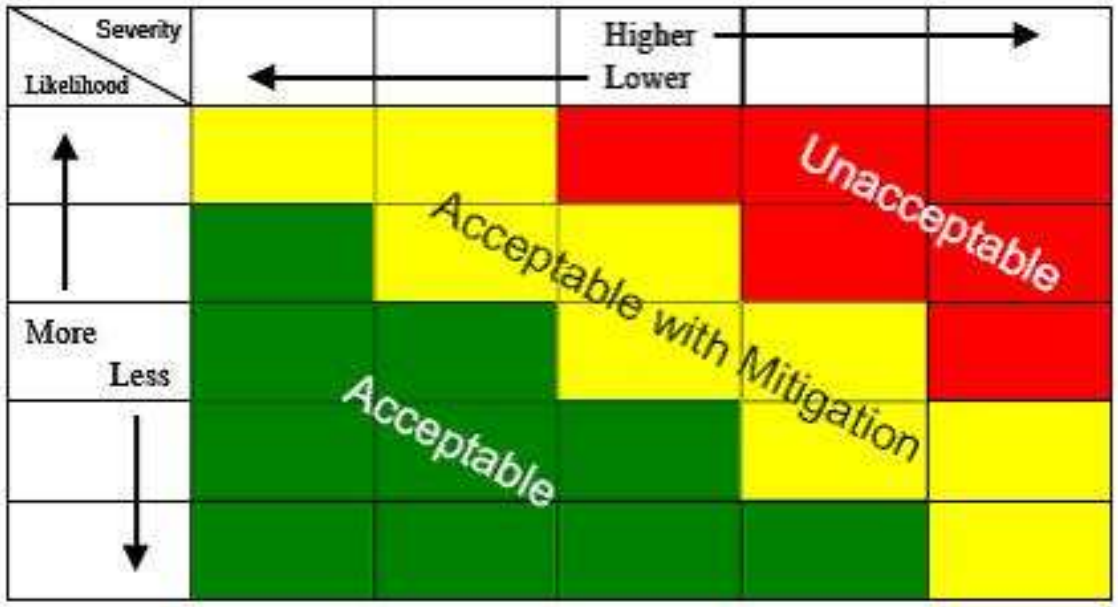
— the similar machinery is in accordance with the relevant type-C standard(s);

— the intended use, reasonably foreseeable misuse and the way both machines are designed and constructed are comparable;

— the hazards and the elements of risk are comparable;

— the technical specifications are comparable;

— the conditions for use are comparable.



Risk Reduction

Risk Reduction

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Risk assessment
(based on defined limits and intended use of the machine)

Protective measures implemented by the designer (see Figure 1)

Step 1 : Inherently safe design measures

Step 2 : Safeguarding and complementary protective measures

Step 3 : Information for use[a]
- at the machine
  – *warning signs, signals*
  – *warning devices*
- in the instruction handbook

Protective measures implemented by user

Provision and use of additional safeguards[d]
- **Use of PPE**
- **Training**, etc.

- **Organization**
  – safe working procedures
  – supervision
  – permit-to-work systems

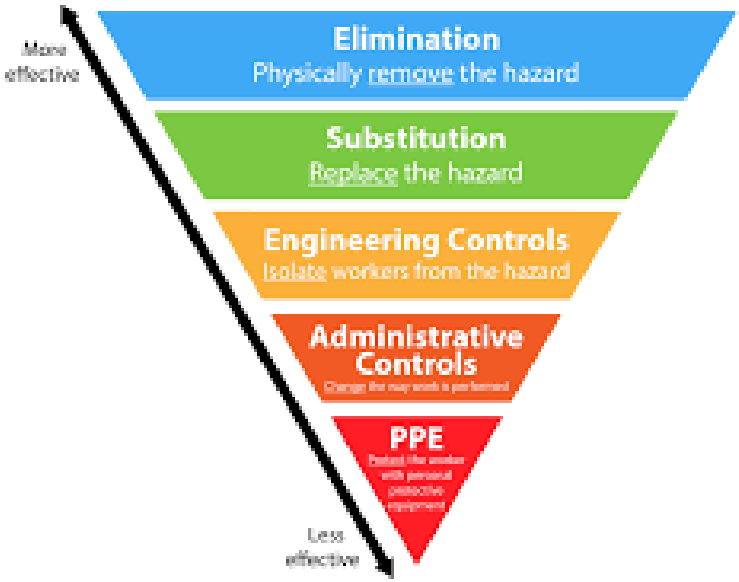
User input[b]

Designer input

RISK

Residual risk after protective measures implemented by the designer

Residual risk after all protective measures implemented



Risk Reduction

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Direct safety - **Prevention** of danger (Safe Design)
Indirect safety - **Protection** against danger (Safety Switchgear)
Indicative safety - **Information** about Danger (Warning Signs/Pictograms)

Initial Risk

Engineering and Administrative Controls

Design out risk

Risk Reduction – Step 1 (Safe Designs)

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- ✓ Consideration of geometrical factors and physical aspects
- ✓ General technical knowledge of machine design
- ✓ Choice of appropriate technology
- ✓ Applying principle of positive mechanical action
- ✓ Provisions for stability
- ✓ Provisions for maintainability
- ✓ Observing ergonomic principles
- ✓ Electrical hazards
- ✓ Pneumatic and hydraulic hazards
- ✓ Minimizing probability of failure of safety functions
- ✓ Limiting exposure to hazards through reliability of equipment
- ✓ Limiting exposure to hazards through mechanization or automation of loading (feeding)/ unloading (removal) operations
- ✓ Limiting exposure to hazards through location of setting and maintenance points outside danger zones

Applying inherently safe design measures to control systems:

- ✓ Starting of an internal power source/switching on an external power supply
- ✓ Starting/stopping of a mechanism
- ✓ Restart after power interruption
- ✓ Interruption of power supply
- ✓ Use of automatic monitoring
- ✓ Safety functions implemented by programmable electronic control systems
- ✓ Principles relating to manual control
- ✓ Control mode for setting, teaching, process changeover, fault-finding, cleaning or maintenance
- ✓ Selection of control and operating modes

Risk Reduction – Step 2

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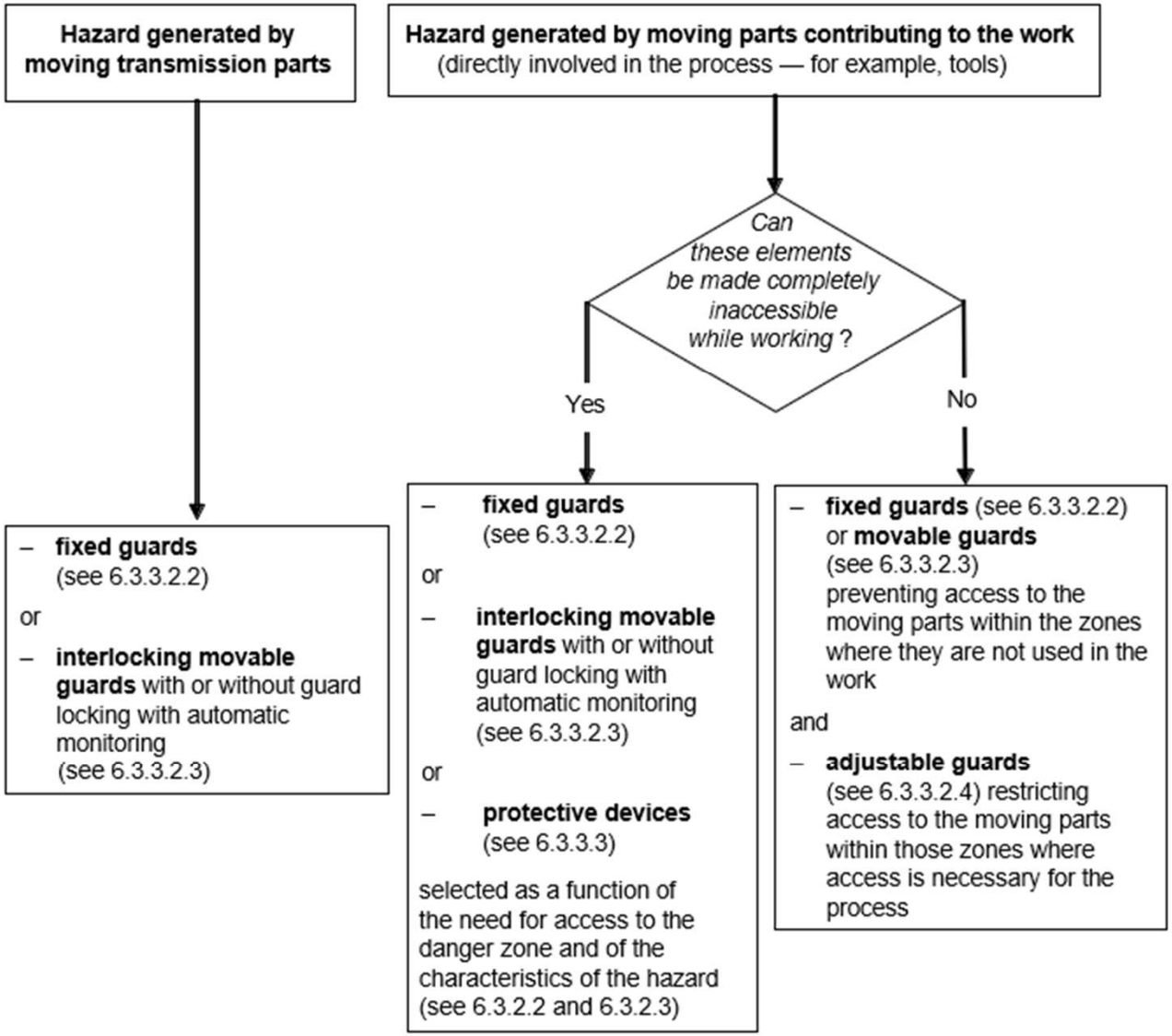

Figure 4 — Guidelines for choosing safeguards against hazards generated by moving parts

Machine Guarding

Types of Machine Guards

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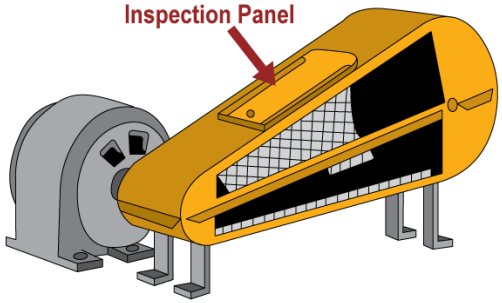

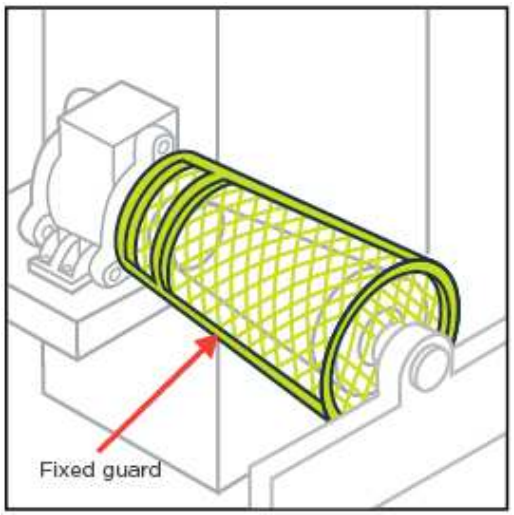

Safety Interlocking

Risk Reduction – Step 2

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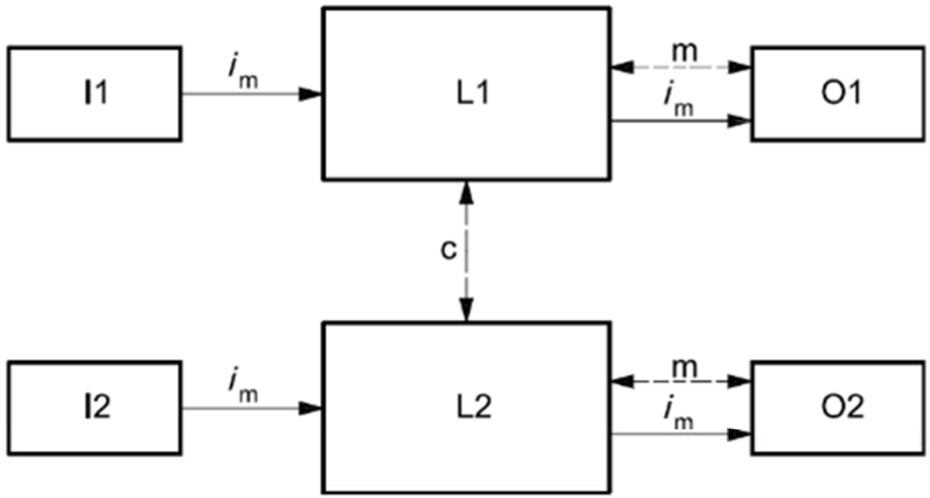
EN ISO 13849-1
Safety Related Parts of the Control System



Key

i_m	interconnecting means
c	cross monitoring
I1, I2	input device, e.g. sensor
L1, L2	logic
m	monitoring
O1, O_2	output device, e.g. main contactor

Safety Functions..

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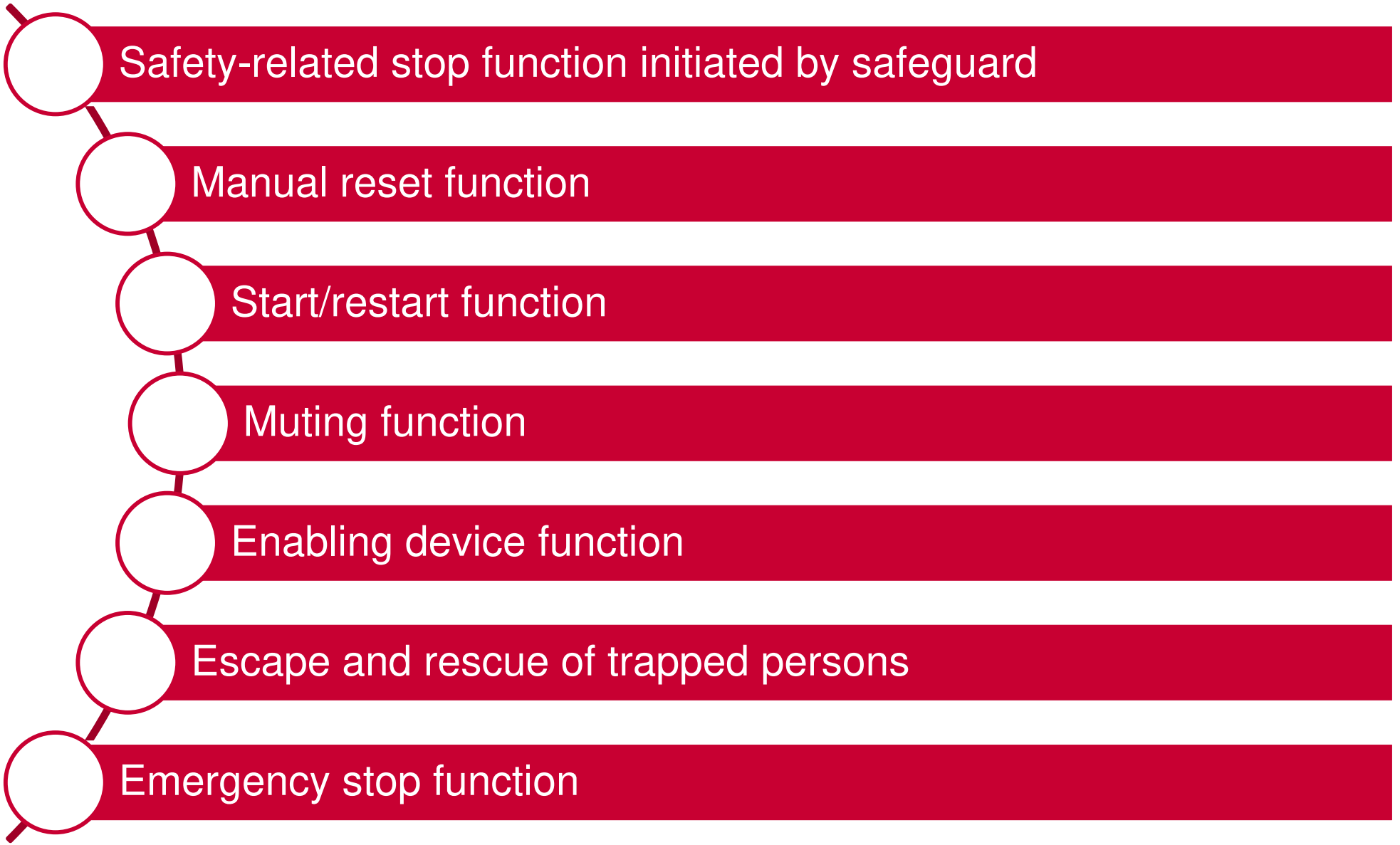

Performance Level

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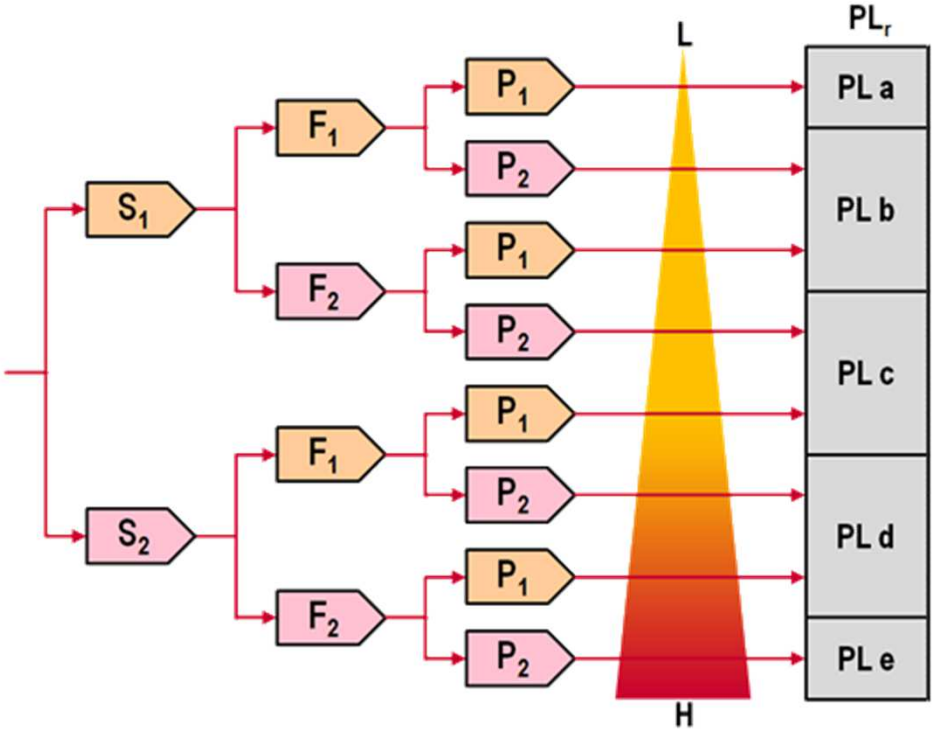
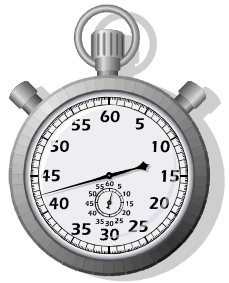
- Estimation of PL_r



	Low (1)	High (2)
S		
F		
P		

Required Performance Level PL_r

S = Severity of injury

F = Frequency of exposure to hazard

P = Possibility of avoiding hazard

Documentation

Risk Assessment - Documentation

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The documentation shall include,

a) the machinery for which the risk assessment has been made (for example, specifications, limits, intended use);

b) any relevant assumptions that have been made (loads, strengths, safety factors, etc.);

c) the hazards and hazardous situations identified, and the hazardous events considered

d) the information on which risk assessment was based (see 5.2):

   1) the data used and the sources (accident histories, experience gained from risk reduction applied to similar machinery, etc.);

   2) the uncertainty associated with the data used and its impact on the risk assessment;

e) the risk reduction objectives to be achieved by protective measures;

f) the protective measures implemented to eliminate/reduce identified risk;

g) residual risks associated with the machinery;

h) the result of the risk assessment

i) any forms completed during the risk assessment

ISO 12100 - Summary

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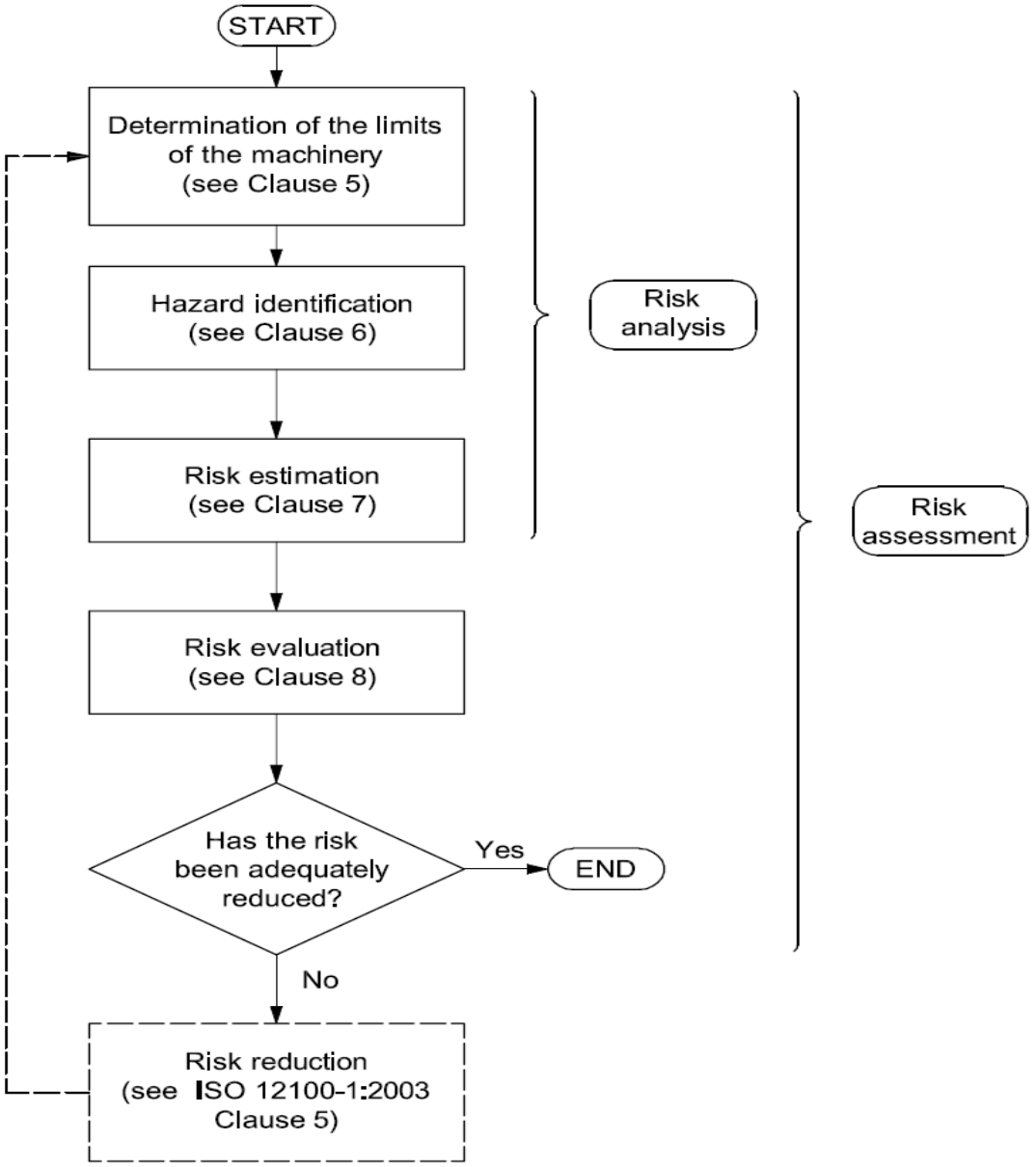
EN ISO 12100:2010 – General Principles for Design, Risk Assessment and Risk Reduction



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Thank you

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